Developing a Risk Management Plan for a Priority Chemical

Guidance Document

Working Draft
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Using This Guidance Document

This document is intended as framework guidance for countries that choose to address priority chemicals using a systematic, country-driven approach. It recognises that countries have different starting points from which a risk management plan for a priority chemical can be developed and implemented. The document also acknowledges the opportunities presented by related international developments/agreements that address individual chemicals/ groups of chemicals.

The guidance is flexible in nature – it is not meant to be prescriptive in any sense. Each country can consider and make decisions regarding the issues raised in accordance with its own preferences and priorities. It is hoped that this guidance document can play a constructive role in this process.

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Note to Reviewers

This draft Guidance Document has been developed based on lessons learned from a European Commission-funded pilot programme on risk management decision-making in Cameroon, Chile, Tanzania and The Gambia, and other related activities. It is hoped that countries and other interested reviewers will make use of the guidance provided in this document and provide critical feedback on the working draft prior to finalisation. Specifically, we ask that the following questions are considered when reviewing the document:

- Is the scope of the document appropriate? Is the information provided too general or too detailed? What additional information or issues should be included, if any?
- Is the guidance and information provided in the document practical? Too theoretical?
- Is the presentation of the information (e.g. language, format) user-friendly?
- Is the information and guidance provided consistent with the needs and circumstances of developing countries and countries with economies in transition with respect to risk management?
- Is the stepwise guidance suggested in Part 2 useful? What are some possible ways in which the suggestions and related guidance could be made more relevant and useful?
- Are there additional types of information that should be included in annexes in order to make the document more valuable to the user?

This draft will be further developed taking into account the general outcomes and ideas generated in the Project, as well as specific comments and feedback on the draft. Your contribution to the further development of this document is sincerely appreciated.

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INTRODUCTION

Over the last 100 years, the production and use of chemicals has grown remarkably and chemical substances have become an integral part of our lives such as in the areas of health protection, food production, and of national economies including input and output of industrial processes. While there are substantial benefits from the use of chemicals in many areas, their use and misuse at any stage in their life-cycle can cause adverse effects on human health and the environment. People are likely to be exposed to an increasing diversity of chemicals in the future even though careful steps may be taken to control and monitor their production, transportation, use and the disposal of chemical wastes. Considering the continued growth of chemical industries, in particular in developing countries and countries with economies in transition, the management of risks posed by these substances throughout their life-cycle must be seen as an integral component of sustainable economic and social development both nationally and internationally.

This Guidance Document aims to assist countries which may be at different levels of technological development to establish a systematic approach for managing risk from priority chemicals, within the context of a national programme for the sound management of chemicals. The purpose of the document is to explain the organisational and broad process-related aspects of risk management rather than to detail risk assessment. The document deals with risk management, decision-making and hazard control processes with the emphasis on adoption of a preventive approach where possible.

Suggestions on practical examples and on tools/techniques of potential use at different entry points during the decision-making process are also outlined in the document. The main goal is a targeted agreement for the control of priority chemical(s). Different strategies to reach the goal are outlined. It is understood that such a process must be carried out in the light of the particular needs and circumstances of each country including their social, economic and administrative characteristics.

The document is divided into two parts:

Part 1 provides a broad introduction to risk management decision-making – the main principles and the basis for action in the context of an effective overall strategy for decision-making for the control of priority chemicals; and

Part 2 concerns the preparatory tasks and considerations that can help to ensure that a solid foundation has been laid for initiating the development and implementation of a risk management plan for a priority chemical, and outlines a flexible, step-wise, cyclical process to foster the development and management of integrated risk reduction strategies including practical suggestions for each of the stages in the process.

The document is not intended as a rigid authoritative manual. Rather, it is presented as an integrated yet flexible approach to chemicals management based on practical knowledge and case experience. It has been written to help responsible individuals and groups develop tailored procedures to meet specific requirements and conditions of a given country as the basis for appropriate management of risk.

PART 1: RISK MANAGEMENT DECISION-MAKING FOR PRIORITY CHEMICALS

The sound management of chemicals throughout their life-cycle is an essential national activity in order to minimise risk, and/or prevent the occurrence of adverse impacts. The aims and implications of risk management are outlined and explained in Part 1 of this document.

> *The function of risk management is to decide whether a level of risk is acceptable, and if not, to translate the information into policies and actions designed to, for example, control exposure, to reduce risk through national legislative action, or to reduce risk in a variety of other ways.*

Human health and environmental risks can occur at any, or all of the stages of a commercial chemical life-cycle, which may consist of:

- extracting and refining industries;
- chemical manufacturers and processors;
- chemical formulators;
- individual customers; and
- chemical disposers.

Consequently, management of such risks is, in practice, a major task involving a series of consecutive steps. The approach described in this document is designed to help the reader gain clarity from the complexity of many chemicals problems. Nevertheless, the process described is not complex. It focuses on the collection and analysis of information and its targeted use to reduce risk especially from priority chemicals. Useful precedents that can serve as examples are outlined as part of the process for establishing effective national and international chemicals management.

1.1 What is Risk Management?

The risks associated with a potential for harm due to exposure to chemicals have to be identified, assessed and managed appropriately. The distinction between assessment and management of risks is a key issue. Much has been written on the purpose and implementation of the risk assessment procedure (see Annex A), which is designed to evaluate, usually quantitatively, the nature and magnitude of a potential risk. But on its own, risk assessment has limited value.

Risk management on the other hand, is the decision-making process to accept a known or assessed risk and/or the implementation of actions to reduce the consequences or probabilities of such an occurrence. Various definitions of risk management have been developed by national organisations and institutions. According to the United States Presidential/Congressional Commission on Risk Assessment and Risk Management (1997), risk management '*is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks, while taking into account social, cultural, ethical, political, and legal considerations.*'

When developing risk management decision-making strategies, two complementary approaches are considered, usually in sequence:

- effects-oriented policies: effects on human health and the environment; and
- source-oriented policies: prevention of effects by controlling releases.

The effects of a chemical on health and the environment via an exposure pathway, for example, represents the first important parameter. Then suitable exposure standards can be developed. These standards are then translated into a source-related policy to control the releases of the chemical to ensure that exposure standards are not exceeded. Risk management therefore considers both policies.

In more general terms, risk management decision-making should embody a systematic, and structured approach to chemical risks, that allows the parties involved to:

- identify risks/problems that need to be eliminated or reduced – *to evaluate*;
- identify ways in which these risks can be eliminated or, 'managed' – *to control*; and;
- decide upon the most appropriate strategy to achieve reduction of risk – *to implement and monitor*.

The risk management process can also be described as comprising a six-step process, ranging from identification of the problem to evaluation of control actions. The process is an iterative one and not a linear sequence of actions. The six steps have been recognised as an important cyclical process to follow so that governments can make informed decisions on priority chemicals. The steps are discussed in detail in Part 3 but in outline they include:

1. Conducting a situation analysis/needs assessment
2. Developing the risk reduction goal, sub-goals and indicators
3. Identifying and evaluating possible risk reduction options
4. Selecting and developing the risk reduction strategy
5. Obtaining commitment from decision-makers and taking action
6. Evaluating Impact

As health and environmental problems caused by chemicals can sometimes be extremely complex to solve, experience from many countries shows that a well-organised risk management decision-making process, such as is outlined here, can assist in problem identification and taking appropriate action. This complexity is caused by a combination of factors:

- the large number of chemical substances in commerce and substances of natural origin with which human beings come into contact, along with pollutants, contaminants in food, commercial and household products;
- limited availability of information concerning chemical use; many countries have insufficient data on the import, manufacture, trade, storage, transport, use and disposal of chemicals and chemical products;
- a high level of uncertainty concerning the precise hazardous nature and impact of chemicals, by themselves or in combination with other substances, on human health and the environment; and

- divergent views amongst stakeholders, including public authorities, industry, consumers, trade unions, environmental groups, etc. with regard to the seriousness of the risks presented by chemicals, and on the appropriate responses.

Bearing in mind the high level of uncertainty surrounding chemical risk issues, it will usually be impossible, and certainly ill-advised to dismiss any of these different views offhand as chemicals may cause human disease in several ways:

- directly from exposure to a specific chemical substance;
- involving exposure as part of a multi-causal relationship; or
- indirectly from exposure by aggravating a pre-existing ill-health condition.

Experience has shown that a well-managed risk management process, and careful use of appropriate decision-making techniques, can assist in meeting the above-described challenges.

1.2 National Context for Risk Management Decision-Making

'Capacity for risk assessment and interpretation' and *'establishment of risk management policy'* were identified in Chapter 19 of Agenda 21: Programme of Action for Sustainable Development, (United Nations, 1993), as some of the basic elements of a national system for the sound management of chemicals. Other elements included *'adequate legislation; information gathering and dissemination; capacity for implementation and enforcement; capacity for rehabilitation of contaminated sites and poisoned persons; effective education programmes; and the capacity to respond to emergencies'*. Within the broader national context for the sound management of chemicals, risk management decision-making on priority chemicals is *one* important instrument for responding to major problems, or potential problems, caused by hazardous chemicals.

Evidence from countries with advanced chemicals management schemes shows that the implementation of an in-depth risk assessment and/or management process is often resource intensive and time consuming. Maximum use should therefore be made of available information, in particular evaluations of risks conducted by other countries. Many experts from developed countries suggest that an in-depth chemical-by-chemical risk management process should only be considered for those chemicals for which standard safety measures do not provide adequate protection. Such standard safety measures include, *inter alia*, the establishment of Material Safety Data Sheets (MSDS, also known as SDS) and labelling schemes, licensing requirements and safety standards. These measures should be considered essential elements of any national programme for the sound management of chemicals.

It should also be highlighted that many problems relating to hazardous chemicals in developing countries, and in countries with economies in transition, are often related to inappropriate handling practices and a weak enforcement of existing laws and safety standards. Problems may also arise from insufficient import controls, and/or a lack of education and training among workers and the general public concerning chemical risks. Thus, it is important to understand and consider the broader context in which a problem is encountered and to view risk management decision-making as *a complement to other national efforts* to strengthen the overall chemicals management infrastructure.

1.3 Identifying Priority Substances for Risk Management

Different circumstances and different kinds of information can trigger a recognition that a risk reduction strategy for a certain chemical needs to be developed. Information or policy guidance from the international community, for example, may serve to initiate a national risk management decision-making process, e.g. through the Prior Informed Consent Procedure (PIC) for Certain Hazardous Chemicals and Pesticides in International Trade of the Rotterdam Convention (see Box A). Similarly, accidents or concerns at the local/national level may indicate the potential need for a risk reduction strategy. In either case, action can be initiated in response to an actual problem, or to address potential risks that may manifest themselves only in the near or more distant future. Recognising the impracticality of applying an in-depth risk management decision-making process to *all chemicals*, each country will need to consider how it will go about deciding which chemicals should be submitted for risk management decision-making.

A number of countries with advanced chemicals management systems have established 'priority substances lists', 'priority existing chemicals (pec's)', and 'multi-problem chemicals lists' where phase-out, restrictions on use, limitations of releases, or bans may be needed. Prioritisation as a concept is essential so that available resources are allocated to issues that pose the highest risk to human health. Nations that are not sufficiently informed about hazards and risks associated with particular chemicals should identify whether such chemicals are produced, in use, or disposed of within their territories, so they have the broadest possible awareness of chemical risks

Potentially Hazardous Chemicals

Hazard identification is a major first step in identifying the potential danger to human health or the environment of the chemical substances of interest. It has been incorporated into regulations related to international classification and labelling of chemical substances, in the control of environmental emissions, toxic waste management, restoration of contaminated land, etc. When quantified and linked to dose-response relationships it provides an assessment of hazard. Some organisations are considering the possibility of establishing direct links between hazard assessment and risk reduction measures without requiring the more usual complete risk assessment.

Hazard can loosely be described as *the set of inherent properties of a chemical, or mixture of chemicals, which under production, usage, or disposal conditions, make it capable of causing adverse effects, depending upon the degree of exposure, on humans or other organisms or ecosystems.* Risk on the other hand, is concerned with the quantification of a probability of causing such an effect. *Hazard assessment should not therefore be confused with risk assessment.*

The main intrinsic properties of a chemical are *toxicity* (acute, sub-acute and chronic) and fate-related properties such as *persistence* and the potential for *bioaccumulation and biomagnification* through food chains. In regulatory protocols, toxicity in environmental terms is usually accomplished using a fixed end-point such as the no observable effects concentration (NOEC), or the concentration lethal to 50% of organisms ($L(E)C_{50}$). Various hazard-identification classification systems have been proposed to inform users and consumers of the potential dangers of the substance. In human health terms, toxicity

more specifically relates to carcinogenicity, mutagenicity, neurotoxicity, and reproductive toxicity.

Most developing and many developed countries are not involved in determining the intrinsic properties – the hazardous nature – of a chemical. They obtain the data from pertinent scientific literature, neighbouring countries, international organisations, etc. The Organization for Economic Co-operation and Development (OECD) through its Chemicals Programme and industry through internationally accepted protocols have undertaken an initial assessment of the risks posed by named High Production Volume Chemicals to human health and the environment. The basic hazardous data on important biological endpoints are known as Screening Information Data Sets (SIDs). These widely accepted data sets have been made readily available through publications of the Chemicals Unit of the United Nations Environment Programme (UN, 1995).

At the national level, identifying a particular chemical that is causing concern via its hazardous properties, the relationship between the dose or concentration of the chemical, and the expression of toxicological effects, is a time-consuming process that is discussed in Part 2. It involves a group of related disciplines – toxicology, pathology, epidemiology, ecotoxicology, etc. – depending on whether the environment or human health is affected.

Chemicals of National and Local Concern

In many cases countries will start to contemplate risk management actions when confronted with indications that an imported or locally produced chemical is causing health or environmental damage. Such indications may consist of, for example, a high incidence of work-related diseases in a chemical processing plant, or repeated cases of poisoning of farmers that use a particular pesticide. Evidence that a chemical is causing health and environmental damage can, furthermore, be derived from health inspections, environment monitoring, observations or repeated occurrence of a particular ailment or cause of death in specific regions (e.g. respiratory ailments affecting the population living downstream from an industrial facility), mortality statistics, skin sensitisation after handling particular chemicals, observed deterioration of the quality and taste of drinking water in certain areas, etc. The importance of involving local investigators who have cultural and language associations with the population being examined cannot be emphasised too strongly.

If an association is observed between some form of health effect and a particular chemical, several criteria can be considered to help establish whether the relationship is one of cause and effect. For example what is the:

- strength, consistency, specificity and timing of the observed association;
- presence of a dose-effect relationship or an observed gradient of an effect;
- scientific plausibility of the association between the effect and the likely cause;
- (occasionally) experimental evidence from the scientific literature that supports the association; and
- (in some circumstances) analogous observations on a structurally related chemical.

While some of these features provide conclusive evidence of a cause-and-effect relationship they can also help collectively to explain the observations and/or accumulated information.

In the previous examples, risk reduction strategies respond to problems and/or damage that have already materialised. Such approaches are *reactive* in nature. However, risk reduction strategies can also be developed in response to information suggesting that the uncontrolled marketing and use of certain chemicals is causing problems or may cause problems in the future. This is a *proactive* approach where impacts are predicted and, if necessary, prevented before they actually occur. For example, import data on a pesticide compared with estimates of pesticide use, based on typical application patterns may indicate that excessive amounts of pesticides are being used or that stockpiles must be accumulating in the country.

In line with the precautionary principle (Principle 15 of Agenda 21), many countries have introduced chemical screening procedures, usually based on hazard, that enable regulatory bodies to identify and estimate future health and environmental risks prior to the release of a chemical substance or product on the market. International expressions of the Precautionary Principle approach have already been applied to specific chemicals-related multilateral environmental agreements, e.g. the Montreal Protocol and the Vienna Convention for the Protection of the Ozone layer, the Stockholm Convention on Persistent Organic Pollutants (POPs) amongst others.

Internationally Identified Chemicals

Chapter 19 of Agenda 21 stresses the need for the international community to work within a framework of co-operation towards the joint goals of ensuring environmentally sound management of chemicals and the prevention of illegal trafficking. Consequently, international policy decisions, information/data generated at the international level, and/or the experiences of other countries may also trigger, or influence, a decision to initiate a risk management process for a chemical. The development of a risk reduction strategy may be initiated in response to commitments under international agreements and conventions. For example, the Stockholm Convention on POPs is global in scope and multimedia in coverage. It focuses initially on 12 chemicals that can be grouped into three categories (see Annex B). These chemicals are not only persistent but they are also bioaccumulated and become biomagnified up the food chain often giving rise to local impacts. The impetus for the treaty stems from growing recognition that POPs pose an international risk to public health and the environment as they are transported through the atmosphere by a 'grasshopper effect' from sites of application/generation to deposition sites in regions far away where they impact on local communities. The treaty sets out control measures covering their production, import, export, disposal and use.

In other cases, a country may decide to introduce risk reduction measures for a chemical that has already caused health or environmental damage in other countries and for which the adoption of risk reduction measures therefore may be warranted. The PIC Procedure of the Rotterdam Convention is particularly relevant in this context, since it creates opportunities for developing countries to be informed by, and make use of, other countries' experience with dangerous chemicals (see Box A). A list of the chemicals that are covered under the Rotterdam Convention is provided in Annex B.[1]

[1] The PIC Intergovernmental Negotiating Committee has also added binapacryl and toxaphene to the interim PIC Procedure and established an Interim Review Committee to consider further chemicals or hazardous pesticide formulations in the procedure. Ethylene dichloride and ethylene oxide have now been added to the Procedure making 31 substances or formulations in all.

Box A: PIC as a Trigger for National Risk Management Decision-making

The Rotterdam Convention on the Prior Informed Consent Procedure (PIC) for Certain Hazardous Chemicals and Pesticides in International Trade was adopted in September 1998 to ensure that certain chemicals that cause significant health and environmental concerns are imported only with the full consent and knowledge of the importing country. The objective is to promote a shared responsibility between the Parties. Chemicals included in the PIC Procedure are either banned or severely restricted for health, or environmental reasons in at least one country, or they are severely hazardous pesticide formulations that cause problems under conditions of use in developing countries. For each chemical included in PIC, a Decision Guidance Document is prepared by FAO/UNEP and sent to all Designated National Authorities along with a request to provide an importing country response. This import response specifies whether, and under what conditions, the chemical can be imported and used. Exporting countries should then ensure that exports take place only in accordance with the import decisions.

Thus, through PIC, national authorities are alerted to chemical risks that exporting countries have encountered, and are advised regarding risk reduction measures that have been adopted in those countries. This information may stimulate the importing country to turn to implement risk reduction measures for such chemicals.

It may be noted that all countries that have made decisions under PIC have gone through a risk management decision-making process, whether in a more formal and structured manner, or an informal manner.

Further information on the Rotterdam Convention can be found at the PIC home page *www.pic.int*.

Another comprehensive measure for the effective control of chemical risks is the International Labour Office's (ILO) Chemicals Convention no. 170 and Recommendations. The Convention established basic principles for the national promotion of chemical safety in the workplace. The focus for the control of chemical risks includes classification and labelling of chemicals, provisions of chemical safety data

sheets, training of workers and minimising their exposure. The aim of these activities is to strengthen local and national systems and legislation, especially industrial activities involving potentially hazardous chemicals.

While the uncontrolled use of chemical substances identified at the international level may often pose a direct risk to the environment and human health at the national level, some chemicals that have been targeted by multilateral environmental agreements pose an important risk to the global environment. Examples include, ozone-depleting substances that are covered by the Montreal Protocol, or the chemicals addressed by the Stockholm Convention on POPs. Thus, in some cases, national action on specific chemicals may be triggered locally as well as internationally because of the human health and environmental risks that manifest themselves globally.

1.4 Major Characteristics of Risk Management Decision-Making

Experience from industrialised countries show that certain characteristics are likely to promote an effective and successful risk management decision-making process. A lack of resources and other constraints in some countries, however, may limit their ability to incorporate all of the issues into the process as outlined by the US Presidential/ Congressional Commission on Risk Assessment and Risk Management (1997). In an abridged format the Commission recommended that an effective risk management decision-making process should be:

- *Cyclical/iterative.* Risk management decisions should be revisited and re-examined as further information becomes known. An iterative approach will help to ensure that risk reduction strategies remain up to date with evolving national policies and priorities, new scientific findings or technological developments, and that they take into account the effectiveness of existing strategies.

- *Participatory.* Risk reduction strategies should be developed and implemented in consultation with a wide range of interested and affected parties. Broad participation improves the quality and diversity of information and opinions that inform the decision-making process, and significantly increase the likelihood that risk management decisions will be accepted and implemented by relevant parties.

- *Informed.* Risk management decision-making requires various types of information and thus often calls for efforts to access and review a wide range of information sources. Different kinds of information, such as statistical data, probability studies, information about local customs and practices, knowledge about the nature of past and present exposure, economic analyses, information about regulatory and other control options, etc. may also be required. While an analysis should ideally be based on the best available scientific, economic and other technical information, other aspects will need to be considered such as the timeliness of action or the likely value of additional information

- *Contextual.* Risk reduction strategies concerning identical chemicals may vary significantly between countries, reflecting the different circumstances of countries, such as differences in culture, climate and geography, differences in the level of training and expertise of the work force, in the state of the national economy, public perception of risk, etc. To be effective, risk reduction strategies should be adapted to the political, cultural and socio-economic context as well as local realities.

- *Holistic*. In many industrialised countries, statutes and legal precedents tend to dictate risk management approaches that focus on the risk posed by a single chemical in a single medium (e.g. air, water, soil, food). While these approaches have reduced health and environmental risks in certain areas, they may not be adequate for solving the more complex problems many countries now face due to the cumulative exposures of various chemicals that are present in different environmental media. More integrated strategies that consider multiple environmental media and multiple sources of risk in order to sustain and strengthen the improvements attained in recent decades are of increasing importance. Consequently, creative and innovative approaches should also be considered that addresses risks to human health and the environment in a more holistic and comprehensive manner.

1.5 Risk Management in the Light of Uncertainty

It is highly likely that *scientific uncertainties, assumptions and other limitations* will be identified during the decision-making process. Information may be fragmentary and incomplete. All information therefore, must be evaluated and its potential impact on decision-making described as part of a transparent process.

A narrowing of the uncertainties is an important activity for it should lead to a more precise calculation of risk. The tendency to over- or under-estimate the risks should be clearly evaluated. Uncertainties with the largest potential impacts should be identified and evaluated first. Uncertainties can have a major effect on the estimated level of risk, especially if solely based on worst-case assumptions within a precautionary approach.

One of the greatest improvements in removing uncertainty has been in expressing exposure parameters more accurately and in using probabilistic approaches for determining exposure distributions and related risk outcomes. As exposure is what bridges the gap between hazard and a risk, variability of exposure within individuals and between sub-groups (e.g. the elderly, or children) can be a significant issue. Decision-makers, therefore, have to consider the most sensitive sub-group. A susceptible worst-case scenario if used, will most probably give rise to a higher estimation of risk than an 'average population' risk.

Risk management decision-makers should include not only uncertainties, variations, possibilities and options, but also all activities of the process so that it is transparent and easily understandable by all stakeholders. Professional judgements and expert disagreements should be clearly stated as the conclusions might not be transparent to others. Although it is important to maintain clear and comprehensive documentation of the process, the extent of documentation needs to be balanced by priorities and resources, especially if the timeliness of the management response is critical. Nevertheless, a succinct summary of the process covering the underlying scientific basis, uncertainties in the facts, and the rationale for any assumptions made should be produced as a minimum.

1.6 Tools and Policy Instruments for Risk Management

There are numerous measures, or policy instruments, for achieving risk reduction and, in most cases, there will be more than one way to achieve a particular risk reduction goal. For example, in order to achieve a given reduction in air pollution, emission standards (defining what releases of pollutants are acceptable) can be imposed through regulation, or adopted voluntarily by industry. Conversely, certain categories of measures and policy instruments may be used to address very different risk reduction goals. For instance, economic instruments might be used to promote cleaner technologies, or to reduce hazardous waste generation. Moreover, policy instruments are not mutually exclusive. In fact, a combination of different instruments may often be the most effective approach; for example, a voluntary agreement may need to be underpinned by regulation.

The most common categories of measures or policy instruments through which risk reduction options can be implemented are outlined below. The instruments/tools are presented along a continuum from the regulatory to the voluntary. The order does not imply a preference for one category over the other, but depending on the nature and particular circumstances of the problem under consideration, each tool will have its

advantages and drawbacks. A key requirement for governments is to assess the extent to which different strategies are likely to achieve risk reduction in a way that is efficient (integrated and co-ordinated), technically competent, accountable and transparent.

Regulatory Controls

A major driving force for environmental and human health protection in most countries has been legislation backed by a regulatory regime that specifies actions to be taken by the regulated community to reach specific objectives. The major advantage of national regulations (often referred to as the 'command-and-control' approach, or 'direct regulations') is its relative certainty of outcome, that is, if regulations are effectively enforced. Regulatory action therefore, represents an effective, preventive approach to reducing risks from industrial pollution, and for reducing occupational risks, or risks to consumers. In particular, a framework of standards to be adopted by industry also illustrates direction. In some circumstances, regulation can also be a powerful driving force for the development of less hazardous substances and production processes.

The main 'downside' of regulatory controls is the often high financial and human resource costs related to their introduction, implementation and enforcement. Additionally, unilaterally imposed, binding regulatory requirements may decrease the willingness of regulated parties (manufacturers or importers of chemicals, professional users of chemical products, farmers, consumers, etc.) to co-operate in a risk reduction strategy. Regulations, therefore, do not by themselves encourage industry to adopt a dynamic mechanism to reform their procedures and practices. Furthermore, incomplete knowledge and the injudicious adoption of the Precautionary Principle can result in standards being set that are unnecessarily stringent, loading industry with high cost implications. Some governments may need to undertake further research to reduce the margin of uncertainty and revise the level of a particular standard on the basis of evidence rather than one of precaution.

In the context of a risk management decision-making process, regulatory options to be considered may include:

- amending existing legislation or regulations, or more effective enforcement of existing controls in order to attain the broad aims of the legislation; and
- developing new regulations and legislation including:
    - developing uniform controls and setting standards (e.g. on chemical use, quality, safety);
    - establishing target-based controls, such as maximum amounts of a substance that can be emitted; or
    - placing restrictions on the manufacture, marketing and/use of the substance.

Considering that in a number of developing countries and countries with economies in transition, regulations exist that are not always, or weakly, enforced, a more differentiated view of the effectiveness of environmental regulation may be warranted. In these circumstances, a careful assessment of means to control and enforce regulations should receive particular attention, including the potential advantages and opportunities of non-regulatory approaches as are discussed later.

Economic Instruments

Economic or market-based instruments aim to reduce health and/or environmental risks by giving parties that are 'responsible' for causing these risks a financial incentive for reducing their undesirable activities. Changes of behaviour can be stimulated either by punishing, or rewarding, the actions of industry.

A range of economic instruments are in use in countries as methods of industrial control and to reduce chemical risks (Box B). In some countries, several of the approaches, both penalties and rewards, are used to encourage more environmentally responsible actions. Economic instruments provide strong incentives for technological innovation and behavioural change, and offer good prospects for achieving environmental and human health objectives in a cost-effective manner. From an industry perspective, emissions reductions, for example, will thus be made where they are least costly, thereby achieving a given reduction in total industry emissions at lower costs. In this case the industry will have carried out cost-effectiveness analysis – a limited form of economic appraisal – on the alternative methods and adopted the least costly. In addition, whereas companies have little incentives to reduce pollution any further once regulatory standards are met, economic instruments can provide a continued incentive for producers, suppliers and customers to reduce risks/emissions beyond legally required reductions.

Box B: Types of Economic Instruments

A range of economic instruments in use include:

- *Fiscal instruments*: to improve environmental and human health performance by a *penalty scheme* supported by pollution, effluent and emission taxes, product taxes, import duties, etc.;
- *Financial instruments*: to improve environmental and human health performance by a *reward scheme* supported by subsidies, soft loans, environmental grants, etc.;
- *Charge systems*: *to charge* for pollution releases by user charges for specific chemicals, impact fees, etc.;
- *Bonds and deposit/refund systems*: to levy bonds *to encourage* better industrial performance, reductions in hazardous waste generation, re-use of solvents, etc.;
- *Liability systems*: to establish a *legal liability* resulting in non-compliance charges, environmental damage charges, etc.; and
- *Market creation*: to establish *tradable permits* for allowing emissions, land contamination in one location with consequent reductions elsewhere, etc.

While economic instruments are not a panacea, and administrative controls are usually required as well, economic or financial incentives should be considered where possible to reinforce the effects of direct regulation. However, lack of practical experience in implementing economic instruments may be a potential obstacle for some countries. In a more general sense, fees levied on imported/produced pesticides to finance country programmes to control and monitor the safe use of pesticides could also be considered an economic instrument.

Codes of Practice and Technical Standards

Codes of management practice embodying technical standards and/or authoritative guidance on safety policies by Trade Associations and International Organisations can help to achieve specific improvements. Codes in general terms can be defined as statements describing the overall results required, and may go on to discuss, for example, how to achieve the results, or how to conform with legal requirements, additional measures, etc. Their use is often to supplement existing conventions, recommendations and technical guidelines, and to stimulate action in a given area at both national and international levels. Codes can take several forms:

- *Voluntary*: failure to follow the code has no direct/indirect legal consequence;
- *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
- *Statutory*: failure to comply is an offence unless it can be shown that other means are equally effective.

Trade associations and other bodies may be prepared to take the lead in devising and/or enforcing such codes, particularly those that are appropriate for spreading best practice. To the extent they exist, use should be made of internationally adopted codes and standards such as the FAO Code of Conduct on the Distribution and Use of Pesticides, or the ILO Code of Practice on the Prevention of Industrial Disasters. However, compliance with advisory or voluntary codes is likely to be uneven. There may be particular problems in sectors with a large number of small- and medium-sized enterprises (SMEs) where there are often financial, technical and institutional barriers. Morover, these are also the sectors where regulation and its enforcement are often most difficult.

Information Programmes and Other Government Initiatives

Better information, or improved communication, can reduce risks if those at risk are exposed unknowingly and unavoidably, and if they could take relatively simple precautions to limit the risk to themselves and others. This necessarily means that those exposed to chemical risks are in a position to influence the decisions taken to assess and manage the risks. Information programmes can also encourage the spread of best environmental practice, particularly 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 SMEs may require special consideration as well as reaching farmers and households in rural areas.

Incentive or certification programmes are another means to spur risk reduction and to promote and reward less environmentally harmful products and production. Examples include the establishment of internationally accepted third-party systems of certifying products or producers. The International Organization for Standardisation (ISO) series of environmental management standards and the European Union's Eco-management and Audit Scheme (EMAS) are widely implemented in many countries. The ISO 9000 as the lead quality management system and the ISO 14000 standard for environmental management systems, are reflections of 'good practice'. The eco-labelling of product groups (e.g. organically grown coffee) is a further example. Investment in infrastructure,

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

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 *self-regulatory action*, including codes of conduct, guidelines, principles, statement, policies, etc., is likely to be of particular relevance where risks are limited to specific industrial locations. Examples include:

- setting company performance targets, e.g. reducing emissions of chemical X by the end of the year by 10%;
- establishing product stewardship, or codes of practice during the products life-cycle, or adoption of life-cycle-based standards for a product;
- providing specific and readily available information or training to workers, e.g. on the information contained in, and the use of MSDS; or
- assisting in restricting a substance to specified uses under specified conditions.

The Chemical Industry Association's 'Responsible Care®' programme to improve health and safety of employees, the community and the environment, is a good example of what can be achieved through voluntary initiatives. The programme is characterised by professional adherence to a number of identified commitments:

- public commitments (principles);
- codes of management practices;
- a national public advisory panel;
- annual self-evaluations;
- executive leadership groups; and
- good faith implementation.

Reports from participating industries stress their annual management performance attainments.

Voluntary Agreements

Voluntary agreements are a relatively new approach that moves beyond the 'command and control' paradigm. Experiences of some countries indicate that industries have considerable potential for risk reduction and can often reach beyond government regulations by improving their environmental performance. This is especially the case where the regulated and the regulator share a common proactive approach of introducing more flexible and sophisticated techniques for setting and implementing standards, emission targets and limits. In practice, voluntary initiatives range from arrangements in which the parties (usually enterprises or their trade associations) set their own targets, on toxics-use reduction for example, and often do their own monitoring and reporting, to commitments made by an industrial sector in negotiation with public authorities, or government. Such actions are designed to meet specific emissions limits or targets within a certain time frame. This approach identifies the goals to be reached, but lets industry determine the most effective technical innovative route for reaching the goals. The U.S. Environmental Protection Agency's 33/50 Programme – to reduce releases and transfers

of 17 toxic chemicals (using the Toxic Release Inventory) by 33% and then by 50% at specific years – is one such example. In addition, there is often an unwritten assumption that the regulatory base will not be moved unless the sector fails to honour its commitments.

Voluntary agreements can preserve flexibility in areas where regulation can be rapidly outdated by developments in scientific understanding, or by a technological break-through. They can be implemented relatively quickly and can offer cost savings to both industry and the regulator – although 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 difficult. They may work best as implementing tools when the policy objective is clear and accepted by all parties and based on some type of legislation or legal mandate. As a wide range of stakeholders are recognised as having an interest in regulatory decisions, it is no longer acceptable for decisions to be negotiated privately between regulator and the regulated.

Experience suggests that voluntary agreements are most likely to be effective when they are set up with:

- companies willing to participate responsibly;
- a limited number of contracting participants with well defined obligations;
- a sound government regulatory and policy framework;
- well defined and published targets, including time frames, that can easily be monitored along with mutual recognition procedures to ensure implementation of policy actions; and
- transparency and openness towards the public and political institutions.

Voluntary agreements incorporating limitations on marketing and use are more likely to be appropriate when the full range of the substance's uses is easily identifiable, and where effective substitute or alternative techniques are readily available and can be introduced without excessive cost. Self-regulation through voluntary agreements can be a viable alternative to direct regulation for large enterprises, but direct regulation often remains the major option for SMEs. Their reasoning is that they have a defence (in terms of liability and clear lines of responsibility) if statutory targets are met, but an environmental problem occurs. However, if such problems occur in a voluntary regime, it can be more difficult to prove that appropriate precautions were taken.

PART 2: PREPARATORY CONSIDERATIONS AND SUGGESTED STEPWISE FRAMEWORK FOR DEVELOPING A RISK MANAGEMENT PLAN FOR A PRIORITY CHEMICAL

2.1 Who Should be Involved in Risk Management Decision-Making?

When identifying the parties to be involved in risk management decision-making, it is important to first establish what entity/entities will be responsible for, and have the authority to, organise the work, to establish its scope, and determine any boundaries to the management process. It is also important to establish who will gather the necessary information, and document and develop the recommended risk reduction strategy. It is furthermore, useful to identify at an early stage which public authority and/or non-governmental organisations (NGOs) might be responsible for the adoption, implementation and assumption of any liability for the risk strategy. Even if some parties are likely to play a main role only later in the process, e.g. during implementation, efforts should be made to involve them at an early stage in the process. Finally, interested and affected parties (stakeholders) that need to be consulted throughout the entire risk management process should be identified so that they adopt the concept of shared responsibilities as outlined in Box C.

Box C: Identification of Partners in the Decision-Making Process

Involving concerned parties and groups in the decision-making process permits the consideration of a diverse range of views, incorporates public perceptions, and invites broad-based input into the search for workable strategies. Being part of the decision-making process may motivate various concerned parties to move away from extreme positions and to accept pragmatic and viable compromises. This increases the chances that risk management decisions will be broadly acceptable. Collaboration provides opportunities to bridge gaps in understanding, perceptions and values. Such a participatory process will also more likely result in risk reduction strategies that are effective, defensible and geared towards national needs and priorities. However, no strategy – no matter how thoughtful or appropriate – can guarantee a universally acceptable decision. Nevertheless, making sure that all partners (stakeholders) are involved at each stage of the process and have opportunities to provide appropriate and constructive input can increase the chances for successful, acceptable and durable decision-making.

Guidelines for stakeholder involvement as identified by the US Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) include the following important principles:

- Regulatory agencies or other organisations considering stakeholder involvement should be clear about the extent to which they are willing or able to respond to stakeholder involvement before they undertake such efforts. If a decision is not negotiable don't waste stakeholders' time.
- The goals of stakeholder involvement should be clarified at the outset and stakeholders should be involved early in the decision-making process.
- The nature, extent and complexity of stakeholder involvement should be appropriate to the scope and impact of a decision and the potential of a decision to generate controversy.

Identifying the Managers of the Process

As many different ministries play a role in the process of managing chemicals at the national level, any one of which may be an appropriate lead agency or supervisor for a particular problem. The title of Risk Manager(s) is sometimes applied to individuals or departments or agencies that will help supervise and manage this process. The relevant ministries/departments involved include:

- *Environment*: concerned with the direct and indirect effects of release chemicals into the environment;
- *Agriculture*: concerned with the use of agricultural chemicals for the benefit of securing food supplies while ensuring a high level of safety;
- *Customs*: responsible for ensuring that chemicals do not enter or leave the country contrary to governmental regulations;
- *Health*: concerned with the short- and long-term health impact of chemical use on the general public and often for the use of chemicals for public health purposes (e.g. vector control);
- *Industry*: concerned with the production of chemicals, their use as industrial inputs and the safety and emissions of industrial facilities;
- *Labour*: concerned with the occupational implications of handling of chemicals in the workplace, which also includes agricultural workers;
- *Trade*: concerned with the import and export of chemical substances. They often have the authority to issue relevant trade permits; and
- *Transport*: concerned with the safe transport of chemicals by air, water and land.

Representatives of many of these ministries, along with local and/or state regulators and officials, should be involved in the risk management decision-making process. Technical experts as well as decision-makers may all be involved depending upon the nature of the issues and the stage of the decision-making process. Risk management responsibilities may well be shared between different ministries depending upon the complexity of the risk situation – multi-media, multi-source, or multi-chemical in context. It is unusual for only one ministry to be involved in such situations.

Identifying Non-governmental Stakeholders

In addition to governmental participants, the risk management decision-making process should be carried out in continuous consultation with interested and affected parties, or ‘stakeholders’. Stakeholders are likely to include all those who are affected by the problem, or who might be affected by a proposed risk reduction measure. They may include, for example, industry associations, worker’s associations, representatives of environmental and consumer groups, communities and citizens. Discussions involving such diverse groups with a wide range of skills and abilities should be conducted in such a manner to be meaningful to participants without specialist knowledge.

In some cases, stakeholders may also come from outside the country: International Agencies such as the World Health Organization, or the World Bank, parent companies of national subsidiaries, neighbouring countries, trading partners, etc. While these ‘external’ stakeholders will certainly play a different role than national stakeholders in a risk management process, their involvement may be important at certain stages, for

example, when identifying and discussing possible risk reduction options and when considering practical aspects of implementing risk reduction strategies.

> *Stakeholders are therefore involved in the entire process, rather than merely being consulted on already drafted proposals.*

Recognising Common and Conflicting Interests of Stakeholders

As risk management involves scientific values, perceptions and judgement, it is a good idea in principle to involve representatives of all legitimate groups that may care about the risk-management actions that are taken. Inclusion, rather than exclusion, of interest groups is an important policy approach as different people hold different values as mentioned in Box C. In the typical case, stakeholder groups will have many overlapping and shared interests but will also hold some concerns that are specific to their group. All parties tend to care about broad categories or possible impacts: the social, economic, health and environmental effects of a chemical control action. However, each party may also have unique concerns. For example, a group from a rural area may have concerns about the economic effects on its community of reducing a pesticide's permitted uses. A multi-national company, on the other hand, may care about market access, or its reputation.

Often stakeholders will agree on certain basic principles but the relative weights that they place on these may vary considerably. For example, while all stakeholders may care about environmental quality and opportunities for economic development, the relative importance given to these two topics may differ substantially. When initiating risk management activities, it is often useful to understand and be aware of the perspectives of various stakeholders. In reality there are always some groups that will not become involved in the decision-making process. For example, if the number of concerned parties is very large it may be impossible, for practical and financial reasons, to involve everyone. In such cases, it is generally advisable to involve groups that will span the range of relevant perspectives and to avoid redundancy in views; the aim is not to hear from everyone but to obtain a representative input of views and perspectives. Stakeholder collaboration is especially important for risk management decision-making, for the different value positions will be made explicit which will help with communications between stakeholders. Some groups may adopt a deliberate strategy of not supporting any initiative. Although it is useful to understand their perspectives, it may be prudent not to directly involve such parties.

In other cases, concerned parties may be missing from discussions because they are not organised, e.g. young children, or because their connection to the decision under consideration is not yet known. No one method for determining or articulating people's values provides a guaranteed solution. The procedures used have to be refined in the light of experience.

2.2 Organising the Decision-Making Process

The risk management decision-making process should ideally be orchestrated by a core working group who can draw on the expertise of, and promote communication among, the various concerned ministries as well as other stakeholder groups. Such a group (or

committee) should typically include, as a minimum, representatives of the Ministries of the Environment, Agriculture, Customs, Health, Industry, Labour, Trade, and Transport. Representatives of other concerned and interested parties outside of government should also be involved, either directly or through some other mechanism. For instance, a technical advisory group could be established comprised, *inter alia*, of experts from industry associations, public and environmental interest groups, universities and national research institutes, to provide input on an ongoing basis to the work of the core working group.

The mechanisms for involving a broad range of stakeholders in the process will also need to be considered. One approach could be based on the distribution of risks – whether they are especially high for people in certain localities, age groups or occupations, or people with certain genetic pre-dispositions. Consequently, discussions could be organised in a number of ways. A selection of possible ways includes: on a regional (within the country) basis; by industrial sector; with communities in proximity to industry sites; or with subpopulations that have been identified as possibly being particularly vulnerable. None of these possible ways is mutually exclusive. For obtaining specific input, a meeting could be held to solicit views of the various stakeholders and to identify their perceptions of the risks posed by the problem. Draft materials could be distributed and reviewed by participants as a means for obtaining practical input. Another approach might be to meet individually with each of the concerned parties so as to obtain their views through one-on-one interaction. Alternatively, a combination of approaches could be used.

The appropriate role of external experts or consultants should also be considered. Such individuals can provide guidance, based on their experience, about what might happen if a particular decision is taken. However, their involvement should be such that the final decision is the result of a nationally-owned process and thus reflects the history, context and culture of the country.

Each country will have to find the organisational arrangement that best meets its needs and that will be most likely to lead to co-operation among concerned parties. The *process* through which risk management decision-making is carried out and the degree to which concerned parties feel appropriately involved often is a key determinant of success and should be carefully considered and clearly communicated from the outset. While each problem may require a different approach for stakeholder involvement, formulating a decision-making process can help to increase transparency and ensure that the various concerned parties know what to expect and understand how they can effectively contribute to the process. Clearly, such a process should ensure that the credibility of the regulators and the government is upheld.

2.3 Introduction to a Suggested Stepwise Framework

Establishing a stepwise process for risk management of a priority chemical assumes that a problem has been recognised, that a particular chemical has already been identified and that the adoption of possible risk reduction measures has been discussed. This decision may have been taken based on concerns raised at the national level or concerns raised at the international level, including adoption of International Conventions (as outlined in Part 1).

A suggested six-step process has been developed which outlines a systematic and comprehensive process for organising risk management at the country level. Each of the steps is discussed separately in chronological order. The emphasis placed on each of the steps, and the time and resources devoted to them, will vary accordingly to the problem chemical and the reliability and comprehensiveness of the information available on that chemical. It is understood that such a process must be carried out in the light of the particular institutional mechanism and circumstances of each country. Thus the guidance and broad suggestions contained in this document should be used and applied in a flexible manner. Briefly described, the steps are as follows:

Step	Action/Task	Aim
1	Conducting a situation analysis/needs assessment	To understand the local/national situation and to identify the actual or potential hazards and problems posed by the chemical substance in the country, including risks to health and/or the environment.
2	Developing risk reduction goal, sub-goals, and indicators	To develop risk reduction goal, sub-goals and indicators on the basis of the situation analysis/needs assessment and relevant national/local situations.
3	Identifying and evaluating risk reduction actions	To identify and evaluate options that could achieve the risk reduction goal and thus control the identified problem(s).
4	Selecting and developing the risk reduction strategy	To select the risk reduction option(s) and develop the implementation strategy to address the risk of concern.
5	Obtaining commitment and taking action	To submit the proposed risk reduction strategy to decision-makers and to take steps to ensure its adoption and effective implementation.
6	Evaluating impact	To evaluate impact of the risk reduction strategy and whether additional action is required.

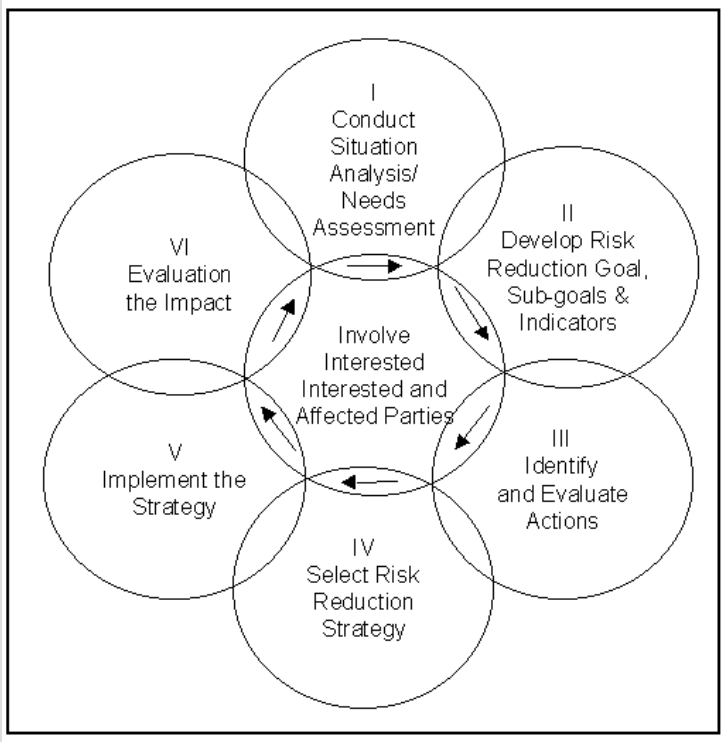
The key features that distinguish the six-step process from national actions in some countries are:

- the explicit separation of functions between the analytical process of identifying priority chemicals and the policy issues that may involve social, economic, national and other considerations;
- the comprehensive description of the types of analysis required to support decisions, their assumptions and uncertainties;
- the emphasis on stakeholder involvement at all stages, especially from recognising and defining the problem through to formulating a strategy for implementation; and
- the transparency and openness of all stages in the decision-making cycle.

The six-step iterative process for risk management decision-making is best illustrated with reference to Figure A. The process has been developed and tested in the course of 1999 through country-based pilot case studies in Cameroon, Chile, Tanzania and the Gambia and provides the basis for a companion UNITAR document entitled ‘Action Plan

Development for Sound Chemicals Management'. More details as well as suggestions and examples for each of the six steps are provided in the relevant sections below.

Figure A: The Conceptual Framework for Risk Management



Adapted from Health Canada, 2000.

2.4 Step 1: Conducting a Situation Analysis/Needs Assessment

Objective: *To develop a detailed situation analysis/needs assessment within which the actual or potential problem posed by the chemical substance in the country can be identified; including an evaluation of risks to health and/or the environment.*

Suggested output: *A refined situation and problem statement, addressing questions such as: At what stages of the life-cycle are the most important risks/problems occurring? Are there specific populations or ecosystems that are particularly affected?*

A clear identification of the chemicals issue, which involves both *an analysis of the situation* in which the issue occurs, as well as *an identification of the problem*, can provide an important foundation for the risk management decision-making process. It is important to note that the order outlined for this step is not necessarily fixed but rather will likely require revisiting certain components. For example, it is likely that the

situation analysis can be initiated but not adequately completed without obtaining information through the development of a problem statement.

2.4.1 Establishing and Evaluating the Situation

An analysis of the situation is the first step and is really an examination of the local/national circumstances or conditions in which the issue occurs. This can provide insight into where challenges lie and where opportunities exist. It involves asking in broad terms: 'what do we have?', 'what do we lack?', and 'what is inadequate?'. Some basic questions could include:

- Which Ministry/Department(s) is/are involved in managing the chemical?
- What chemical-specific legislation/regulations are in place in the country?
- Is enforcement of regulations (if they exist) undertaken as necessary?
- What relevant industry(ies) use the chemical? Are there university departments or research institute that are undertaking relevant research/investigations?
- What level of understanding exists in government and industry about the hazards the chemical poses?
- What level of awareness exists in workers and the public concerning the chemical?;
- What related technical infrastructure exists (e.g. information on quantities produced/generated, imported, in use)?
- Are there any 'bottlenecks' in the management of the chemical nationally and/or locally?
- Are there cases of accidents, poisonings, contamination, etc. involving the chemical, and routinely reported to the relevant authorities?

Such questions may have already been answered during preparation of a 'National Profile to Assess the National Infrastructure for Management of Chemicals'.

Analysing the Broader Management Infrastructure and Context in which the Chemical is Used

It is important to analyse and diagnose the broader context and circumstances in which the chemical is used. It will help identify the reason(s) why a certain problem and exposure to a chemical is occurring. In addition, such an analysis must often be considered key to the development of an effective risk reduction strategy that is adapted to local circumstances.

> *A full understanding of the context of a risk problem is essential for effectively managing the risk.*

To fully understand the environmental and health problem associated with a specific chemical, it is important to consider the strengths and weaknesses of the related chemicals management infrastructure, including legal, technical, administrative or institutional aspects. An example of such issues is included in Box D. In many cases, weaknesses in the broader infrastructure may provide an obstacle to solving the problems.

Box D: Management Information Needs – An Example

A pesticide chemical which has been banned in country A is still being imported and causing health and environmental problems in certain rural areas. Obviously, the risks associated with the chemical have been recognised by the country (a ban is in place) but the problems associated with the pesticide have not been resolved as the substance is still entering the country illegally. Weaknesses in the customs department, and in the legal and enforcement infrastructure are preventing the problem from being solved. Possibly a lack of laboratory support for chemical analysis of suspect pesticides may also have prevented effective cross-border controls in the past. In this case, a broader analysis of the enforcement infrastructure, including responsibilities of various parties, is likely to be important to fully understand the problem.

Another example is included in Box E. In this situation it is not weaknesses of the broader infrastructure that are important. Rather it concerns problems associated with pesticides when farmers store the active material in their homes whether due to purchases that are surplus to requirement, or that are purchased many months prior to their intended use.

Box E: A Broad Chemicals Context – An Example

Poisoning cases have repeatedly been reported in rural areas of a country with children drinking pesticide X due to inadequate storage of pesticides in rural households. The pesticide is highly toxic (also in comparison to other pesticides used) and one of the most common pesticides used in the country.

Any risk reduction strategy for pesticide X should therefore take into consideration that the same problem may be caused by other chemicals stored in rural households, although the effects of poisoning from pesticide X may be particularly severe because of its high toxicity. We should deal with a multi-chemical problem and a risk reduction strategy as targeting only pesticide X is likely to be ineffective. For example, reducing, or banning, the use of pesticide X might simply result in higher poisoning cases from other pesticides. Thus, the problem statement of pesticide X should clearly take into account similar risks by other chemicals otherwise the risk management strategy may not effectively address the actual problem.

The range of different types of risks that can be considered within a broad infrastructure is another important consideration. This concept is illustrated in Box F.

Box F: Identifying Chemical Risks

When considering health end environmental problems that are, or may be, caused by a chemical, a variety of different risks can potentially be identified:

- From the perspective of an individual, 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. In addition, risks can result from both one-time and repeated exposure.
- With regard to pollution sources, a distinction can be made between risks from point sources (e.g. emissions from a factory) and diffuse sources (e.g. pesticides in agriculture). 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.
- From the perspective of a chemical substance, risks can arise throughout the various life-cycle stages of the chemical, from production and/or import, to transport, use and final disposal.

While such an infrastructure analysis may be conducted on a case-by-case basis, countries may also want to draw upon the information contained in their National Profile to be used as a reference document for their risk management activities.

Experience has shown that it is essential to also consider the broader environmental and socio-economic context of a chemical-related problem. It is usually not sufficient to consider one chemical, one environmental medium, and one risk at a time, for this narrow context does not reflect the true complexities of many chemicals problems.

A problem's context can include risks from other chemicals and other environmental media. Understanding the context is essential for effective management of the risk.

For example, it may be important to consider the values and perceptions among specific populations at risk, or the corresponding level of education. In some cases one may also face a situation where populations and ecosystems are: exposed to other chemical risks at the same time that may also need to be considered *(multi-chemical situation)*; facing other risks such as food shortage/malnutrition, malaria, etc. *(multi-risk situation)*; or facing other multiple exposures to the same chemical *(multiple-exposure situation)*.

This risk characterisation process should, therefore, aim to highlight the broader context of a chemicals-related problem. This will help those involved in the risk management exercise to also address more general environmental and socio-economic factors that may be relevant for adequately addressing the problem and chemical risks.

2.4.2 Developing a Problem Statement

Identification of the chemicals problem is the second important component when initiating the analysis. This means that the risks to health and/or the environment – the problem – will be considered in the local or national context – the situation. When identifying the issue it is important at this stage to have *an appreciation of the magnitude of the problem*. Was it a 'one-off' event, or is the problem an on-going one? Are large numbers of people directly affected from chemical usage, or has the problem arisen through misuse?

Several general tasks are listed in Box G that can help with identification of the problem or chemicals issue, although these will vary depending upon the root cause of the event.

Box G: Identifying the Issue and its Context – General Tasks

Content-related tasks:
- identify the issue;
- begin to characterise the risk;
- put the issue into an appropriate context; and
- identify issues relevant to hazard and risk assessment.

Process-related tasks:
- allocate resources for issue identification and hazard and risk assessment;
- establish the hazard and risk assessment team if necessary;
- identify roles, responsibilities and accountabilities; and
- identify interested and affected parties.

Both the sequence of these tasks and whether they are performed sequentially or simultaneously may vary depending upon the specific issue and the context involved.

Modified from Health Canada (2000)

As is shown in Box G, a distinction can usefully be drawn between *the content*, which may raise important considerations that need to be raised with regard to problem chemical, and *the process*, which is associated with administrative action to deal with such a chemical. The quality of the decision will be determined by how well both tasks are undertaken. While local problems caused by a chemical substance are likely to be of major concern, risk reduction strategies may in some cases also be initiated based on concerns raised at the regional or global level. For example, national action to phase out ozone depleting substances (as identified by the Montreal Protocol) or the possible phase-out of certain POPs would be conducted in response to global environmental and human health concerns. Thus, in certain circumstances the identification of chemicals related problems may also take into account problems which are caused outside the geographical boundaries of the country.

The problem statement summarises the reason for considering action and defines (to the degree it is understood) the problems, which are being encountered. In addressing these issues, the problem statement should highlight areas that are not well understood and that

should be clarified through the risk characterisation. In developing the problem statement, countries may want to focus on two main questions:

- Why is action being initiated?
- What is the exact nature of the problem?

Concerns in relation to the health and environmental risk of a chemical substance are raised, either because there is some evidence that a particular problem is already occurring, or because a problem may occur in the near or more distant future. For example, in some cases a chemicals-related problem may be well recognised because of information obtained from local health inspectors, hospital data, poisoning statistics, reports in the media about chemicals related accidents or diseases, or legal action by an importing country (e.g. an import ban due to health concerns). Other concerns may have arisen through reports of health effects from misuse of chemicals, or lack of enforcement of safety legislation.

In other cases, there may be evidence that a problem may occur in the near future if no preventive action is taken. For example, legal action by one or several countries to ban or severely restrict a chemical may indicate that the continued unregulated use of the chemical in the country is likely to result in environmental and human health problems in the future. Broadly speaking, identifying a problem can be based on, and take account of, various types of information, including:

- national and local data and information regarding health and environmental incidents;
- national and local information on existing management practice, etc.; and/or
- information, data and assessments that are available internationally.

The nature and importance of such sources will vary with the specific issue involved. Where possible a multi-disciplinary approach should be used to ensure that as many aspects of the issue are identified as possible.

While in some cases the chemical and the problem/risk may be well understood, in other cases there may be considerable amount of uncertainty about the nature of the chemical and the potential environmental and health problems. Based on current knowledge, the problem statement should provide a brief summary of the issues that are being confronted, as well as areas of uncertainty that may need to be addressed through a more detailed risk characterisation. Questions to be addressed may include:

- How and for what purposes is the chemical substance being used?
- Through what activities is the chemical causing harm (e.g. through normal use, due to accidental spills or intentional misuse)?
- What ethnic or socio-economic, group or geographic areas are affected?
- What is the magnitude of the problem?
- Is urgent action needed?
- What are potential implications for the future if action is not taken?

These questions are based on a problem caused by chemical usage. But as mentioned in this section there is a range of different chemicals issues and consequently different entry points to the formulation of a problem statement.

Identifying Human Health and Environmental Problems

Identifying human health and environmental problems associated with use or misuse of a chemical is one of the main initial tasks towards developing a problem statement. Problem formulation is vital in ensuring that all relevant factors are considered in this evaluative stage. Identifying such problems may draw on various types of complementary information, including:

- *Regulatory measures taken in other countries*, e.g. bans and restrictions as made available through the PIC Procedure of the Rotterdam Convention. Regulatory measures taken by other countries may provide useful information as to the potential human health and/or environmental risks associated with the use of a chemical. In general, such regulatory measures are taken in response to specific problems that have been encountered. While different circumstances in countries may warrant different regulatory measures for the same chemical, reviewing the basis for regulatory action by other countries will often provide valuable and low-cost insights as to the possible human health and environmental risks under local conditions of use.

- *Actual evidence of problems*, e.g. reported poisonings, contamination, misuse. Reports of poisoning cases, or contamination of certain sites or waterways will often provide a clear indication that some chemical-related problems are occurring. Accident reports provide evidence of high and possibly lethal exposure to a chemical and may, in many cases, be sufficient as a basis for initiating control action. While local information on chemical-related incidents is highly valuable, the quality and reliability of such information tends to be uneven. For example, the specific chemical causing the problems may not be known. Did the exposure occur under 'normal' conditions of use? Was the exposure due to inadvertent or deliberate misuse?

- *Potential problems identified by a hazard or risk assessment*. Hazard and risk assessments provide a mechanism for a structured review of information relevant to estimating health and environmental effects and potential risks of a chemical. Hazard and risk assessments conducted internationally and by other countries are available for a wide range of hazardous chemicals. Whereas a review of such assessments by countries can often be useful to estimate human health and environmental effects and risks under local conditions of use, conducting a risk assessment is highly resource-intensive and is generally not recommended.

- *Other relevant information such as quantity and type of use of a chemical*. A number of other types of information may also be used to estimate or determine human health or environmental problems. For example, import restrictions on certain agricultural products by trading partners due to high pesticide residue levels may provide clear evidence to a country that chemical use and/or management practices are inadequate. Also, import data for a pesticide combined with knowledge of typical application patterns can give an indication of whether too much of the pesticide is being used in agriculture.

In determining human health and environmental problems related to a chemical, much national and international attention has been given to *hazard and risk assessments* as an

important element and scientific basis for developing risk reduction strategies. The concept of hazard and risk assessment is discussed below.

Elements of the Process of Hazard and Risk Assessment

The reader is referred to Annex A for an overview of the four main stages of a risk assessment. Briefly, risk assessment is a conceptual framework that provides the mechanism for a structured review of information relevant to estimating health and environmental risks of a chemical. The risk assessment process is typically divided into four distinct steps: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment and (4) risk characterisation.

> *Experts from developed and developing countries generally agree that the initiation of risk reduction measures for priority chemicals does not always need to be preceded by an in-depth risk assessment. Information from a hazard assessment may be adequate.*

There are different scenarios in which countries may move directly to risk reduction measures. For example, if:

- the risk management policy of a country is based on hazard and there is an assumption made that members of the public are being exposed. For example, in the European Union (EU), a chemical is automatically banned for consumer use if it is classified as carcinogenic;
- evidence exists that the chemical is not being used as intended (e.g. use of a pesticide in agriculture which has only been registered for public health purposes) or misused (e.g. illegal use of a pesticide for fishing, as a suicide agent);
- a chemical has similar hazard properties, use patterns and exposure potentials as other chemicals that have already been targeted for risk reduction; and
- the chemical has already been banned in several other countries and/or is subject to the PIC procedure.

➢ *Making Use of Availability of Hazard and Risk Assessment Information*

Hazard and dose-response information is available at the international level for a vast array of chemicals that are common in international trade and commerce. In many cases, such information is freely available. Countries are increasingly sharing this type of information and are collaborating in its development, in light of the high costs and time needed. Standard testing procedures have been adopted at the international level, for example by the OECD, to facilitate the exchange and use of such information.

It is recommended that countries make maximum use of available information and materials. Some main sources of information which countries may want to consult at this stage include the websites of various organisations and institutions and data networks (see Box H).

Internationally available data and information can also be used in specific models to gain a better understanding of potential risks under certain specified conditions. A range of

Box H: Selected Sources for Chemicals Information

Selected Internet Sites for Chemicals Information

The following provides a selection of Internet Homepages where valuable chemical specific information can be found:

- WHO Pesticide Evaluation Scheme (WHOPES): *www.who.int/ctd/html/whopes*
- UNEP/FAO PIC Procedure: *www.pic.int*
- UNEP POPs : *www.chem.unep.ch/pops*
- OECD Environmental Health and Safety Unit: *www.oecd.org/ehs*
- US Toxicology Data Network: *http://toxnet.nlm.nih.gov/servlets*
- US Agency for Toxic Substances and Disease Registry (ATSDR): *www.atsdr.cdc.gov/atsdrhome*
- CEPIS/PAHO: *www.cepis.org.pe*

Additional data sources include:

- Environmental Health Criteria series. The series provides comprehensive and peer reviewed information on the risks of specific chemicals. It is published by the International Programme on Chemical Safety (IPCS) and booklets in the series are regularly sent to national IPCS focal points in countries (usually Ministries of Health);
- Chemical Safety CD ROM by WHO/IPCS;
- Screening Information Data Sets (SIDS), on High Production Volume chemicals published by OECD and UNEP;
- Risk assessments carried out by other countries or organisations;
- MSDS/chemical safety cards (published by IPCS/ILO);
- Information on limit values used by other countries or recommended by international organisations;
- Information provided through existing international agreements affecting the substance (e.g. conventions, protocols) or other international discussions/policy developments of relevance to the selected chemical; and
- 'International' standards for classification, packaging and labelling, e.g. standards used in the European Union, those under development in the context of the Globally Harmonised System (GHS).

computer-based models that have been developed for all stages of the hazard and risk assessment procedure for both human health and environmental impacts are available.[2] Some of these, such as the European Union System for the Evaluation of Substances (EUSES), can be used as both a training and an assessment tool.

With regard to the potential use and applicability of computer-based tools to support risk management decision-making, the following points can be made:

- *Transparency is important*: the user must fully understand what is happening in the model, including assumptions made. Detailed knowledge of risk assessment is

[2] For more information, contact UNITAR.

essential, otherwise the model becomes a "black box" that can be used and misused.

- *Stakeholders should be involved early on in the risk assessment stage*: it is recommended that risk assessment methodologies be mutually agreed upon before assessments are made. If stakeholders understand the process of risk assessment (the model), the acceptability of the results/output of the risk assessments will increase.

Risk assessment tools can be used in developing countries provided that the necessary data are available: (1) for screening purposes (e.g. for identifying priority chemicals); and (2) to aid in comparing alternative chemicals and to conduct impact assessments.

➢ Assessing Exposure to Chemicals Under Local Conditions of Use

Information from international sources is often very useful at the exposure assessment stage. Often this information provides some benchmark on exposure levels under 'normal' conditions of use, i.e. in accordance with manufacturers directions, with proper safety equipment, etc. However, exposure assessments from other countries or regions should be interpreted with care due to differences in local climatic conditions, handling and use practices, levels of education and nutrition, etc.

Gathering sufficient exposure information does not need to be a costly and time-consuming endeavour and can be based on estimates or available facts. The objective of this step is to gather information held by individuals or organisations. An example could be the high incidence among farmers of symptoms associated with pesticide exposure (e.g. irritated eyes, headaches) together with knowledge of which pesticides they are applying might be used to estimate likely exposure levels.

Some of the main sources and types of information at the country level that may be of use to determine or estimate exposure levels are listed in Box I.

Box I: Information of Use When Establishing Exposure Levels

A variety of information sources to help establish exposure levels include:

- production and import data of the chemical in the country (e.g. is the chemical/product imported and if so, how much per year? Is it produced/mined domestically and if so, how much per year and by what type of enterprises and using what processes/technologies?);
- information on use and handling practices of the chemical in the country (including products which contain the chemical, as well as certain geographical regions and/or times of the year in which the chemical is primarily used);
- data on human exposure (e.g. at the workplace, through consumer products, through foods);
- incidence of accidents/poisonings involving the chemical; emissions/releases of the chemical into the environment (e.g. air, water, land);
- reports of adverse effects to humans and/or ecosystems; existing stockpiles and/or disposal sites;
- available monitoring data (e.g. concentrations in environmental media, food, humans); and
- information from producers, workers, or consumers, media reports, local experts; evidence of environmental impact (e.g. dead animals, or plants, bad odours).

Information obtained at this stage should indicate the extent to which, and at what stages of the life-cycle, exposure to the chemical is occurring, or is likely to occur. While information on chemical hazards is generally available at the international level, information to be used in assessing chemical exposure under local conditions of use will often have to be gathered, or estimated at the country level. While local information on chemical exposure is highly valuable, the quality of such information tends to be uneven: sometimes it will be carefully documented; at other times it will be anecdotal. Also, data gaps will undoubtedly be encountered and there will be aspects for which national/local information will simply not be available. It is important to assess the reliability of information and to note possible information gaps and deficiencies, so that these can be taken into account in the risk characterisation.

Risk characterisation is the final step in the process and aims to summarise and assess scientific evidence and exposure information in order to help risk managers determine whether there is a need for action, and to assist in identifying possible risk reduction options and strategies. Scientific uncertainties that exist as well as public perceptions of the risk are further factors to consider as discussed in Part 1.

The United States Environmental Protection Agency (USEPA, 1996) defines risk characterisation as:

> *'A summary, integration, and evaluation of the major scientific evidence, reasoning and conclusions of a risk assessment. It is a concise description of the estimates of potential risk and the strengths and weaknesses of those estimates'.*

Whereas the European Commission (Hertel, 1996) defines risk characterisation as:

> *'The estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental sphere due to actual or predicted exposure to a substance, and may include risk estimation, i.e. the quantification of that likelihood'.*

In order to determine risk characterisation, that is the accumulation of risk information, the following components of a checklist should be established:

- Is there a particular population at risk?
- What is the damage scale of the risk?
- What is the probability of occurrence of this risk?
- What are the characteristics (irreversible, reversible, transient) of the risk?

The risk characterisation therefore summarises risk in an integrated and evaluated form that is clear and transparent and includes attendant uncertainty.

Formalising the Problem Statement

Based on the analysis of the human health and environmental risks as well as the diagnosis of the chemicals related infrastructure and broader socio-economic context, it should be possible to formalise the problem statement. In simple terms, this statement characterises the risks to human health and the environment from the various stages of the chemical's life-cycle (i.e. production, import, transport and storage, handling and use,

disposal) and includes a diagnosis of the chemicals management infrastructure and socio-economic context. With regard to the risks during various stages of the chemical life cycle, it may be useful to develop an overview table, an example of which is provided in Table A.

Table A: Overview of Risks Identified throughout the Life-cycle of the Chemical

Life Cycle Stage	Description of Identified Risks	Target Group(s)	Level of Concern (low, medium, high)
Production			
Import			
Storage and Transport			
Handling and Use			
Disposal			

The approach is designed to be used in a qualitative way to estimate environmental and human health risks, including levels of concern, for example, severity and consequence, on a three-banded scale. A three-banded judgement scale only is proposed so that both scientific/technical and community stakeholder perceptions of impacts causing the greatest concern can easily be stated. The overview 'banding' approach could also be extended, providing some data and information are available, to better consider the scale of risk. Concepts such as severity, persistence, reversibility, etc. could be included in the discussions and may help refine the problem and help determine its magnitude.

The problem statement should also include a recommendation on whether further action is necessary to reduce the chemical risks. For example, the analysis might suggest that:

- The chemical, initially thought only to cause major risks when used in household products by non-professional users, is also likely to be of concern in industrial settings due to the inadequacy of protective equipment used by workers.
- Conversely, the risk characterisation might indicate that the environmental threats posed by the chemical are less severe than previously thought, thereby calling for a review of previously formulated priorities and a possible decision to abandon the development of a risk reduction strategy for that substance.
- Or, the risk characterisation might uncover high levels of uncertainty surrounding the possible impact of a prioritised chemical. In this case, a first course of action might be to generate and/or gather more information about the substance in question.

Identifying human health and environmental risks often uncovers gaps in information and uncertainty about the actual risks posed by a chemical substance. Uncertainties often result from the incompleteness and/or unavailability of scientific data. Scientists may therefore make assumptions, inferences and judgements, in order to estimate risks as discussed earlier in Part 1.

Documentation of the Situation, the Problem and the Analysis

A record of all of the information used in the problem analysis should be established as an example for future evaluators to study. Specific details should include not only the basic data and information, but also assumptions, controversies, uncertainties, etc. What data gaps were uncovered and how they were considered within the risk management options under discussion, are two further critical questions. Information should be stored not only on the immediate problems and their effects but also on the underlying causes so that a longer-term perspective is established. Such as approach should also help increase the degree of confidence within which the options were considered.

Receiving feedback on the problem analysis from affected communities and will also help strengthen the analysis. This sharing of knowledge helps create the shared responsibility necessary to select and develop the risk reduction strategy in Step 4. The collection of such information constitutes in itself an important element of the analytical process.

Checklist for Step 1

- *Detail the main conclusions of the situation analysis, relate them to the broader chemicals management context and report whether weaknesses in the national/local infrastructure are connected with the chemical problem.*
- *Establish the causes of the problem in hierarchical order.*
- *Develop the problem statement, i.e. the main reasons why the chemical is considered as a potential target for risk reduction measures.*
- *Characterise the main environmental and human health risks associated with the chemical, the basis for the risks and report whether a risk assessment was necessary, or whether other national assessments were reviewed.*
- *Specify whether particular vulnerable target groups or stages in the chemical's life-cycle are posing a particular problem.*

2.5 Step 2. Developing the Risk Reduction Goal, Sub-goals and Indicators

Objective: *To develop a risk reduction goal, sub-goals and a series of related indicators based on the problem statement.*

Suggested output: *A concise statement of the risk reduction goal.*

Goal Setting

Based on the Situation Analysis/Needs Assessment and Problem Statement described in Step 1, the aim of Step 2 is to develop the risk reduction goal, the sub-goals to be met so that the goal can be reached and to develop indicators to reflect successful risk reduction

actions. The sub-goals provide the basis for the development of the actions and options for the risk reduction strategy during Steps 3 and 4.

> *Setting a goal for the risk reduction strategy is an important part of the decision-making process, in that it sets the direction for subsequent stages and makes clear the intended results or outcomes of the implementation phase.*

In developing a risk reduction goal, it is important to distinguish between environmental and human health goals. *Environmental and/or health goals* can in most circumstances be considered overarching or ultimate goals, as we are initiating a risk management process concerned with protecting human health and the environment. Examples of environmental and human health goals include:

- 'Prohibition of the import and use of an internationally-specified POPs chemical'; and
- 'Replacement of a specified hazardous PIC pesticide with a less harmful alternative'.

It is generally recommended that the setting of a risk reduction goal at this stage include an identification of whether the goal is based on human health impacts and/or on the environment.

> *It should be recognised that defining a goal is also a form of decision-making. Thus it is important that the process be transparent, that stakeholders be involved, and that it be explicitly acknowledged if there are any issues/aspects of the problem that have been forsaken.*

Further Guiding Principles for Setting a Risk Reduction Goal

Experience from countries has shown that it is often useful to *link a risk reduction goal to the broader national goals* and policies pertaining to chemicals management, environmental and public health protection, and/or economic development. For example, reference can be made to national laws, policy initiatives and/or obligations as a party to international conventions, to which the risk reduction effort will contribute. In situations in which additional policy support for risk management activities is sought, identifying such linkages may be a particularly important aspect to consider.

When identifying a risk reduction goal, efforts should be made to ensure that the goal can be described as '*SMART*':

- **S**pecific
- **M**easurable
- **A**ssignable
- **R**ealistic
- **T**ime-related

A measurable goal is by definition quantifiable for it indicates when the goal has been reached. While defining a smart goal is often helpful for the risk management process,

there may also be situations which are fairly complex and where environmental and human health goals should be defined in a more generic manner. For example, given the complexity associated with a particular chemical problem, it may be useful to state as an environmental/human health goal that: 'Risks from chemical X should be reduced to an acceptable level, taking into account international norms and safety standards'.

Although such a goal may not be easily quantifiable, the goal is still action-oriented and indicates the direction of the action. While health and environmental goals may in some cases be phrased in a more generic manner, all efforts should be made to ensure that management goals are 'SMART'.

Experience has shown that when establishing a risk reduction goal *uncertainty about risk estimations* should also be taken into account. Uncertainties can result from incomplete or unavailable scientific data thus making it difficult to accurately determine the level of risk involved and hence the exact goal to be achieved. Other important factors to consider in goal setting include *social, economic, legal or political considerations*. For example, due to particular societal values and perceptions, it may be decided that protecting the health of children, or other vulnerable populations such as ethnic communities, may be of high priority. Or, due to impact on international trade, a country may decide that the focus of the risk reduction strategy should be on safe handling and use of a specific chemical in agriculture and/or manufacturing to avoid contamination of exports.

> *In many cases, it will not be realistic to assume that the risk reduction strategy will be able to address all risks associated with the chemical. For example, it may be too optimistic, and thus not feasible, to aim at eliminating all environmental and health risks posed by the chemical. However, ensuring that the chemical will only be used for specific applications for which no suitable substitutes are yet available, for example, or ensuring that risks due to exposures during transport will be reduced, are goals that may be realistically achievable. In this context it may often be useful to highlight and explain why certain risks are not intended to be addressed through the risk reduction strategy.*

Identifying Sub-goals

As an overall goal may be the object of various actions, it is often broken down into a range of sub-goals (referred to as objectives in some documents), each of which has to be attained before the goal can be said to have been achieved.

An example of a qualitative goal and two related sub-goals could be:

- ***Goal***: 'To reduce health risks to sensitive groups of people arising from a specified chemical'
- *Sub-goal 1*: 'To reduce health risks of farmers to the lowest practical level'
- *Sub-goal 2*: 'To reduce health risks of pesticide applicators to the lowest practical level'

Indicators to Quantify and Qualify Attainment of Goals and Sub-goals

A risk reduction goal or sub-goal may be expressed in either, qualitative or quantitative terms. If the goal is 'to reduce the risks associated with pesticide use nationally to the lowest practically possible', then:

- A *quantitative sub-goal* could be stated as: 'To reduce by the year X the number of accidents per year of pesticide Y by at least S% compared to current levels'.
- A *qualitative sub-goal* could be stated as: 'To reduce within the next 12 months any unnecessary risks from pesticide Y to farmers and the population in rural areas, with a particular focus on the risks to children.'

It will depend on the situation at hand whether a quantitative or qualitative description of the goal or sub-goal is more helpful. In any event it is important to draft the statement in a format that will allow for subsequent assessment of whether, and to what extent, the goal or sub-goal has been reached. Measurements of the achievement of the action can be presented as an indicator that can be reported periodically.

Considering that the goal will be the ultimate benchmark against which the success of a risk reduction strategy should be measured, it is important to consider already at this stage how the achievement of the goal could be measured (quantitative) or evaluated (qualitative) in practice. An indicator-supported goal, or sub-goal, provides one effective method for evaluating the planning and implementation strategies. For example, are there certain 'indicators' that could be used as evidence that the desired outcome has been realised?

> *An indicator is not an activity or a task but describes the result of an action undertaken.*

The quantitative sub-goal example mentioned earlier can also be seen as a pro-active indicator quantifying progress towards goal attainment. Further *qualitative goals* (or sub-goals comprising the goal) which indicators would report, could include:

- to reduce the importation of particular hazardous pesticide/pesticide formulations during the next 2 years and hence reduce the health risk to susceptible groups;
- to reduce exposure of pesticide applicators and farmers to pesticide Y by running specific training programmes;
- to reduce specific health risks to sensitive groups by adoption of an international convention (POPs); and
- to reduce risks to workers in a particular industry following adoption of the Responsible Care® procedures.

It is not necessary to discuss in any detail during Step 2 how the achievement of the goal and associated sub-goals would actually be measured or who would undertake the measurements. A more detailed discussion on measurements of goal attainment is provided in Step 6.

Checklist for Step 2

- *Develop a well-defined risk reduction goal statement to address the problem.*
- *Ensure transparency in goal selection especially through stakeholder forum discussions.*
- *Prioritise problem-solving sub-goals in order to reduce first the most important risk to human health and the environment.*
- *Link the selected goal and/or sub-goals into the wider national chemicals forum.*
- *Establish preliminary qualitative and quantitative indicators to benchmark progress toward attainment of the goal and/or sub-goals.*

2.6 Step 3. Identifying and Evaluating Possible Risk Reduction Actions

Objective: *To identify and evaluate options that should achieve the risk reduction goal and thus control the identified problem.*

Suggested output: *An evaluation of the advantages and drawbacks of possible risk reduction options that could be used to prevent, or reduce the risk of concern.*

Development of a Shortlist of Actions

The main objective of this step is to identify and critically analyse potential actions to prevent, or reduce the risk of concern – to deliver the goal. It is useful at this stage to provide an open-ended listing of known actions that risk managers can refer to when seeking to identify activities that may prevent or reduce the risk. Local and national circumstances are likely to influence the range of actions. Nonetheless, the following are three approaches that may be useful:

- strengthening of existing national measures including enforcement of national legislation, import control procedures, etc.;
- reviewing risk reduction measures which have been introduced in neighbouring or other countries, or measures that have been implemented for other but similar chemicals (see Box J); and
- identifying new and innovative risk reduction measures. Brainstorming sessions can be particularly helpful in this regard.

Box J: Learning from Others about Risk Reduction Actions

Information about the measures and policy tools used elsewhere for a particular chemical or problem can often be a valuable input into the risk management decision-making process. Suggestions can be obtained from:

- consulting the laws and regulations of other countries, some of which may be available via the Internet;
- interacting with neighbouring countries and countries in the region;
- (for chemicals that are part of the PIC Procedure of the Rotterdam Convention), finding out through the Decision Guidance Documents what other countries, apart from those that have decided to ban the substance, are doing to reduce risks. As an information exchange procedure for chemicals that are restricted, but not severely restricted or banned, will be put into place under the Rotterdam Convention, such information may also be of interest to countries; and
- finding out from Industrial Organisations, NGOs, etc. about alternatives to the chemical, including non-chemical alternatives.

Several challenges may be encountered when making use of this information. These may include difficulties of accessing information on risk management decisions made by countries, given that such information may not always be documented in a useful form; lack of access to the Internet; and insufficient information about whether alternative substances are really less risky than the substance that is causing problems.

It should be recognised that many actions may be applicable, not just to the chemical in question, but to a broad range of chemicals. There are a relatively small number of chemicals for which new and specific measures are likely to be needed. When considering actions, it may be useful to consider how *existing* tools and measures can be made more effective. A lack of active enforcement of current regulations, or lack of awareness within the regulated community, may be apparent.

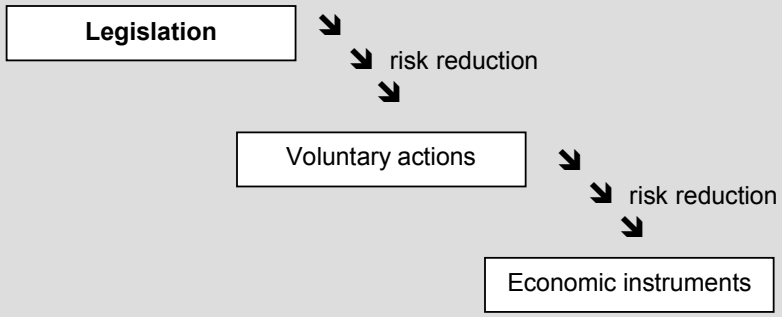
Countries may also wish to adopt a series of actions as a 'package' designed to reduce the risk from potentially hazardous chemicals. Such a package could include a series of sequential actions designed to reduce the number and volume of harmful chemicals in use by introducing safer alternatives, more effective monitoring of chemical usage, increasingly rigorous compliance with guideline values and severe financial penalties for illegal practices. An illustration of such a package is outlined in Box K.[3]

[3] The control elements mentioned in this box were discussed earlier in Part 1, Section 1.6.

Box K: Risk Reduction Based on a Series of Preventive Options

Legislation represents national policy for controlling risks from chemicals. Owing to various reasons, including legislative gaps and insufficient resources for implementation, such control may not be effective for priority chemicals. To obtain further commitment for action to reduce use of, or emission of, such chemicals, the government may reach a voluntary agreement with relevant chemical enterprises. Such an agreement may negate the need for expensive enforcement of the legislation. If industrial options have still not resulted in the required reduction in risk, economic instruments can be applied. Positive economic incentives are designed to encourage production of less harmful chemicals, while negative economic incentives increase enterprise liability costs.

The three options are presented as an integrated step-wise package to sequentially reduce risks. At each stage during implementation, the extent of risk reduction can be measured and further targeted steps undertaken as necessary.



As always, it is important to involve stakeholders in this process, particularly when novel risk reduction actions are being considered. Industry representatives, for example, may be able to provide valuable insights on where in the production process new risk control measures could be introduced. NGOs may also have valuable ideas to contribute, such as insights on how to reach particular target groups.

Identifying Criteria for Selecting Actions

Once an initial list of potential actions has been developed, it may be useful to conduct a preliminary screening that would result in a more manageable shortlist that can then be subjected to a detailed analysis. The screening process aims to eliminate those actions that are highly unlikely to be effective and/or manageable or enforceable by the country. For example, one may decide to remove all actions that require 'excessive resources' for successful implementation, or that would require long-term external support. Similarly, actions may be eliminated that require sophisticated technologies and highly trained staff. In other circumstances, the risk reduction goals may state that human health risks need to be eliminated in a very short time period. Thus, all actions that may take longer than two months to have an impact can be eliminated. Again, the precise circumstances will determine what kind of screening may be most appropriate.

In order to conduct a transparent and objective evaluation of the actions included in the shortlist, it is essential to identify decision criteria, i.e. criteria against which the various actions can be evaluated (see Box L). The expected effectiveness of potential actions and legislation, national obligations and limitations are key considerations.

Box L: Decision Criteria for Analysing Risk Management Options

- How quickly must the risk be addressed?
- What are the risks versus the benefits?
- What are the costs of implementation?
- What are the risks and their costs compared with the benefits, i.e. efficiency?
- How are the distribution of risks, costs and benefits distributed, i.e. fairness?
- What are the available resources?
- What are the unintended consequences, i.e. creation of new risks?
- What is the residual risk, i.e. the level that remains after implementation?
- What are the perceptions, concerns and values of interested and affected parties?
- How do interested and affected parties view risk acceptability, options and residuals?
- What other criteria can be used for option analysis in similar situations?

The decision criteria mentioned in this list provide a tentative inventory of actions but they may have to be adapted to the circumstances of the country, including local perceptions and values. Other criteria may be required to ensure compatibility with existing national policies, goals and prior practices.

Evaluating Risk Management Actions

From a practical point of view, a simple way to structure and summarise discussions between stakeholders consists of developing an overview table for evaluating the best of a range of actions. Table B outlines one such approach – an Option Assessment Matrix – using pre-defined criteria. As such, it can be used as a means of comparing risk management actions listed as options, and/or prioritising them through discussions within the group of stakeholders.

Table B: Evaluating Risk Management Actions*

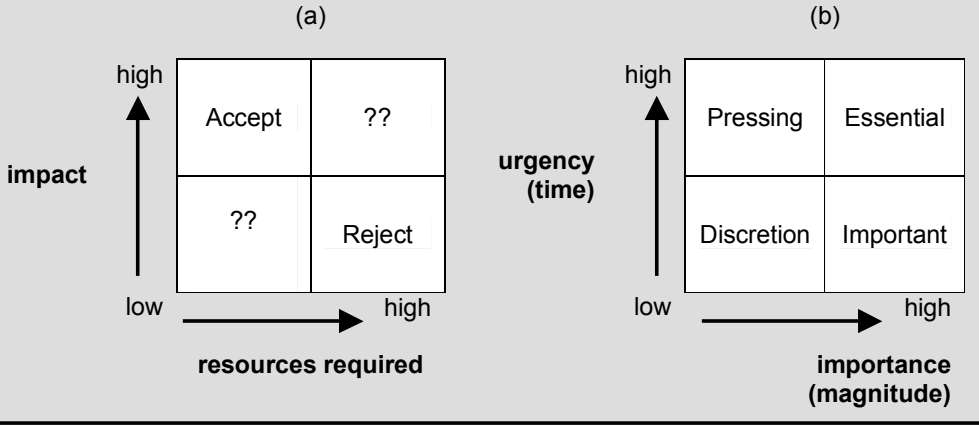
Criteria	*Option 1*	*Option 2*	*Option 3*	*Option 4*	*--------*
Effectiveness	2	1	4	5	
Feasibility	4	3			
Acceptability	5				
Monitorability					
Practicability					
Cost					
Cost/benefit					
Risk/benefit					

*Note: The numbers in the table can be interpreted in the following manner:
1= decision-criteria speak strongly against the action
2= decision-criteria speak against the action;
3= decision-criteria does neither support no speak against the action
4= decision-criteria supports the action
5= decision-criteria strongly supports the action

Evaluating all of the actions against the decision criteria will allow a simple comparison of the relative advantages and disadvantages of the each and thereby facilitate further group discussion. However, such a table, or other mechanistic tool, should not be seen as an end in itself. It is, first and foremost, an evaluative tool. Also it is not a mechanism to determine overall risk-management decisions. Simple addition of numbers does not include the different weights that may be assigned to particular criteria. The score means nothing in isolation, it represents but one useful approach to prioritisation of actions.

In some countries more simple prioritisation schemes can be considered that avoid the need for extensive detailed discussions on trade-offs between the different risk criteria outlined in Table B. For example, a more flexible matrix scheme could be based on a comparison of the risk versus the need for resources to reduce the risk as shown in Box M. This approach helps identify which action produces the greatest outcome for the least costs. Such an approach is easily grasped but it involves real understanding of the situation and its context (Step 1) as discussed earlier and the goal (Step 2).

Box M: Two Risk Matrix Examples



From figure (a) in Box M it can be seen that the action requiring least resources yet giving rise to the greatest benefit would be the preferred option. Similarly, figure (b) illustrates that it is essential to undertake the most important and most urgent issue. From a practical view in discussions involving the matrix approach, it is only necessary to carry out an adequate analysis. Action will only be built around the priorities agreed by the stakeholders. It is vital that the stakeholders agree on the balance between the necessity for urgent action, the resources required and the importance of the action to reduce risks from priority chemicals.

The options being addressed must be checked against the set of sub-goals to show that if implemented, the risk reduction goal can be achieved.

One key consideration when analysing actions and determining priorities is that the same measures proposed can affect different populations in different ways depending on a range of risk factors involved such as gender, age, ethnic origin, social situation, economic conditions, education, cultural or personal views. It may be necessary to tailor actions to meet the needs of specific groups, such as infants and children, or to use different options for different populations, such as minority-group communities.

Thus the evaluative process should involve:

- scientific and professional criteria;
- national policy considerations; and
- societal acceptance.

Who gains the benefits arising from risk reduction and who bears the costs are further important aspects when options are being evaluated.

Finally, an examination of the actions should include a consideration of whether any action may give rise to an adverse consequence. In other words, while reducing the risk of concern, it may increase a different type of risk. For example, banning one pesticide because of cancer risks may give rise to the use of a different pesticide that is harmful to wildlife. Thus trade-offs between different risks must be included when management actions are evaluated.

Checklist for Step 3

- *Compile an open-ended list of known risk reduction measures as possible options that address the problem.*
- *Identify the options that make existing measures more effective as well as outline new initiatives.*
- *Consider whether all the options listed are likely to achieve the required risk reduction goal bearing in mind a range of risk factors, i.e. ethnic origin, age, etc.*
- *Obtain stakeholder agreement on decision-criteria to use to select likely options from those proposed, including their feasibility, benefits, acceptability, etc.*
- *On the basis of the decision-criteria, evaluate strengths & weakness of each option.*

2.7 Step 4. Selecting and Developing the Risk Reduction Strategy

Developing the Strategy Further

Countries should now select the risk reduction strategy based on the evaluation of actions conducted during Step 3. The detailed strategy would include:

- selecting and prioritising the specific courses of action as option(s) for risk reduction;
- developing the risk reduction strategy necessary to achieve the sub-goals;
- planning the implementation assignments; and
- drafting of the risk reduction strategy.

Selecting the Specific Option(s) for Risk Reduction

When selecting the option(s) *it may be useful to consider that a combination of various actions may be the best way forward*. For example, a decision to restrict the use of a pesticide to certain applications may be complemented by training of farmers and distributors, and the promotion of a different pesticide for the remaining applications and/or a non-chemical alternative.

Another way forward could entail the adoption of a step-by-step approach in which increasingly stringent measures are implemented, if previous less stringent measures prove not to be sufficient. This may also be an effective way forward providing the choices are not limited by legislation. Thus the strategy may also involve various actions that are implemented in a sequential manner, taking into account results of interim evaluations and or monitoring.

Developing the Risk Reduction Strategy

When developing the strategy, the extent to which interested and affected parties were involved in selecting the risk management options should be considered. Strategy development based on decisions made through consensus may require more time and effort than a decision imposed by a regulatory agency.

An effective strategy should lead to a reduction or elimination of risks in the ways illustrated in Box N.

Box N: Possible Guidelines for Decision-Making

- Maintaining and improving health is the key objective of risk management.
- Where possible, give priority to preventing risks rather than controlling them.
- Consider government, departmental, branch and programme priorities when selecting risk management strategies.
- Consider the issue in context, to ensure that the strategy is comprehensive enough to achieve the desired risk management goal.
- Base the decision on the best available scientific, economic, and other technical information. Take note of the weight of evidence supporting conclusions and uncertainties, assumptions and their potential impacts.
- Select risk management options that are feasible, effective and whose expected benefits are reasonable given the cost.
- Be sensitive to potential social, cultural, ethical, environmental, economic and other indirect health impacts. Consider these relative to the expected benefits.
- Where possible, use a flexible approach for risk management, rather than relying solely on regulation

Adapted from the U.S. Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) and Health Canada (2000).

A key factor for developing an effective risk reduction strategy, and generating necessary support, is to clearly spell out the goal and sub-goals (see Box O).

Box O: Risk Reduction Strategy – An Example

Due to its high toxicity, a pesticide X is causing unacceptable risks to farmers if used without adequate safety precautions. The risk reduction strategy for pesticide X proposes that the use of the pesticide be restricted to certain limited applications. In addition, farmers as well as distributors should be trained to ensure that its use is limited to certain crops and farmers wear adequate safety equipment.

A possible environmental and health goal may include: 'Reduction of severe poisoning cases from pesticide X by 50% from current levels within one year';

In simple terms: an analysis of the risk reduction strategy will help determine whether the goal is being achieved. Both management and policy activities need to be clearly identified in the risk reduction strategy.

Planning Implementation Arrangements

The detailed risk reduction strategy should include arrangements for successful project implementation and including:

- *How* – under what legal mandate will the activity be undertaken and with what resources;

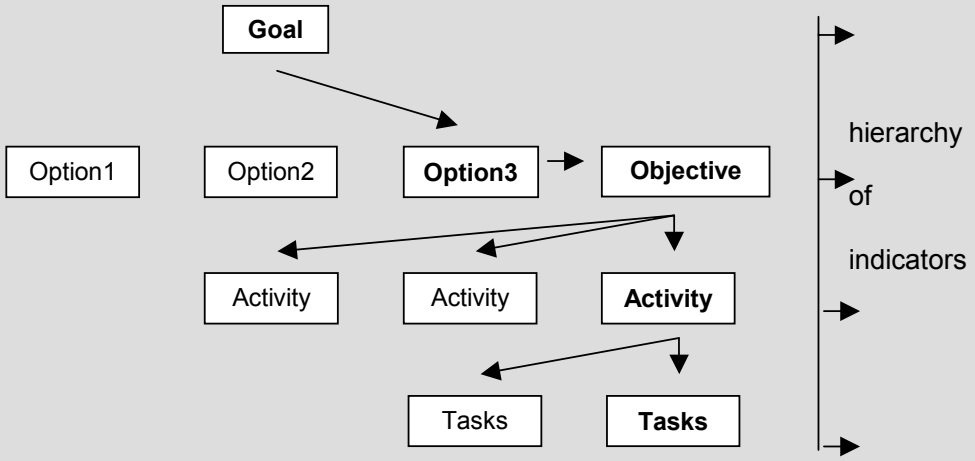
- *When* – what is the realistic timeframe for the actions; and what milestones that indicate key events should be identified; and
- *By whom* – which ministry, agency, or stakeholder group will be involved in implementing the strategy.

In addition, any action needs to be placed within the political, administrative and scientific framework of the country or local area.

In order to proceed logically with the planning arrangements, the specific option should be broken down into a range of *activities* and still further into *tasks* depending upon the size and complexity of the problem. Box P illustrates these relationships diagrammatically.

Box P: The Framework of a Risk Management Strategy

The goal was identified earlier in Step 2 and the risk reduction options listed in Step 3. In this diagram, Option 3 was chosen and action plans developed including selecting the objective. Achieving the objective will accomplish the goal. Three activities have been identified and one of them broken down into tasks. Indicators can be developed at each level in the hierarchy to illustrate and monitor/measure the successful completion of each of the steps illustrated in the Box.



Resource requirements and the timelines necessary for implementing the activities and tasks also need to be identified (making use of the traditional Gantt Chart can be helpful to show the relative timings of activities and tasks). The use of a Critical Path Analysis Chart may also be necessary, to establish the ideal sequence of tasks and respective expenditure of resources. Identifying resources – financial, personnel, facilities, equipment, materials – for each of the activities and tasks can be tabulated in a matrix to simplify subsequent allocation of resources. Such a matrix will help establish responsibility for subsequent implementation.

Assigning responsibility or identifying those who would be responsible for implementing the risk reduction strategy may be a relatively easy task if a particular

Ministry/Department has staff and facilities available. More usually in developing countries, and if the problem and hence the option is not a simple one to implement, a multidisciplinary project team may be required as mentioned in Part 1. In such situations responsibilities will have to be assigned based on:

- which organisation will be involved, and who will assume overall responsibility;
- which persons have the expertise and experience to participate; and
- who has to agree to the commitments to undertake the activities, tasks and work assignments.

Various tools can be used to help organise responsibilities, the most useful being the Responsibility Assignment Matrix, where the tasks and organisations are matched depending upon the three points mentioned above. However, the details of specific project planning, financial and resource assignments and overall project implementation are the responsibility of the country and are outside the scope of this document.

Considering the Evaluation Criteria

Evaluation must be considered as integral part of any proposed risk reduction strategy for it will provide a justification for action and help determine whether further measures may be needed. Although the actual evaluation will be undertaken during Step 6, the use of indicators to quantify or qualify fulfilment of the sub-goals as mentioned earlier in Step 2 should be further discussed and relevant indicators adopted as part of the risk reduction strategy. Indicators that evaluate *both the process and the implementation strategy* should be considered. Necessary monitoring data and/or implementation information will need to be agreed and related to the agreed sub-goals for achieving the human health and/or environmental goal.

Drafting the Risk Reduction Strategy

In order to communicate the proposed risk reduction strategy to decision-makers as well as other parties that may have a role in its development and/or implementation, it is recommended that a Risk Reduction Strategy Document be prepared. The document is meant to clarify the goal, sub-goals, activities, tasks and implementation arrangements of the risk reduction strategy. It is one of the most important documents prepared during the risk management process. Once adopted, it will provide a reference document for those involved in the implementation and/or evaluation of the strategy.

This document can be seen as a specific tool helping to achieve risk reduction.

The precise format and level of detail of such a document will depend on a number of country and problem chemical factors. Amongst others, it will depend on the:

- national legal or regulatory framework;
- requirements for risk management;
- decision-makers to which the document will be submitted, their level of interest and awareness on the issue;
- urgency of action; and
- specific donor/agency/ministry requirements.

Checklist for Step 4

- *Involve all interested and affected parties in the development of the risk reduction strategy.*
- *Identify which risk reduction option, or combination of options should be selected and developed into the strategy document.*
- *Consider the option in context to ensure that the proposed strategy and its sub-goals is likely to achieve the desired risk reduction.*
- *Prioritise options into timely activities and tasks that are feasible, effective and whose expected benefits are reasonable, given the cost.*
- *Establish the parameters necessary to draft and hence submit a Risk Reduction Strategy Document with regard to its 'audience' and future implementation.*

While many of these factors will need to be considered prior to drafting the risk reduction strategy document, it will be particularly important to consider whom the document will be submitted to, and how it is expected to be used by the country in the future.

2.8 Step 5. Obtaining Commitments from Decision-Makers and Taking Action

Objective: *To submit the proposed risk reduction strategy to decision-makers and to take steps to ensure its adoption and effective implementation.*

Suggested output: *Adoption of the strategy, commitment of resources and implementation of the plan.*

The Decision-Making Process

As actual decision-making will often be the responsibility of the relevant public authorities, such as regulatory agencies, ministerial departments, ministers, several ministries acting jointly, etc., decision-makers should be explicitly briefed on:

- the problem and its context;
- the proposed goal and relevant sub-goals;
- the costs and resources that will be needed; and
- the implications and benefits of the proposed risk reduction strategy.

Linkages between the proposed risk reduction strategy, national policies and on-going budget priorities, should also be made to increase the likelihood of obtaining the necessary resources and support (see Box Q).

Box Q: Obtaining Decision-maker Support

When communicating with high-level decision-makers it is important to focus the message on a few key issues, in particular those likely to be of political importance. The expected benefits of risk reduction should be sensitively presented within national, social, cultural, environmental and economic norms, so that decision-makers can feel responsible for undertaking such actions.

Good timing can in many cases also be an important aspect in obtaining necessary support for a risk reduction strategy. Experience has shown that governments are sometimes more likely to act upon a problem following certain recent incidents, such as poisoning accidents, import bans on agricultural produce because of high level of pesticide residues, etc. Presenting a risk reduction strategy on a chemical that has just received major attention may substantially increase the chances of obtaining necessary policy support and resources. This approach is, in effect*, converting the problem into an opportunity* for effective implementation.

Several further points should be made clear to the decision-makers:

- *What are the specific decisions that will need to be taken and by whom?* For example, will parliament need to pass a new act? Will certain ministers need to adopt/revise policies? Will an industry association need to formally adopt the strategy and make it a requirement for its members?
- *What specific actions will be needed to implement the strategy?* For example, if a specific regulation will need to be written, which ministry/agency will be responsible for taking this action? What actions will be expected of industry and/or other concerned parties? What action will be needed by provincial/municipal authorities?

Answers to such questions will help to focus the decision-makers on those actions needed on their part to set the strategy into motion.

> *Considering that decision-makers are unlikely to read an extensive Risk Reduction Strategy Document, it is often useful to prepare a separate Briefing Paper that provides a summary of the key points where decisions are required.*

The absence of adequate legislation, or policies for chemicals management, can pose a challenge to this approach. In some countries where the legal framework has not been fully developed, the management policy of who has the authority and ability to control chemicals may not have been formally established. It may not even be clear who the relevant decision-makers are. There may not be anyone, or any organisation, that has been given the legal mandate needed to act upon the proposed strategy. Consequently, the approach outlined here may have to be adapted to re-frame the proposal within a less co-ordinated institutional setting.

Financial Commitments

In order to implement a risk reduction strategy, support by decision-makers is necessary including their commitment of financial and other resources. Acquiring the budget needed to implement the strategy can be a particular challenge. Understanding the government's budgetary and policy priorities, and making a link between those issues and the strategy, can increase the chances that the strategy will be funded. Points to consider include:

- *What preparatory steps and resources may be needed to ensure that the strategy can be effectively initiated by the relevant parties?* For example, what are the specific information needs to implement the strategy? Is there a need for certain awareness-raising activities? Is training needed to provide relevant individuals with the

necessary skills? In case certain regulatory provisions are proposed, how can their implementation be enforced?

- *What are the likely resource requirements and time frames?* For example what funds are needed and at what point in time? Are ministerial budgets sufficient to implement the strategy, or are additional resources needed? Are national sources of funding sufficient?

The inclusion of a benefit statement – a comparison of risks and benefits – could be included in the briefing package for decision-makers. Only those benefits of most relevance would be included, highlighting for example, the need to address specific at-risk groups or other affected parties. This approach differs from the more traditional cost/benefit approach where costs of control measures are compared with the expected benefits. Such an approach can contribute to the decision-making process.

Taking Action

Once the enforcement mechanisms, training plans and local communication plans and co-operation have been established, staged implementation will get underway as resources permit. Not only must the actions required be fully identified, but they must also be undertaken in a logical sequence as mentioned in Step 4. As it may be necessary to complete one action, or set of actions before another should begin, the time schedule also has to be followed. Simple flow charts – Gantt charts – or chain diagrams provide a useful way to follow the schedule as it is undertaken.

Critical paths, i.e. the timing of crucial actions, may also need to be followed depending upon the risk management issue. Bad weather can easily create serious delays with implementation plans; for example, if the new low-risk pesticide is unable to be delivered during an important stage in the growing season or, if commercial pesticide applicators are unable to travel to the region where human health problems occur. Consequently a countermeasures plan should be considered if relevant in order to either prevent the cause of the problem, or to minimise its effects.

In some cases it may not be possible to implement the action plan all at once due, for example, to resource constraints. In such cases, it may be useful to consider whether there are aspects of the strategy that can be implemented immediately to reduce risks to human health or the environment in the most cost-effective manner.

Monitoring the Implementation of Activities

In all cases it is important to follow and monitor the implementation of activities and tasks. Monitoring should reveal any deviation from the plans and the reasons for this will have to be addressed. It may be that the implementation plan will have to be modified if the length of time for implementation of particular tasks by partner organisations was underestimated, or when delayed by bad weather as already mentioned. Monitoring in this situation is in effect a *feedback* on the implementation process.

Monitoring the progress of implementation can also be considered as part of *learning by doing*.

Checklist for Step 5

- *Identify the decision-makers who need to endorse/adopt the strategy and provide them with the Risk Reduction Strategy Document plus supporting Briefing Papers.*
- *Obtain the financial and other resources needed to support the risk reduction strategy.*
- *Identify whether any initial steps are needed to ensure effective strategy implementation, e.g. training of those involved in implementation.*
- *Involve interested and affected parties in implementation of the risk reduction strategy and identify milestones and other important timelines.*
- *Monitor the effective implementation of the risk management strategy with regard to milestones and timelines.*

2.9 Step 6. Evaluating Impact

Objective: *To evaluate progress with, and impact of, the risk reduction strategy and whether additional action is required.*

Suggested output: *An evaluation on the strategy's effectiveness as measured against the baseline situation and in light of the risk reduction goal; whether the current strategy should be continued, and if not, recommendations for additional risk reduction measures.*

The Benefit of an Evaluation

The risk reduction sub-goals and associated indicators, as identified in Step 2, and adopted in the risk reduction strategy (Step 4) should serve as the basis for the evaluation. An evaluation is an important and integral part of the risk management decision-making process for it helps quantify the attainment of the goal and sub-goals. It provides information on results of present actions as well as on what lessons can be learned to guide future risk management decision-making, including:

- whether the actions were implemented as planned (milestones and time frames) – as conducted in Step 5;
- whether assumptions made during identification of the problem and its context were correct;
- whether the actions have resulted in risk reductions; and
- whether new information has emerged that requires a strengthening and/or modification to the risk management plan.

The evaluation results should be communicated to all stakeholders as part of an accountability process.

Planning an Evaluation

Means and mechanisms for an evaluation will have been built into the risk reduction strategy procedure at Step 4. Issues to consider include:

- why is the evaluation being conducted;
- when will the evaluation be conducted;
- who should conduct it and what resources are required;
- what should be evaluated; and
- who will receive the evaluation and what will they do with it.

In reality, evaluation is concerned with examining the outcomes of the strategy, gathering the supporting information and determining if the actions implemented successfully reduced the risk – did the results measure up to the goal?

Undertaking the Evaluation

Evaluation of the strategy asks simply 'did it achieve the goal'? This often involves an evaluation of the **longer-term outcomes** that may take several or more years to be measurable let alone clearly apparent that the risks have been reduced. Such a delay before the outcome may be seen may arise from the time between exposure reduction to a particular chemical and speed of development of the effect. In some cases where the length of time for an effect to develop is long, the use of biomarkers – measurements on sensitive tissues, proteins, enzymes – can provide a useful index.

> *As the credibility of the evaluation and the evaluators is involved, stakeholder participation is essential. However, the amount of effort devoted to the evaluation should be commensurate with the magnitude and severity of the risk.*

In order to evaluate the risk reduction strategy, several basic steps are involved. These involve especially an evaluation of the chosen indicators to examine whether the sub-goals were met and the overall goal achieved. The steps include:

- collection of relevant information, and listing of the actions taken;
- analysis of the information, methods adopted and judgements made;
- preparation of conclusions of the effectiveness of the strategy and recommendations; and
- documentation and reporting on the evaluation.

To ensure cost-effective evaluations, maximum use should be made of existing information rather than develop extensive monitoring programmes. It is usually not necessary to have an elaborate information and resource intensive monitoring scheme. Linkages should be made with other types of monitoring programmes for use in establishing baseline information. The indicators developed in Step 2 for quantifying sub-goals would be used as the evaluation tools.

The Role of Indicators

Indicators as outlined in Step 2 are part of the reporting procedures for evaluating the extent to which actions taken during Steps 1 – 5 have achieved the required outcome and hence the desired goal. For example, if the management action involved a reduction in unintended by-product emissions of a particular hazardous chemical then were the sources of the emissions as measured by inventories and release estimates, reduced by the target amount; or, was the ambient concentration reduced to the policy goal? Another example could involve compliance with regulatory guidelines. Did the enforcement programme achieve the stated sub-goal? Have the actions achieved the necessary human health protection as envisaged in the initial policy development? If not then what elements within the six-step cycle have to be revised and re-applied?

Indicators can also indirectly quantify likely outcomes by reporting on, for example, a reduction in quantities of imported chemicals. This may be used to estimate likely use patterns and hence industrial or agricultural worker exposure. Another example of risk reduction could be reflected in the national compliance with international phase-out conventions and agreements. Another useful indirect example would be reflected in a government's procurement decision to import a safer pesticide that ensures a reduction in non-target organism impacts. Such an action would undoubtedly 'feedback' to commercial enterprises and would be expected to have significant effects on specific pesticide manufacture.

Irrespective of the evaluation approach adopted, a view on how successful the implementation plan has been – the purpose of Step 6 – can be gauged with reference to 'evaluating progress towards meeting the goal of risk reduction'. This evaluation of progress is often referred to as measuring 'distance to goal'.

The Need for Change

The evaluation may reveal that the implementation process was not effectively addressed by some stakeholders, or, there were faults in the design of the risk reduction strategy. Alternatively, critical information gaps during the planning stage meant that the effectiveness of the risk reduction was reduced.

Irrespective of the reason for the evaluation being only a partial success, further action may be necessary. This could take the form of new toxicity data, or other information being sought that initiates a modification to the risk reduction strategy. Consequently the sub-goals may need to be revised, but the goal remains the same. The implementation process may have to be revised and re-drafted as necessary and several of the cycle steps repeated.

The whole six-step process may not have to be modified following an evaluation. Rather it may entail a re-definition of a particular step(s). The process is an iterative one but as the time-scale is often long between initiating Step 1 and the outcome as measured by Step 6, a flexible risk reduction procedure should be adopted. The extent of the problem(s) and whether it frequently occurs will affect the implementation of the six-step process. New information, new ideas, new procedures and new perspectives may need to be integrated into the procedure to revise management actions.

Risk management does not end with successful implementation. The risk reduction plan may start slowly and with increasing experience may gradually build in momentum and enable other priority chemicals to be tackled more rapidly. An opportunity to 'wave the banner' to raise the visibility of the risk management programme should be promoted through the stakeholders, as well as through the lead government agency. In this way the action can become a promotional device for addressing the next risk management activity.

Checklist for Step 6

- *Were the agreed-to sub-goals met?*
- *Was the risk reduction goal achieved, was it cost-effective?*
- *Is further action required to modify the strategy and/or to continue with the implementation?*
- *What lessons can be learned regarding the basis for the strategy, i.e. a review of adverse problems, unexpected effects, and institutional co-operation?*

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ANNEX A. PRINCIPLES FOR THE ASSESSMENT OF RISKS TO HUMAN HEALTH FROM EXPOSURE TO CHEMICALS

Summary

Control of risks from exposure to chemicals (chemical safety) requires first of all a scientific, ideally quantitative, assessment of potential effects at given exposure levels (risk assessment). Based upon the results of risk assessment, and taking into consideration other factors, a decision-making process aimed at eliminating or, if this is not possible, reducing to a minimum the risk to the chemical(s) under consideration (risk management), can be started.

Risk assessment is a conceptual framework that provides the mechanism for a structured review of information relevant to estimating health or environmental outcomes. In conducting risk assessment, the National Academy of Sciences risk assessment paradigm divides the risk assessment process into four distinct steps: hazard identification, dose-response assessment, exposure assessment and risk characterisation.

The purpose of the hazard identification is to evaluate the weight of evidence for adverse effects in humans based on assessment of all available data on toxicity and mode of action. It is designed to address primarily two questions: (1) whether an agent may pose a health hazard to human beings, and (2) under what circumstances an identified hazard may be expressed. Hazard identification is based on analyses of a variety of data that may range from observations in humans to analysis of structure-activity relationships. The result of the hazard identification exercise is a scientific judgement as to whether the chemical evaluated can, under given exposure conditions, cause an adverse health effect in humans. Generally, toxicity is observed in one or more **target organ(s)**. Often, multiple end-points are observed following exposure to a given chemical. The **critical effect,** which is usually the first significant adverse effect that occurs with increasing dose, is determined.

Dose-response assessment is the process of characterising the relationship between the dose of an agent administered or received and the incidence of an adverse health effect. For most types of toxic effects (i.e. organ-specific, neurological/behavioural, immunological, non-genotoxic, carcinogenesis, reproductive or developmental), it is generally considered that there is a dose or concentration below which adverse effects will not occur (i.e. threshold). For other types of toxic effects, it is assumed that there is some probability of harm at any level of exposure (i.e. that no threshold exists). At the present time, the latter assumption is generally applied primarily for mutagenesis and genotoxic carcinogenesis.

If a threshold has been assumed (e.g. for non-neoplastic effects and non-genotoxic carcinogens), traditionally, a level of exposure below which it is believed that there are no adverse effects, based on a no-observed-adverse-effect level (NOAEL) (approximation of the threshold) and uncertainty factors, has been estimated. Alternatively, the magnitude by which the no (lowest)-observed-adverse-effect level (N(L)OAEL) exceeds the estimated exposure (i.e. the 'margin of safety') is considered in light of various sources of uncertainty. In the past, this approach has often been described as a 'safety evaluation'. Therefore, the dose that can be considered as a first approximation of the threshold, i.e. the NOAEL, is critical. Increasingly, however, the 'benchmark dose', a model-derived

estimate (or its lower confidence limit) of a particular incidence level (e.g. 5%) for the critical effect is being proposed for use n quantitative assessment of the dose-response for such effects.

There is no clear consensus on appropriate methodology for the risk assessment of chemicals for which the critical effect may not have a threshold (i.e. genotoxic carcinogens and germ cell mutagenesis). Indeed, a number of approaches based largely on characterisation of dose-response have been adopted for assessment in such cases. Therefore, the critical data points are those that define the slope of the dose-response relationship (rather than the NOAEL, which is the first approximation of a threshold).

The third step in the process of risk assessment is the **exposure assessment,** which has the aim of determining the nature and extent of contact with chemical substances experienced or anticipated under different conditions. Multiple approaches can be used to conduct exposure assessments. Generally, approaches include indirect and direct techniques, covering measurement of environmental concentrations and personal exposures, as well as biomarkers. Questionnaires and models are often used. Exposure assessment requires the determination of the emissions, pathways and rates of movement of a substance and its transformation or degradation, in order to estimate the concentrations to which human populations or environmental spheres (water, soil and air) may be exposed.

Depending on the purpose of an exposure assessment, the numerical output may be an estimate of, the intensity, rate, duration or frequency of contact exposure, or dose (resulting amount that actually crosses the boundary). For risk assessments based on dose-response relationships, the output usually includes an estimate of dose. It is important to note that the internal dose, not the external exposure level, determines the toxicological outcome of a given exposure.

Risk characterisation is the final step in risk assessment. It is designed to support risk managers by providing, in plain language, the essential scientific evidence and rationale about risk that they need for decision-making. In risk characterisation, estimates of the risk to human health under relevant exposure scenarios are provided. Thus, a risk characterisation is an evaluation and integration of the available scientific evidence used to estimate the nature, importance, and often the magnitude of human and/or environmental risk, including attendant uncertainty, that can reasonably be estimated to result from exposure to a particular environmental agent under specific circumstances.

The term ‘risk management’ encompasses all of those activities required to reach decisions on whether an associated risk requires elimination or necessary reduction. Risk management strategies/or options can be broadly classified as regulatory, non-regulatory, economic, advisory or technological, which are not mutually exclusive. Thus legislative mandates (statutory guidance), political considerations, socio-economic values, cost, technical feasibility, populations at risk, duration and magnitude of risk, risk comparison, and possible impact on trade between countries can generally be considered as a broad panoply of elements that can be factored into final policy or rule making. Key decision factors such as the size of the population, the resources, costs of meeting targets and the scientific quality of risk assessment and subsequent managerial decisions vary enormously from one decision context to another. It is also recognised that risk management is a complex multidisciplinary procedure which is seldom codified or

uniform, is frequently unstructured, but which can respond to evolving input from a wide variety of sources. Increasingly, risk perception and risk communication are recognised as important elements, which must also be considered for the broadest possible public acceptance of risk management decisions.

Chemicals have become an indispensable part of human life, sustaining activities and development, preventing and controlling many diseases, and increasing agricultural productivity. Despite their benefits, chemicals may, especially when misused, cause adverse effects on human health and environmental integrity. The widespread application of chemicals throughout the world increases the potential of adverse effects. The growth of chemical industries, both in developing as well as in developed countries, is predicted to continue to increase. In this context, it is recognised that the assessment and management of risks from exposure to chemicals are among the highest priorities in pursuing the principles of sustainable development.

Source: *Environmental Health Criteria no. 210*, International Programme on Chemical Safety, Geneva.

ANNEX B. PIC AND POPS CHEMICALS

PIC Chemicals

The following 31 chemicals, pesticides and certain pesticide formulations are covered under the Prior Informed Consent Procedure of the Rotterdam Convention:

Pesticides

- 2,4,5-T
- Aldrin
- Captafol
- Chlordane
- Chlordimeform
- Chlorobensilate
- DDT
- Dieldrin
- Dinoseb & dinoseb salts
- 1,2-dibromoethane (EDB)
- Fluoroacetamide
- HCH (mixed isomers)
- Heptachlor
- Hexachlorobenzene
- Lindane
- Mercury compounds including inorganic mercury compounds, alkyl mercury compounds and alkyloxyalkyl and aryl mercury compounds
- Binapacryl
- Pentachlorophenol
- toxaphene

Severely hazardous pesticide formulations

- Monocrotophos (soluble liquid formulations of the substance that exceed 600g active ingredient/l)
- Methamidophos (soluble liquid formulations of the substance that exceed 600g active ingredient/l)
- Phosphamidon (soluble liquid formulations of the substance that exceeds 1000g active ingredient/l)
- Methyl-parathion (emulsifiable concentrates (EC) with 19.5%, 40%, 50%, 60% active ingredient and dusts containing 1.5%, 2% and 3% active ingredient)
- Parathion (all formulations – aerosols, dustable powder (DP), emulsifiable concentrate (EC), granules (GR) and wettable powders (WP) – of this substance are included except capsule suspensions (CS)

Industrial chemicals

- Crocidolite
- Polybrominated biphenyls (PBB)
- Polychlorinated biphenyls (PCB)
- Polychlorinated terphenyls (PCT)
- Tris (2,3-dibromopropyl)phosphate
- Ethylene dichloride
- Ethylene oxide

POPs chemicals

Twelve chemicals are currently listed in The Stockholm Convention on Persistent Organic Pollutants. They are:

Pesticides

- Aldrin
- Chlordane
- DDT
- Dieldrin
- Endrin
- Heptachlor
- Mirex
- Toxaphene

Industrial chemicals

- Polychlorinated biphenyls (PCBs)
- Hexachlorobenzene (also a pesticide and an unintended by-product)

Unintended by-products of combustion and industrial processes

- dioxins
- furans

ANNEX C. TYPES AND SOURCES OF CHEMICAL RISKS

A brief list of risk reduction options at various stages of the chemical life-cycle is outlined in this annex in order to illustrate possible health and environmental actions. Risks can be acute, sub-chronic and chronic but are considered here as a single concept.

Countries should address public health and environmental concerns within a consistent and scientific framework for risk management as is described in Steps 1-6 of Part 2 of this document. They may wish to use the list as a starting point for discussions on identifying risk reduction options and consequent actions especially during Step 3. Countries are encouraged to update and complete the list on the basis of their actions and experiences for future reference and use as appropriate.

➢ Potential risks from manufacture and industrial use

Occupational and worker risks can arise from direct and indirect exposure caused by a variety of different industrial procedures:

- Inhalation of emissions to the atmosphere including within the workplace. Examples involve emissions from reaction systems and material separation processes including controlled releases from vents and chimneys; fugitive emissions from pumps, valves and joints or during sampling; transfer hose emptying; venting from pressure relief devices; tank and container cleaning with solvents; solvent degreasing; handling of powders; and evaporation from non-catastrophic liquid leaks and spills.
- Indirect ingestion of waste effluents distributed to water bodies or to soil. Examples include authorised discharges to watercourses or sewage treatment works; leaks from pipeline and tank drainage; leaks, spills and wash water from processing plant; wastewater treatment units and storage facilities.
- Dermal contact. Examples involve contact with skin or eyes from hand-wipe rag solvents; including hand-to-mouth contact when handling cigarettes, food.

➢ Potential risks from distribution and storage

Direct and indirect exposures can also occur to people at this stage arising from inhalation, ingestion or dermal contact. There are inhalation risks from vapour and dust from filling and emptying containers; ‘breathing’ or venting of storage tanks; dermal contacts from spills from container failures; releases during transit, loading or unloading or during cleaning of tanks; spills from mishandling; or failure to store under the correct conditions.

➢ Potential risks from professional and domestic use

Worker and consumer risks can arise from exposure during initial use and subsequent maintenance or replacement caused by:

- Inhalation of emissions to the atmosphere. For example, inhalation of solvents from thinning, drying and curing of paints and lacquers, resins, adhesives and polishes; spray applications.
- Emissions to water and soil. For example, through over-use, spillage or disposal to sewage treatment plants of substances such as detergents, disinfectants and paints.

- Direct dermal contact. For example, contact with skin or eyes from household chemicals such as ammonia and sodium hydroxide drain cleaners.
- Ageing or weathering in use of products such as paints and coatings, and do-it-yourself actions such as paint stripping.

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 with industrial use, it is more difficult to ensure that specific substances are safely stored and properly used.

It is even more difficult to enforce similar controls on domestic use, and unlike what is often the case with professional users, domestic users are not covered by occupational safety legislation. The primary goal should be to ensure that consumers have and understand the basic information they need to make responsible product choices based on their own requirements and values. Therefore, when assessing risks arising from domestic use, and as a reasonable worst-case scenario, it should be assumed that exposure will in general be uncontrolled, and that susceptible individuals – for example children and the elderly – are involved. In certain circumstances the same assumptions should be made about exposure from use in small and medium-sised enterprises.

- **Potential risks from waste management**

Risks can arise from exposure due to industrial wastes, - gaseous, liquid and solids:

- Inhalation of vapour emissions. For example, from incineration, poor handling techniques or inadequate ventilation; decomposition in landfills; direct evaporation; and air stripping in waste-water treatment plants.
- Direct and indirect ingestion of emissions to water or soil. For example, leachate run-off from landfills into rivers and groundwater; spreading of sludge containing metals or persistent organic substances onto land; residues from incomplete decomposition in waste-water treatment plants. Substances from all of these actions may enter the food chain.
- Direct dermal contact. For example, dermal exposure of workers to hazardous substances at waste management facilities.

When considering types and sources of risk, the distinctions between *perceived risks*, including 'public values' as held by members of the lay public, and *scientific or technical risks*, as understood by risk managers, should be taken into account. It should also be kept in mind that any alternative practices may involve risks, thus a decrease in the risks from one source (e.g. through reduced imports of one chemical) may simply serve to increase the risks from another source (e.g. from another chemical, either imported or produced domestically).

ANNEX D. EXAMPLES OF RISK REDUCTION OPTIONS

The following provides a comprehensive though non-exhaustive list of risk reduction options at various stages in the chemical life-cycle in order to prevent and control human health risks. Emphasis has been placed on human health concerns, especially on exposure reduction, but these may not directly translate to wider environmental risk reduction options. The lack of ecosystem analogues of many human responses and the greater degree to which non-human organisms are coupled to their environment, means that detailed environmental risk reduction requires further considerations beyond the scope of this annex.

It is intended that the list complement international regional control measures, but should not be seen as unnecessarily impeding legitimate trade and safe use of chemicals throughout industry whether as raw materials, commodities, preparations and in goods and products.

Countries should address public health and environmental concerns within a consistent and scientific framework for risk management as is described in Steps 1-6 of Part 2 of this document. They are encouraged to use the list as a starting point for discussions on identifying risk reduction options especially during Step 3. Most of the options listed relate to operational factors at enterprises that can usually be addressed and implemented within a very short period, rather than design features that typically require insight and research. Within the operations factors most of the options can be identified as *'source-related'* reductions of risk by controlling emissions, while *'effects-oriented'* policies that address effects on human health also relate to source reduction.

The focus for describing risk reduction options is, for the most part, on a single action or strategy, or on a single medium. The compartmentalisation of possible control actions has been adopted for ease of description of overall concepts and procedures. Further effort may be needed to quantify and prioritise a range of possible actions in order to develop effective risk reduction at enterprises, locally and nationally. Laboratory-based techniques and analytical instruments necessary to provide reliable measures of human exposure, perhaps necessary for prioritisation have not been discussed. The question of available techniques and instruments has to be viewed in particular chemical contexts, exposure scenarios and biological end-points of concern.

Countries may want to update and complete the list on the basis of their actions and experiences.

➢ Risk reduction options related to manufacture, industrial and professional use of chemicals

- Selecting and minimising material loss to air, land or water;
- Inspecting sites of manufacture to determine remedial action and the extent of clean-up required following a management audit;
- Adopting safe systems of work, such as specified standards of physical containment, or extraction ventilation at operational facilities;
- Applying good manufacturing practice within company policy guidelines, e.g. under ISO standards or EMAS criteria;
- Adopting Product Stewardship or Responsible Care® programmes;

- Classifying and labelling all products;
- Separating personnel from hazardous operations by physical or by vapour barriers;
- Monitoring and adequate maintenance of process equipment;
- Using dust suppression methods, such as the use of substances in tablet or pellet form;
- Using powder coatings in place of solvent-based coating formulations;
- Using less hazardous solvent degreasers for cleaning machine parts;
- Setting occupational exposure limits and/or air monitoring in the workplace;
- Providing accurate hazard information, e.g. MSDS, and/or better delivery of safety information such as clearer labelling, to ensure correct handling of spills, and/or the provision of warning signs in the workplace;
- Measuring biological exposure indices and/or biological monitoring of workers;
- Adopting regular medical surveys of workers;
- Providing coherent operator and employee training and awareness raising for staff at all levels;
- Providing and mandating the use of personal protective equipment;
- Licensing of operators, or of certain production processes;
- Establishing 'end-of-pipe' controls to minimise, neutralise or render less harmful any emissions that cannot practically be avoided;
- Adopting limit values for permissible emissions accompanied by effluent monitoring;
- Complying with environmental quality standards, and/or environmental monitoring legislation;
- Setting restrictions on the marketing and/or use of a specified substance;
- Re-designing the product life-cycle, substituting, reformulating, or using alternative materials to ensure statutory compliance.

➢ **Risk reduction options related to packaging, distribution and storage of chemicals**

- Setting minimum standards for container sise, shape and strength;
- Adopting maximum concentrations in formulations;
- Applying controls for loading and unloading of containers and substances;
- Observing adequate controls on storage, e.g. floating-roof tanks for VOC control, or conservation vents on fixed-roof tanks;
- Adopting safety requirements for emptying and cleaning tanks;
- Setting vehicle standards, use of approved hauliers and designated distribution routes or methods for the transport of products;
- Providing training for drivers and hazardous waste hauliers for off-site disposal;
- Fixing appropriate hazard warning signs on packages and/or vehicles;
- Classifying and labelling of all products;
- Adding stabilisers to reactive ingredients;
- Ensuring proper segregation of workers from hazardous operations;
- Establishing criteria for storage such as security, fire resistance and secondary containment for fire-fighting water to prevent extensive soil and water pollution;
- Introducing re-useable and recyclable packaging;
- Using less harmful substances in packaging.

- **Risk reduction options related to domestic and consumer use of chemicals**

- Restricting the sale of hazardous substances to the general public;
- Prohibiting the sale of the specific substances to specified vulnerable groups;
- Prohibiting the sale of specific substances through self-service vending machines;
- Licensing vendors;
- Restricting the marketing of the substance to specified applications and/or formulations;
- Restricting the use of specific substances to industrial/professional users;
- Adopting restrictions on sises of containers;
- Improving design of containers including non-spill or narrow-neck containers;
- Placing limits on concentrations of components in consumer products;
- Producing design changes of products, e.g. encapsulation to eliminate consumer exposure to dust;
- Placing limits on the overall quantity of products available for each particular use;
- Adding an emetic, a staunching agent or a colorant to deter illegal use of solvents;
- Placing restrictions on use of the product. As scope for enforcement is limited, clear labelling is essential;
- Adopting adequate classification and specific labelling of domestic and consumer products;
- Placing hazard warnings and/or use instructions on packaging;
- Providing tactile danger warnings;
- Providing child-resistant closures.

- **Risk reduction options related to management of chemical waste**

- Classifying materials as hazardous waste if scheduled;
- Labelling that assures identity of the hazardous materials, to encourage responsible disposal;
- Adopting producer responsibility schemes;
- Investing in the establishment and use of recycling ‘banks’;
- Establishing duty of care systems;
- Supporting compulsory acceptance of outdated products, or products for return and their containers;
- Detailing specified disposal methods and/or conditions, e.g. incineration temperature and time;
- Introducing ‘end-of-pipe’ controls and progressively introducing cleaner technologies;
- Supporting use of secure containers for hazardous waste management;
- Adopting controls on movements of hazardous wastes, including prevention of illegal traffic in toxic and dangerous products;
- Ensuring detailed labelling of hazardous wastes;
- Observing use of personal protective equipment by hazardous waste handlers;
- Issuing guidance documents and providing training support for hazardous waste handlers;
- Requiring the use of licensed contractors for hazardous waste management;
- Setting standards for emissions and monitoring of environmental quality at hazardous waste management facilities and disposal sites.