

Components of National Programs for Assessing and Managing the Risks Posed by Industrial Chemicals to Human Health and the Environment

1. Introduction:

Chemicals have become essential components of modern societies because they contribute in numerous ways to establish and/or preserve an elevated standard of living in countries at all stages of development. They play important roles in addressing many current issues, such as health care, food production and telecommunications, and they are used in developing solutions to a wide variety of problems. They are used in producing almost all man-made products, including formulations¹ and articles², and while some of these uses may be obvious to the public (*e.g.*, shampoos, cleaning products), many are not so evident (*e.g.*, high technology materials used in telecommunication devices). With continuing demands for new and improved materials, new chemicals are constantly being developed and introduced into commerce to enable ongoing advances in such high technology areas as electronics, bioengineering and telecommunications.

In addition to the tens of thousands of chemicals that are currently produced each year for commercial purposes, many chemicals are unintentionally produced as by-products in industrial, manufacturing and combustion processes. These may be present as contaminants in formulations, articles, products, wastes and releases to air, water and soil.

Release into the environment of intentionally or unintentionally produced chemicals can result in local, regional and/or global contamination, degradation of environmental media and the consequential exposure of humans and wildlife. Thus, *policies for the sound management of chemicals are now recognized as essential components of overall public policy in many countries at all stages of development due to the potential impacts of chemicals on human health, the environment, economic growth and development and, ultimately, global sustainable development.*

While chemicals may be used in a wide variety of applications, there are four major use categories:

- pesticides, which are used by governments, industry and individual consumers in a wide range of pest control applications (*e.g.*, agriculture, forestry, water treatment, public health management (*e.g.*, disease vector control), wood treatment, etc.);
- food additives, which are introduced into foodstuffs during processing and manufacturing operations;
- pharmaceuticals, which are included in products for human and veterinary applications; and
- industrial chemicals, which are used in formulations, articles and other products for applications other than as pesticides, food additives or pharmaceutical products.

While most countries have review and regulatory programs for pesticides, food additives and pharmaceuticals, many lack similar programs for industrial chemicals or do not have comprehensive programs to address the full range of hazards and risks posed by these chemicals (*e.g.*, for uses in industry, consumer products, etc.). *The present document includes an outline of the types of measures that can be taken at the national level to implement the sound management of hazardous industrial chemicals.* While this document has been developed by the Secretariat of the Rotterdam Convention, and includes measures that could be taken to implement the Rotterdam Convention, this document includes measures to address

¹ A *formulation* is an intentional mixture of two or more substances.

² An *article* is a manufactured item that is formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design.

the full range of activities associated with industrial chemicals and by-products. While the measures presented in this document represent a comprehensive approach, actual practices at the country level will vary depending on each country's level of development and specific economic and political considerations.

2. General Considerations:

In developing and implementing programs to address the health and environmental risks posed by industrial chemicals, national authorities need to include measures that respond to their national policies, priorities and needs as well as their international obligations that come with being a Party to various regional and global agreements.

To give a perspective on the task faced by a national authority in addressing its international obligations, there are more than 50 legal agreements that address the following main areas of interest related to the sound management of chemicals³:

- occupational risks;
- biodiversity impacts;
- air pollution;
- water pollution;
- prevention of accidents and emergency response measures;
- transportation and storage;
- trade;
- chemical weapons;
- production, use or release to any environmental medium; and
- transboundary movement and disposal of hazardous wastes.

While any given national authority will not have to address all these agreements, the authority will be faced with significant challenges in attempting to balance national and international obligations and priorities.

Existing global chemicals measures were established to address the health and environmental risks presented by the physical, chemical and toxicological properties of chemicals. Pertinent decision-making processes to implement these measures typically involve knowledge development, information acquisition, participation by stakeholders in decisions on risk assessment and risk management, applying the precautionary approach, and engaging industry to clarify its roles and responsibilities in the sound management of chemicals.

The following activities have influenced the development and implementation of national and international measures to address the sound management of chemicals, and should be considered in developing a national program for assessing and managing hazardous industrial chemicals.

- Fostering the development of knowledge on the scientific, technical and economic aspects of industrial chemicals. This includes both human resource development and the establishment of institutions that will be needed to support the decision-making processes.
- Making decisions on the extent to which the public will be involved in the overall process and the mode of public access to information and participation in decision-making in the sound management

³ A summary of this information is included in the report *Global Pursuit of the Sound Management of Chemicals*, prepared for the World Bank by John Buccini, World Bank, Washington DC (February 2004).

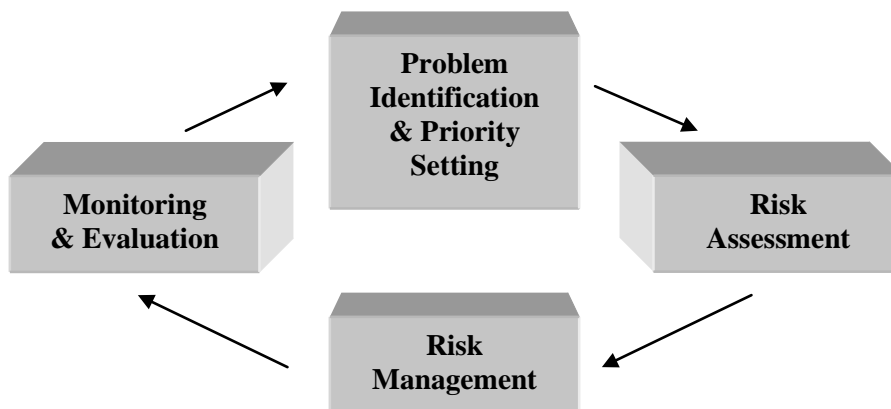
of chemicals. The term “right-to-know” is frequently used to describe the rights of people to have access to information on issues that affect them. This includes issues related to chemicals that may affect individuals or communities, such as workplace safety, preparation for and response to accidents at industrial sites, public information on releases of chemicals from sites that manufacture or handle chemicals, and involvement of national stakeholders in national plans to implement domestic measures in response to national priorities and international obligations.

- Implementing comprehensive “life cycle” assessment approaches to identify, early in the planning process, the potential risks associated with chemicals to permit the design and implementation of appropriate risk management measures. This could be accompanied by the “cradle-to-grave” management approach, in which identified risks are subjected to management measures at appropriate stages of the life cycle, and the “cradle-to-cradle” approach, in which the objective is to design a product so that when it completes its originally planned use or lifespan, it constitutes an input to another process or product and, thus, is not a waste.
- Promoting the use of “sustainable chemistry”, the objective of which is to reduce the health and environmental impacts associated with the production and use of chemicals by maximizing resource efficiency, conserving energy and non-renewable resources, minimizing risk, preventing pollution, minimizing waste at all stages of a product’s life cycle and developing durable products that could be re-used and recycled.
- Incorporating the precautionary approach in an appropriate and meaningful manner in policy and legislation to control hazardous industrial chemicals.

3. A Model for Assessing and Managing Industrial Chemicals:

Science-based processes have been developed to identify the hazards of chemicals, assess the pertinent risks and, where there have been found to be unacceptable risks, impose risk management actions to prevent, reduce or eliminate the risks. In general, these processes include four main activities: problem identification and priority setting; risk assessment; risk management; and monitoring and evaluation. The relationship between these activities is shown in Figure 1.

Figure 1: The four main activities involved in assessing and managing chemicals.



Problem identification and priority setting involves scientific activities carried out with information and data provided by a wide range of sources, including government, academia and industry. Potentially hazardous chemicals may be identified through routine or targeted environmental or human health monitoring programs, laboratory or field toxicology studies, or ongoing government programs involving

the screening of new or existing chemicals. At this stage, identification of an emerging issue or priority for further action can result in a demand for a risk assessment to determine whether the initial indication of a problem is valid or not. New issues may be identified at this stage of the cycle as well as different aspects of previously considered issues, for example through outputs from *monitoring and evaluation*.

In *risk assessment*, a chemical, a class of chemicals or a complex mixture is subjected to a critical review of available data on: sources of releases to the environment; presence, levels and trends in environmental media and organisms; and exposure of and effects on humans and environmental organisms. Risk assessment methods evolve with time due to continuous developments in the science involved and changes in understanding of the mechanisms of action of toxic chemicals. Indeed, risk assessment processes create demands for new scientific methods, data and information. Approaches vary significantly from one jurisdiction to another, although international organizations such as the OECD and the World Health Organization (WHO) are making efforts to bring some commonality to the approaches used. This is predominantly a scientific activity to determine whether a substance poses a risk to human health or the environment.

Substances that have undergone risk assessment and are found to pose an unacceptable risk may then be subjected to *risk management*, wherein consideration is given to the need to impose measures to control or manage the risk. While science remains an important factor in risk management, other key factors must also be considered such as socio-economic considerations, the availability of technology and alternative products and processes, international comparisons and impacts, and communication and consultation with the public and stakeholders that will be affected by proposed changes. In many ways, risk management is the most complex of the four activities and, in the final analysis, usually involves political considerations.

Monitoring and evaluation of the effectiveness of implemented risk management measures includes scientific activities that may be performed by government, academia, industry, etc. and can occur at the national or international levels. These activities are of a similar nature to those involved in problem identification and priority setting and if risk management measures are not appropriate or adequate, monitoring and evaluation data can lead to the identification of new aspects of an issue that had been previously addressed.

Public participation in these activities varies with the consultation policies and legal or other mandates that govern the respective programs.

This model reflects the approaches used in countries with well-established risk assessment and risk management programs, including most developed countries, and the approaches that have been incorporated into some current international chemicals agreements (e.g., Rotterdam and Stockholm Conventions). For countries with economies in transition and developing countries, not all these stages may be followed, at least not in all cases, due to inadequate legal measures and/or lack of scientific and technical staff and resources to carry out the required activities to identify, assess, manage and monitor toxic substances.

4. Policy, Legislative and Regulatory Measures:

This section identifies the types of measures that could be included in policies, legislation and/or regulations at the national level to assess and manage the health and environmental risks posed by industrial chemicals. The measures included in this section constitute a comprehensive approach that reflects current practices in many developed countries. Developing countries would need to assess which measures would be required – or feasible – to meet their national needs and circumstances.

4.1 Criminal Powers:

In most jurisdictions, environmental laws pertaining to hazardous and toxic chemicals make it a criminal offence to contravene the law. This is an important characteristic that signals the seriousness of the risks posed by such chemicals and allows for jail terms and/or large (*i.e.*, multimillion dollar) fines to be handed out to those persons or corporations convicted of crimes related to hazardous industrial chemicals.

4.2 General Policies, Principles and Approaches:

The development of a national program to assess and manage the risks of hazardous industrial chemicals could begin with the development of a policy statement that outlines the scope and objectives of the initiative. The objectives of the policy could include:

- protecting human health and the environment;
- protecting and conserving biodiversity; and
- contributing to sustainable development;

This could be followed by the development of new or amended legislation and/or regulations to implement risk assessment and management measures for industrial chemicals, wherein consideration may be given to incorporation of:

- the “life cycle” approach, to identify, early in the planning process, the potential risks associated with industrial chemicals and to permit the design and implementation of appropriate risk management measures;
- the *Precautionary Principle*, which has been used to guide the development of risk management measures at the international and national levels when there are strong indications of the need to take action but there is not full scientific certainty to support imposing measures; and
- the *Polluter Pays Principle*, to ensure that the burden of costs associated with some measures is borne by the industry or sector that produces, distributes or releases a problem chemical.

4.3 Scope:

In order for the national government and authorities to be able to address the full range of issues associated with industrial chemicals, legislation should provide the government with the power to collect information on and assess and manage the risks of a chemical that is:

- an element or compound;
- an individual chemical (*e.g.*, benzene, lindane, mercury);
- a class of chemicals (*e.g.*, PCBs, PAHs, PBDEs);
- in use in commerce or proposed for use;
- a formulation (*i.e.*, an intentional mixture of two or more substances);
- an article (*i.e.*, a manufactured item that is formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design); or
- a by-product of a manufacturing or combustion process (*e.g.*, dioxins and furans).

Separate approaches may be established for industrial chemicals that are already in use (usually referred to as “existing chemicals”) and for chemicals that are being proposed for entry into commerce (usually referred to as “new chemicals”).

4.4 Institutional Arrangements:

One decision that should be taken early in the process of developing the proposed scheme for industrial chemicals is the identification of the institution(s) that will be assigned the responsibility for

implementation of the measures. It is also desirable to establish the coordination and consultation arrangements for ensuring timely and meaningful consultation with interested stakeholders, including various levels of government, industry, academia, the general public and, where appropriate, intergovernmental organisations.

If the program will be implemented through a product register or licensing scheme, this should be identified early on in the development process to ensure the affected stakeholders are involved at the earliest stages to ensure that a practical and affordable approach is implemented.

4.5 Information and Consultation Measures:

As all four activities included in Figure 1 require information and data to make decisions on chemicals, the national government and authorities should be provided with the powers to;

- conduct research and collect information on the scientific, technical and economic aspects of chemicals;
- compel a person or organisation to submit information in its possession on a specified chemical;
- compel a person or organisation to conduct research on a specified chemical and provide the results to the government;
- specify criteria for identifying information that could be considered as “confidential business information” and establish measures to protect such information from unauthorized release;
- establish a national pollutant release and transfer registry (PRTR); and
- publish and/or make publicly available information on:
 - “ the identification of chemicals as priorities for risk assessment and risk management;
 - “ the results of monitoring and evaluation activities, including information on the presence, levels and trends of chemicals in environmental media, wildlife and/or humans;
 - “ the results of risk assessments of chemicals; and
 - “ proposed risk management measures.

An integral aspect of information collection and sharing is the need to define consultation mechanisms to ensure full and meaningful engagement of the various interested parties (*e.g.*, other government ministries, other levels of government, industry, academia, public interest groups). Consideration should be given to specifying such matters in legislation to provide an open, inclusive and transparent process for all activities pertaining to industrial chemicals.

4.6 Risk Assessment Measures:

Legislation should provide the national government and authorities with the power to assess the risks posed by a chemical to human health and the environment. Risk assessment typically involves the following main steps:

- assessing the chemical and physical properties of a substance and available data on its presence, levels and trends in environmental media, wildlife, food and humans, to gain an understanding of how the chemical is distributed, transformed and transported in environmental media once it is released to the environment;
- estimating exposures of humans and/or environmental organisms to the chemical from various uses, media, products and food;
- assessing the toxicological properties and associated dose-response relationships of the chemical in humans and other organisms, based on laboratory and field studies;
- comparing predicted and/or actual exposure levels of humans and/or other organisms to the dose levels that cause toxicological effects; and

- drawing a conclusion on the likelihood of adverse effects on humans or environmental organisms at various exposure levels to decide whether risk management measures should be implemented to reduce or eliminate identified risks.

Because the specific properties, release conditions and environmental fate are unique to each substance, chemicals need to be assessed systematically to see whether they will be broadly distributed following release to the environment or will preferentially concentrate in one medium (air, water, sediment, soil, or biota). Systematic assessments are important in ascertaining the nature and extent of local, regional and global impacts of chemicals that are released to the environment as a result of their generation, use, release and/or disposal.

In assessing the risks posed by a chemical, it is important to include consideration of releases from the widest range of activities including during research and development, manufacturing and processing, handling and transportation, storage, accidents involving manufacturing and transportation, the use of products and articles, and disposal of wastes from manufacturing processes and from the end-of-life stage of products. This is sometimes referred to as assessing the *life cycle* of the chemical.

In developing legislation and regulations, consideration should be given to including a definition or criteria for identifying chemicals that should be subjected to risk management measures. Such provisions ensure that risk assessment and risk management decision-making processes are predictable and transparent.

4.7 Risk Management Measures:

Legislation should provide the national government and authorities with the power to develop measures to prevent or control the generation, use and/or release of chemicals to reduce or eliminate the unacceptable risks that are identified in the risk assessment process. Risk management typically involves the following main steps:

- developing options to prevent or control the hazards and risks identified in a risk assessment or to implement measures at the national level to fulfill the obligations of a Party under an international agreement;
- reflecting national policies and priorities in the process of selecting options to prevent or control risks;
- considering the pertinent socio-economic factors associated with proposed options;
- consulting with interested ministries within government, other levels of government within a country, affected industries and the public;
- drafting of legislation and/or regulations to implement the selected risk management option(s); and
- developing compliance and enforcement programs to ensure that the risk management measures are properly implemented by the affected industries and that the measures are producing the desired results.

While heavily influenced by the scientific and technical information generated during the risk assessment, the development of risk management measures also relies on economic, policy and political considerations.

5 What Do Parties Need to Implement the Industrial Chemicals Provisions in the Rotterdam Convention?

In order for a Party to fully implement its obligations under Article 10, paragraph 2 of the Rotterdam Convention, it must be able to make timely decisions on whether it will allow the import of a chemical that is listed in Annex III of the Convention. In essence, this is a risk assessment decision. If the

consequence of this decision is the taking of action to prevent the import of a chemical, or to allow its importation subject to conditions, this constitutes a risk management action.

Under Article 5, paragraph 1 of the Rotterdam Convention, Parties must inform the Secretariat when they take a final regulatory action to ban or severely restrict a chemical and provide the information specified in Annex I of the Convention. Where possible, copies of the text of a final regulatory action and the supporting risk evaluation should form a part of the supporting documentation that is submitted with the notification. Thus, the basic information required for a Party to submit a notification relates to national risk assessment and risk management practices.

Thus, the core competencies that are required by a Party to properly implement the main actions under the Convention are the ability to assess the risks associated with the proposed importation of the chemicals listed in Annex III of the Convention and the ability to make risk management decisions for those chemicals that are deemed to present risks, especially if the chemicals are allowed to be imported for use by the Party.

It is acknowledged that numerous developing countries lack policies, legislation and/or regulations to assess and manage the risks posed by hazardous industrial chemicals. The Annex to the present document includes a “checklist” that can be used to assess the characteristics of country programs for industrial chemicals.

Annex: Checklist to Assess Country Programs on Industrial Chemicals

1. Is there a policy, legal or administrative framework in place or in development?
 - Policy statement?
 - Legislation and regulations?
 - Administrative framework?
 - Criminal or other type of offences?
2. Are the overall objectives of the program specified?
 - Protecting human health? (workers? general public?)
 - Protecting the environment?
 - Protecting and conserving biodiversity?
 - Contributing to sustainable development?
3. Are any principles, policies or approaches incorporated in the framework?
 - Life cycle approach?
 - Precautionary approach?
 - 'Polluter Pays' Principle?
4. Has the scope of the program been clearly defined?
 - Elements and compounds?
 - Individual chemicals?
 - Classes of chemicals?
 - Formulations (*i.e.*, intentional mixtures of two or more substances)?
 - Articles?
 - By-products of manufacturing or combustion processes?
 - All industrial chemicals, or only hazardous ones?
 - New chemicals? Existing (in-use) chemicals?
5. What institutional arrangements are in place or proposed?
 - Has an institution been assigned the responsibility for implementation of the program?
 - Does the program include a product register or licensing scheme?
 - Is there an open, inclusive and transparent process for all activities pertaining to industrial chemicals?
6. Are there coordination and consultation arrangements to engage interested stakeholders?
 - Various levels of government?
 - Industry?
 - Academia?
 - General public?
 - Intergovernmental organisations?
7. Does legislation or regulation provide the national government and authorities with the power to:
 - Assess the risks posed by a chemical to human health and/or the environment?
 - Assess the chemical and physical properties of a substance and available data on its presence, levels and trends in environmental media, wildlife, food and humans, to gain an understanding of how the chemical is distributed, transformed and transported in environmental media once it is released to the environment?
 - Consider releases from the widest range of activities including during research and development, manufacturing and processing, handling and transportation, storage, accidents involving manufacturing and transportation, the use of products and articles, and disposal of wastes from

- manufacturing processes and from the end-of-life stage of products (i.e., the *life cycle* of the chemical)?
- . Estimate exposures of humans and/or environmental organisms to the chemical from various uses, media, products and food?
 - . Assess the toxicological properties and associated dose-response relationships of the chemical in humans and other organisms, based on laboratory and field studies?
 - . Compare predicted and/or actual exposure levels of humans and/or other organisms to the dose levels that cause toxicological effects?
 - . Make conclusions on the likelihood of adverse effects on humans or environmental organisms at various exposure levels?
 - . Decide whether risk management measures should be implemented to reduce or eliminate identified risks?
8. Does legislation or regulation provide the national government and authorities with the power to:
- . Request, collect and assess the information and data needed to implement risk assessment and risk management activities?
 - . Conduct research and collect information on the scientific, technical and economic aspects of chemicals?
 - . Compel a person or organisation to submit information in its possession on a specified chemical?
 - . Compel a person or organisation to conduct research on a specified chemical and provide the results to the government?
 - . Specify criteria for identifying information that could be considered as “confidential business information” and establish measures to protect such information from unauthorized release?
 - . Establish a national pollutant release and transfer registry (PRTR)?
 - . Publish and/or make publicly available information on:
 - . the identification of chemicals as priorities for risk assessment and risk management?
 - . the results of monitoring and evaluation activities, including information on the presence, levels and trends of chemicals in environmental media, wildlife and/or humans?
 - . the results of risk assessments of chemicals?
 - . proposed risk management measures?
9. Does legislation or regulation provide the national government and authorities with the power to:
- . Develop measures to prevent or control the generation, use and/or release of chemicals to reduce or eliminate the unacceptable risks that are identified in the risk assessment process?
 - . Develop options to prevent or control the hazards and risks identified in a risk assessment or to implement measures at the national level to fulfill the obligations of a Party under an international agreement?
 - . Reflect national policies and priorities in the process of selecting options to prevent or control risks?
 - . Consider the pertinent socio-economic factors associated with proposed options?
 - . Consult with interested ministries within government, other levels of government within a country, affected industries and the public?
 - . Draft legislation and/or regulations to implement the selected risk management option(s)?
 - . Develop compliance and enforcement programs to ensure that the risk management measures are properly implemented by the affected industries and that the measures are producing the desired results?