

**United Nations Environment Programme  
Environmental Law and Institutions  
Programme Activity Center  
International Register of Potentially  
Toxic Chemicals**

**GUIDANCE ON CHEMICALS LEGISLATION: OVERVIEW  
Final Draft**

*One of a series of publications which provides guidance on chemicals legislation.*

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*[incorporate charts/boxes/graphics into table of contents or make separate list?]*

## EXECUTIVE SUMMARY

1. Agricultural productivity and industrial development have been made possible by an increase in the quantity and variety of chemicals. The enhanced availability of chemicals, however, has led to thoughtless, excessive chemical use resulting in human poisonings and global contamination. Every day more pollutants are released into the environment through the use of chemicals at home or at work and as a result of accidents. Human beings are exposed to chemicals through the air they breathe, the water they drink, the food they eat and countless other acts of daily life.
2. To maximize the benefits and minimize the costs of using chemicals, countries have tried to control them by establishing policies, creating ministries, enacting laws, training personnel and distributing information. Their efforts, however, have not been entirely effective due to an absence of political commitment, insufficient resources, legislative gaps, a lack of inter-sectoral coordination, inadequate enforcement, poor training/education or other constraints.
3. The human health and environmental price of inadequate chemicals control has become unacceptably high. In recognition of this fact, countries participating in the 1992 United Nations Environment and Development Conference (UNCED) approved an environmental action plan which includes a chapter on the environmentally sound management of toxic chemicals. In Chapter 19 of Agenda 21, countries agreed they should take concrete steps to increase awareness of chemical dangers and reduce harmful exposure to chemicals. Specifically, they concurred on the need to improve the evaluation and communication of chemical risks. They also acknowledged the importance of identifying safe or safer alternatives to toxic chemicals and otherwise preventing additional chemical poisoning or pollution.
4. In Chapter 19, countries noted that achievement of such chemical management goals requires increased collaboration among different sectors at the national and international levels. Intersectoral coordination is necessary because environmentally sound chemicals management is integrated and comprehensive in nature, *i.e.*, it links all sectors involved in any kind of chemical activity. Important sectors involved with chemicals management include different government ministries, industry, academia and non-governmental organizations. Strengthened intersectoral cooperation permits the "lifecycle" management of chemicals from their production to their disposal. This lifecycle approach recognizes that a chemical can cause harm and needs to be monitored during all stages of its "life". Through lifecycle management, countries can track and then limit human and environmental exposure to harmful chemicals.
5. Implementation of lifecycle management demands that people modify the way they now think about and handle chemicals. Strong national legislation can help bring about these changes in human attitudes and behavior. For this and other reasons, countries have acknowledged the need to enact better chemical laws as well as to improve the implementation and enforcement of those laws. Such legislative efforts are fundamental to the establishment of national systems for environmentally sound chemicals management. Moreover, a domestic regulatory program for chemicals is crucial to the accomplishment of another Chapter 19 objective; full implementation of the Prior Informed Consent (PIC) procedure.
6. The PIC procedure helps countries without adequate chemicals control learn more about the characteristics of harmful chemicals being shipped to them. It is based on the principle that chemicals which are banned or severely restricted for health or environmental reasons should not be exported to countries without their prior, informed consent. Under the procedure, countries can make decisions about the future import of certain chemicals and can disseminate these decisions to others. Both the PIC principle and the procedure are described in two voluntary international agreements known as the Amended London Guidelines for the Exchange of Information on Chemicals in International Trade (1987, amended 1989) and the International Code of Conduct on the Distribution and Use of Pesticides (1985, amended 1989). The United Nations Environment Programme (UNEP) oversees implementation of the amended London Guidelines and the Food and Agriculture Organization of the United Nations (FAO) supervises implementation of the Code of Conduct. Although UNEP has primary responsibility for industrial and consumer chemicals and FAO has primary responsibility for pesticides, the two organizations jointly implement the PIC procedure.

7. International chemicals control, under programs like PIC, depends on adequate national chemicals control. Accordingly, UNEP has prepared this Overview to assist countries in the development and strengthening of their chemicals legislation, especially for unregulated chemicals or chemical activities. UNEP views the Overview as a tool which can help countries diagnose their overall situation regarding chemicals legislation. Within this diagnostic process, countries can identify legislative needs/priorities and formulate solutions to identified problems. The Overview is intended to complement the work of other international organizations and to provide simple, realistic and flexible guidance for countries interested in improving their national chemicals legislation.

8. The Overview is subdivided into seven parts. Part 1 introduces the general subject of chemicals management and defines some relevant terms. It explains the role of legislation in managing chemicals, how chemicals legislation has evolved and common problems which have been encountered in the development of chemicals laws.. It also identifies a wide range of legislative provisions related to chemicals.

9. In essence, chemicals legislation states national policy regarding why and how chemicals need to be controlled. It creates an administrative framework and procedures for managing chemicals. It authorizes the gathering/evaluation of chemicals information and the making of chemical decisions. It places obligations or restrictions on chemical handlers and also provides positive incentives. It encourages proper chemical use, monitors compliance and punishes illegal practices.

10. Each of these major legislative components, *e.g.*, organizational structure, knowledge base, risk reduction measures and compliance, is discussed in more detail within Parts 2-5 of the Overview. Part 2 focuses on legislative provisions related to policy, authority and coordination. Part 3 outlines the legislative basis for collecting, interpreting and disseminating chemicals information. Part 4 describes the legal obligations or restrictions which are to be placed on chemical production, transport, storage, distribution, use and disposal. It also mentions government efforts to use economic instruments to achieve better chemical management. Part 5 addresses means for promoting, monitoring and compelling compliance with chemicals legislation. Within Parts 2-5, UNEP has attempted to address concrete problems such as inter-ministerial competitiveness, inadequate access to and assessment of chemicals information, insufficient measures for controlling how chemicals are handled and the inability to detect or stop improper chemical practices.

11. Part 6 of the Overview shows how chemicals legislation might be developed in stages from a simple scheme to one increasingly more complex. Part 7 contains a list of selected references for additional information. To maximize its usability, the Overview also provides practical suggestions and useful resources throughout its substantive parts.

12. Although the Overview follows the format of a typical law, it is not intended to serve as a model law which must be implemented in its entirety. The Overview also is not a manual which gives detailed advice on how to draft a chemicals law. Instead, the Overview is a broad survey of legislative provisions used to manage chemicals. For countries with little or no chemicals legislation, the Overview is intended to: (1) describe the major components of chemicals legislation, (2) discuss various legislative options and (3) generally show how chemicals legislation can be developed. For countries which already have some form of chemicals legislation, this Overview offers ideas for: (4) updating or upgrading existing legislation, (5) better coordinating, implementing and enforcing legislation and (6) ensuring coverage of currently unregulated chemicals or chemical activities. As with any legislative guidance material, countries are encouraged to consider the information and ideas presented in light of their own experience, national priorities and available resources.

13. With this Overview, UNEP begins a series of publications designed to provide guidance on chemicals legislation. The second document in the series will discuss in more detail a specific topic of chemicals legislation, *i.e.*, implementation of the PIC procedure for international trade in banned or severely restricted chemicals. Other supplemental publications on different aspects of chemicals legislation will follow as they are developed. UNEP welcomes any suggestions for improving or expanding the series.

## INTRODUCTION

### What is chemicals management?

14. Chemicals management is the continuous process of assessing and reducing chemical "risk"--the likelihood that chemicals will cause harm to human health or the environment. Because chemical risk varies according to the circumstances, chemicals management is a complex task. To manage chemicals successfully requires a sense of priorities and a spirit of cooperation. It also requires a desire to anticipate and prevent chemical problems rather than to simply react to them.

15. Chemicals subject to management take many forms. They include single elements like lead, compounds like sulfur dioxide and mixtures like DDT. Together, elements and compounds are referred to as chemical substances. A combination of two or more chemical substances, without a chemical reaction, is called a chemical mixture or chemical preparation. Some chemicals occur naturally, while others are manufactured. Once produced, the same chemical might be used as an agricultural pesticide ingredient, a consumer food additive or an industrial raw material.

16. Chemicals management involves supervising activities related to chemicals, *e.g.*, the production, transport, storage, distribution, use and disposal of chemicals, so as to prevent any harm to human health or the environment. Together, these activities make up a chemical's "lifecycle" and mark its existence from "cradle to grave". Chemicals can cause harm and need to be monitored during each phase of their "life". Lifecycle management strives for the sensible handling of chemicals by everyone who comes into contact with them. In addition to ensuring the safe use of chemicals, lifecycle management promotes the development of safer chemicals and "clean" technology which can help minimize exposure to harmful chemicals and prevent pollution. It also can assist the integration or coordination of different chemicals management efforts.

### Who manages chemicals?

#### Nationally

17. Chemical producers, chemical distributors and government bear the primary responsibility for proper chemicals management. Specifically, industry has the duty to produce and distribute quality chemicals which can be used safely. It should test chemicals for any adverse effects and inform users of necessary safety precautions. Government, on the other hand, must decide which chemical uses are unacceptable because of the risk they present to health and environment. Government further should supervise industry and educate the public about its rights and obligations regarding chemicals management. In countries where government functions as industry, it must fulfill both sets of obligations.

18. National governments can never fully control all chemicals because of their sheer number and the diverse ways in which they are used. Countries, therefore, have begun to place more and more responsibility on the industries which produce and distribute chemicals. They also have started to encourage greater public participation in the chemical management process.

19. Important sectors involved with chemicals management include: (1) various government ministries (primarily Agriculture, Environment, Health, Industry, Labor, Trade/Customs and Transportation), (2) chemical manufacturing, trade and other industry associations, (3) scientific agencies, universities and research institutes, (4) trade unions, environmental organizations and consumer groups (5) legislators and judicial officers, (6) individual producers, distributors and handlers of chemicals and (7) regional or international organizations. Cooperation among these different sectors is crucial to the lifecycle management of chemicals. Without inter-sectoral coordination, chemicals management can be neither comprehensive nor effective.

#### Regionally/Internationally

20. The European Community (EC), a political body involving 12 countries, has developed a fairly comprehensive approach to chemicals management. The Nordic countries also have well-developed programs. Countries in transition from one economic system to another are actively strengthening their national chemical

control schemes. Other regions show growing interest in chemicals management as well, from the control of radioactive materials in the Pacific, to the control of hazardous waste in Africa, to the prevention of illegal traffic in Asia and the Americas. The Organisation for Economic Co-operation and Development (OECD), an intergovernmental body with members from 24 developed countries in several regions, has prepared many useful policies and procedures for better managing chemicals.

21. Activities of intergovernmental bodies, international industry associations and international public interest groups contribute much to chemicals management efforts. As at the national level, no single organization deals with the entirety of chemicals management. The United Nations Environment Programme (UNEP) primarily is concerned with industrial chemicals and environmental effects, the Food and Agriculture Organization of the United Nations (FAO) with agricultural and domestic pesticides, the World Health Organization (WHO) with pharmaceuticals and human health effects, the International Labour Organisation (ILO) with the safe use of chemicals at work, the United Nations Industrial Development Organization (UNIDO) with matters affecting the chemical industry, the International Maritime Organization (IMO) and the United Nations Economic Commission for Europe with issues related to transport and the International Agency for Research on Cancer (IARC) with the carcinogenic effects of chemicals. To facilitate coordination of their different chemical safety activities, three of the organizations (ILO, UNEP and WHO) collaborate in the International Programme on Chemical Safety (IPCS). This programme now is being expanded to include other organizations.

### **How are chemicals managed?**

#### Nationally

22. Government, industry, academia, workers, consumers and the public are all involved in the management of chemicals through a mixture of legal, economic, scientific, technical and social means. For example, chemicals are managed by:

- \* regulations requiring government approval for chemical manufacture or import
- \* subsidies for the installation of clean technology
- \* taxes to discourage chemical use
- \* voluntary industry programs to reduce chemical emissions
- \* studies which evaluate chemical exposure or identify chemical alternatives
- \* the use of personal protective equipment
- \* the monitoring of chemical injuries and accidents
- \* consumer selection of environmentally friendly products

23. Despite some progress in chemicals management, many problems still remain. Depending on a country's level of economic development, they could include: lack of serious political commitment; inadequate or uncoordinated legislation; agencies working in isolation; insufficient scientific/economic information on chemicals in use; lack of health or environmental monitoring; lack of trained staff, equipment and other resources; absence of labelling or foreign labelling; faulty packaging or repackaging; lack of poison centers or accident preparedness; inappropriate transport; unsafe storage; easy accessibility to toxic chemicals; high risk methods of use; excessive use or misuse; lack of or failure to use protective equipment or clothing; and lack of disposal facilities for obsolete or waste chemicals.

24. Every country has the capacity to improve the management of chemicals within its borders. Actual improvement of chemicals management, however, requires commitment and action. Typical chemicals management resources include: legislative authority (power to collect information, decide on regulatory measures, compel compliance), adequate funding (national budget, bilateral aid or multilateral assistance), organizational procedures (coordination networks, decisionmaking criteria, enforcement scheme), information systems (national databases, libraries, research institutes, universities, access to international publications or databases, exchange with other countries or organizations), scientific assessment expertise (chemistry, environmental chemistry, toxicology, occupational health, biology, eco-toxicology, law), technical skills (trained scientists, laboratory technicians, computer technicians, information specialists, administrative personnel, inspectors and other enforcement staff) and equipment (facilities, communication tools like facsimile or telex machines, computers, computer links to other systems, monitoring devices, sampling tools, laboratory instruments, vehicles, protective

gear, environmentally sound technology). By listing these resources, it is not implied that all of them must be in place before chemicals management can begin. Available or accessible resources must be identified, however, before a country can consider making use of them.

#### Regionally/Internationally

25. The EC sets legislative standards and issues binding regulations for its member states. Legislation and programs of the EC offer useful ideas regarding many aspects of chemicals management, e.g., classification, packaging, labelling, new chemical notification, implementation of Prior Informed Consent and freedom of environmental information. Countries in various regions of the world have entered into regional agreements on different environmental issues, e.g., European Convention on Transboundary Air Pollution (1979), Bamako Convention on Hazardous Wastes (19\_\_), South Pacific Nuclear Free Zone Treaty (\_\_) and regional seas conventions. Countries in the Pacific region have formed a South Pacific Regional Environment Programme (SPREP). For a number of years, the OECD has been active in the preparation of uniform chemical testing guidelines, standards for good laboratory practices, procedures for sharing chemicals information, guidelines for the prevention of chemical accidents, summaries of national risk reduction programs and other helpful projects. The United Nations has several regional economic and social commissions now engaged in chemical management activities.

26. International organizations like UNEP, FAO, ILO, WHO, IMO, UNIDO and IARC promote the safe use of chemicals through: the adoption of legally binding international agreements, the approval of voluntary international codes or standards or guidelines, the promotion of research, the maintenance of chemical information databases, the publication and distribution of scientific and educational materials, and the provision of direct technical or financial assistance to countries. For example, UNEP has adopted the Basel Convention and the amended London Guidelines. UNEP's International Register on Potentially Toxic Chemicals maintains a chemical database for countries' use, operates a query response service and publishes a scientific bulletin. Together with WHO and ILO, UNEP regularly distributes Environmental Health Criteria documents and Health and Safety Guides. Other UNEP programmes deal with the link between industry and environment as well as global environmental monitoring.

27. As mentioned in the Executive Summary, the environmental action plan for the future (Agenda 21) approved at UNCED makes a substantial international contribution to environmentally sound chemicals management. Chapter 19 of Agenda 21 provides much useful information on improving the international assessment of chemical risk, the harmonization of chemical classification and labelling, the exchange of information on toxic chemicals and chemical risk, the establishment of risk reduction programs, the strengthening of national chemical management capabilities and the prevention of illegal traffic in toxic and dangerous products.

### **Role and Evolution of Chemicals Legislation**

#### Generally

28. Legislation provides the impetus and framework for chemicals management efforts. Chemicals "legislation" may take the form of laws, decrees, orders, regulations, rules, standards, norms or similar written statements of national policy and requirements for behavior. National chemicals legislation usually is composed of one or more general laws (primary legislation) implemented by specific subsidiary regulations (secondary legislation).

29. Countries rarely, if ever, have a single chemical law. The word "chemical" may not even appear in the title of a law which governs chemicals. Instead, separate pieces of legislation and separate ministries commonly regulate chemicals as:

- (1) poisons/pharmaceuticals/food additives,
- (2) narcotics,
- (3) explosives/arms,
- (4) pesticides/fertilizers/feed,
- (5) toxic substances/general chemicals,

- (6) dangerous goods in transport,
- (7) pollutants/contaminants,
- (8) hazardous waste,
- (9) hazards to occupational health and
- (10) radioactive materials

Each of these legislative topics represents an aspect of the comprehensive management of chemicals. Their inter-relatedness shows the need for government ministries, or divisions within a ministry, to co-operate in the development, implementation and enforcement of chemicals legislation.

30. Interest in a more co-ordinated approach to chemicals has prompted several countries to consolidate two or more chemical laws into a single law. These consolidated laws often are supplemented by separate sets of regulations for different categories of chemicals, *e.g.*, pesticides and industrial chemicals. Some countries have considered regulating all chemicals and chemical activities under one comprehensive law. This seems impracticable because of the breadth and complexity of chemicals management. The enactment of simple framework laws is feasible, however, especially in countries with no existing chemicals legislation. Many countries already have existing pieces of chemicals legislation which they find difficult or impossible to merge into one whole. For them, a preferable goal may be to harmonize the provisions of existing or new chemical laws and to coordinate the actions of ministries which regulate chemicals.

#### Historical Development

31. Despite having different names and different subjects, chemicals legislation has evolved similarly in many countries. Early efforts to regulate chemicals focused on their direct harmfulness to human health. For this reason, laws were created to regulate the production, distribution and use of pharmaceuticals, food/feed additives, cosmetic ingredients, pesticides and general "poisons". Such legislation was intended primarily to protect consumers from dangerous or toxic chemicals, especially those which were of poor quality or easy to misuse. To protect workers from harmful chemical exposure, occupational safety and health laws were enacted or revised.

32. Concern about the ecological and indirect human health effects of chemicals released into environment led to the passage of pollution laws. Most of these laws limited the amount of harmful chemicals which could be discharged into the air or water. Later legislation provided for the complete phasing out of unacceptably harmful chemicals, *e.g.*, chlorofluorocarbons (CFCs) and polychlorinated biphenyls (PCBs). Environmental legislation in some countries also has been directed at the proper disposal of hazardous chemical waste and the cleanup of chemically contaminated sites. Other legislation has encouraged the prevention of pollution through safer chemicals and clean technology.

33. To lessen the adverse health and environmental effects of chemical accidents, countries enacted laws governing the transport of dangerous goods or hazardous materials. Additional, newer legislation has focused on accident prevention at industrial facilities which manufacture, store or use significant quantities of dangerous chemicals. Related legislative provisions have required these facilities to publicly report the amount of certain toxic chemicals they keep in stock and the quantity they emit into the environment.

34. To fill gaps left by earlier legislation, laws were developed to better identify and control all chemicals being manufactured and marketed which might have adverse effects on human health or the environment. This broader chemicals legislation helped regulate those chemicals not already covered by an earlier pharmaceutical, pesticide or food additive law. Commonly, these toxic or hazardous substances laws provide for the listing of existing chemicals and the notification of new chemicals being manufactured, imported or used. They often classify chemicals by hazard and prioritize chemicals for control. With their emphasis on assessing chemical risk, these broader chemicals laws are aimed at preventing rather than reacting to health or environmental problems. During the last few years, a number of OECD countries have revised their general chemical laws to reflect technical and social progress in chemicals management.

#### Current Situation

35. The extent to which chemicals are legislatively controlled varies greatly from country to country. At one end of the spectrum, there is still a total lack of chemicals legislation in some countries. At the other end, many countries have ten or more laws which control chemicals in various ways. In the middle of these two extremes, there are countries which have outdated chemical laws that regulate chemicals poorly or general environmental laws that do not regulate chemicals at all.

36. There are countries which have drafted chemicals laws but never enacted them and countries which have enacted chemicals laws but never implemented them. Industrializing countries occasionally have suspended or loosened application of chemicals legislation to encourage economic development. Developed and developing countries with several different chemicals laws have experienced poor coordination among the different ministries responsible for such laws. They also have observed a lack of comprehensiveness in their legislation which allows some chemicals or aspects of chemicals management to "fall through the cracks." Finally, countries have noticed that the effectiveness of their legislation is reduced by weak or nonexistent enforcement.

37. All of these issues have caused both developed and developing countries to look more closely at the adequacy of national chemicals laws. They also have triggered international debate on how chemicals could and should be better managed.

### **Major Components of Chemicals Legislation**

38. The next four sections focus primarily on those laws which regulate the marketing of chemicals. Less attention is paid to specific laws which govern chemical transport, occupational safety, environmental pollution and hazardous waste. Radioactive materials, narcotics, explosives and chemical weapons are not addressed in any detail.

39. Whether a chemical has an agricultural or consumer or industrial use, certain aspects of its legislative control will be similar. Pesticides laws, pharmaceuticals laws and industrial chemical laws all provide a system for screening chemicals before they enter the market. This means information on chemicals is gathered, potentially harmful chemicals are identified and measures are taken to protect health and environment from risk of harm. The regulatory emphasis may vary as a result of the different uses to which chemicals are put. For example, pharmaceutical and pesticide laws are more concerned with quality and efficacy standards than are laws on industrial chemicals. Similarly, the environmental impact of chemicals when used as pharmaceuticals, food additives or cosmetics is less than when chemicals are used as industrial materials or pesticides.

40. Although the form and content of such chemical laws vary, they all have four major components: (1) an **organizational structure** (infrastructure) which states chemical management policy, establishes the authority and ability to control chemicals and coordinates related chemical management efforts, (2) the building of a chemical **knowledge base** that collects, interprets and disseminates information on which decisions are made regarding which chemicals are safe for use and under what conditions, (3) the establishment of **protective measures** which ensure the proper production and handling of chemicals and (4) a **compliance scheme** necessary to monitor, compel and promote observance of legislative provisions.

41. Taken together, these components function as a national checklist for determining which aspects of chemical management have been implemented, which should be considered for action and which might be postponed until later. As this document is meant to be an overview, a number of ideas are mentioned but few are explained thoroughly. Later legislative guidance documents will go into further detail regarding selected components.

## MAJOR COMPONENTS OF CHEMICALS LEGISLATION

<p><b>Organizational Structure</b></p> <ul style="list-style-type: none"> <li>* Statement of chemical management policy</li> <li>* Establishment of authority and means to implement legislation</li> <li>* Coordination of legislation with related inter-agency, inter-sectoral and international activities</li> </ul>	<p><b>Knowledge Base</b></p> <ul style="list-style-type: none"> <li>* Collection and organization of chemical information</li> <li>* Interpretation and weighing of information to make chemical control decisions</li> <li>* Dissemination of chemical information to other agencies, sectors and countries</li> </ul>
<p><b>Protective Measures</b></p> <ul style="list-style-type: none"> <li>* General and specific obligations to handle chemicals safely throughout their lifecycle</li> <li>* Restrictions</li> <li>* Economic instruments</li> </ul>	<p><b>Compliance Scheme</b></p> <ul style="list-style-type: none"> <li>* Monitoring of compliance</li> <li>* Compelling of compliance</li> <li>* Promotion of compliance</li> </ul>

## **ORGANIZATIONAL STRUCTURE**

### **\* Statement of chemical management policy**

Legislative purpose or objectives

Scope of law's chemical coverage

Definitions of terms used in law

### **\* Establishment of authority and means to implement law**

Designation of a particular agency or official

Description of administrative powers

Identification of means to carry out legislative policy

### **\* Coordination**

Inter-agency

Inter-sectoral

International

## ORGANIZATIONAL STRUCTURE

42. Legislation usually begins with a statement of its objectives, a description of its scope and definitions of any uncommon or important words used in its text. These types of provisions introduce the law, declare the national policies it is expected to further and often explain how the law relates to other legislation. Additional sections identify the government body responsible for putting the law into effect and provide the authority or means needed to implement the law. Similar administrative provisions explain the role of other relevant sectors and arrange for necessary inter-sectoral coordination.

### Statement of Policy

#### Purpose or Objectives

43. Legislative objectives explain why a particular law has been written and what it hopes to accomplish. The main purpose of chemicals legislation is to protect human health and the environment from harmful chemical effects. In its statement of purpose, a law usually summarizes how it will achieve this purpose, *e.g.*, by requiring the notification of any new chemical placed on the market, by identifying facilities which handle hazardous chemicals, by classifying, labelling and packaging dangerous substances, by prohibiting the use of an unregistered or unapproved chemical, by substituting less harmful chemicals wherever possible, etc.

44. Legislation related to chemicals can have more than one objective. In addition to protecting health and environment, a law might implement a government's obligations under an international instrument, *e.g.*, the Montreal Protocol on Substances Which Deplete the Ozone Layer (1987, amended 1991). Sometimes a law will indicate its purpose is to avoid the creation of any unreasonable obstacles to chemicals trade.

#### Scope

45. Scope provisions describe who or what the law covers, *e.g.*, which persons, chemicals, chemical uses and chemical activities are subject to regulation. Legislative obligations often are directed at producers, distributors and/or users of chemicals, but some can apply to anyone handling a chemical. Depending on the law's definition of the term "chemical", it generally covers substances and mixtures. Occasionally, goods or articles containing chemicals also will be regulated. More recent legislative provisions cover naturally-occurring toxins as well as chemicals obtained from micro-organisms or biotechnology.

46. Sometimes only certain quantities of chemicals are subject to regulation. For example, some chemical laws exempt from regulation chemicals used in small quantities, *e.g.*, research chemicals or amounts less than 100 kg. Various pollution and accident prevention laws also have limited their coverage to certain threshold quantities of listed chemicals. Some laws are limited in scope to those chemicals used as pesticides or pharmaceuticals. Other laws are limited to a particular chemical activity such as transport. Still other laws are limited to places where chemicals can be found such as the workplace.

47. To improve the coordination of chemicals management efforts, some countries have widened the scope of newer chemicals laws so they act more as framework laws. Many other countries see no reason to change existing legislation for the sake of change, if it adequately controls certain chemicals. They also appreciate the experience gained in regulating certain groups or aspects of chemicals and are reluctant to disrupt established systems. These different viewpoints show how a law's scope reflects a country's chemicals management policy.

#### Definitions

48. Most laws define the "responsible person", "manufacturer", "processor", "carrier", "seller", "commercial user" or other persons covered by the law. These words can refer to both individuals and corporations. Shorthand references to officials or agencies ("Director" or "Ministry" or "Inspectorate" or "Commission") usually are explained. In addition, specific government officers like "analyst", "inspector" or "investigator" might be described.

49. In addition to defining the word "chemical", many laws define related terms such as "toxic chemical", "hazardous chemical", "dangerous chemical", "poison", etc. Although the choice of words varies from country to country, they all mean essentially the same thing. That is, they refer to chemicals which, based on their harmfulness, have been set apart from other chemicals. These more harmful chemicals are subjected to stricter control. Some laws define certain kinds of chemicals by referring to a list, e.g., a list of banned or severely restricted chemicals. Any chemical on the list automatically has a particular legal significance. Certain laws also distinguish a "new substance" from a "substance" because each is treated differently. Terms such as "mixture", "preparation", "product", "good" or "article" have been distinguished from each other as well.

50. Some chemical laws explain the general term "hazard" (inherent ability of chemical to cause harm under certain conditions), while others define specific chemical hazards such as "toxic" (capable of causing serious injury to health) or "non-biodegradable" (cannot naturally break down into harmless elements). The term "risk" (likelihood that a hazardous chemical will cause harm upon exposure) also may be distinguished from "hazard". If environmental effects are covered by the law, the word "environment" might be explained.

51. A broad term such as "handling" has been used in legislation to refer to all activities related to chemicals. Other laws define specific activities such as "production" or "processing" or "formulation", "packaging", "labelling", "import/export", "trade", "commerce", "distribution", "advertisement", "use" or "disposal". Items involved with chemicals such as "label" or "container" might be explained and terms like "permit", "license" or "application" have been defined.

### **Establishment of Authority and Means**

#### National Chemical Authority

52. In accordance with national practice, legislation often gives a specific official or government body the general authority to implement its provisions. Sometimes two ministries, e.g., Health and Environment, are given joint responsibility to implement a chemical law. An entirely new agency or an inter-ministerial body also might be created to implement a unique or comprehensive chemical law.

53. Within countries that have several different laws related to chemicals, legislative responsibilities for chemicals management typically are divided as follows:

Agriculture	pesticides, fertilizers
Environment	chemicals not otherwise regulated; environmental effects; accidents; hazardous waste
Health	pharmaceuticals; cosmetics, food additives; pesticide residues; poisons; health effects
Industry	production
Labor	use; occupational safety and health
Trade/Customs	imports/exports
Transport	packaging and shipment of dangerous goods

#### Powers

54. Legislation "enables" or authorizes a government body to carry out the law's aims by taking certain action. Depending on a country's legal tradition, this delegated authority may be broad or narrow in scope. With broad authorization, an agency can act more quickly in a variety of ways to effectively implement the law.

55. At a minimum, officials or ministries responsible for implementing chemicals legislation should have the authority to: (1) issue necessary regulations which establish procedures, requirements or standards, (2) require the submission, by chemical producers and others, of various chemicals information, (3) restrict or otherwise control chemical uses and activities, (4) communicate with other countries or international organizations regarding chemicals and (5) generally carry out and ensure compliance with the law.

56. Various chemical laws further authorize government, among other things, to (6) accept and rely on trustworthy chemical assessment data from other countries, (7) support research, (8) classify or categorize chemicals, (6) make interim or emergency decisions concerning a chemical's use and (9) require the assistance of or delegate authority to other ministries or state/local bodies.

57. To ensure the fair exercise of governmental authority, chemicals legislation often enables (gives the right) members of the regulated community to seek administrative or judicial review of harmful regulatory action. Some chemical laws also enable members of the public to obtain chemicals information and to take direct legal action against government or industry for improper acts and omissions.

### Means

58. Chemicals legislation usually sets out the mechanisms by which its provisions will be carried out. For example, various laws (1) establish advisory bodies to support and coordinate chemical control efforts, (2) set up inventories and/or databases, (3) outline necessary administrative or other procedures, (4) create personnel positions, (5) identify priorities or criteria for decisionmaking, (6) authorize a fee system or other method of obtaining needed financial resources and, generally, (7) provide the institutional means needed for the law's implementation.

## **Coordination**

### Inter-agency

59. Each new piece of chemicals legislation explains its relationship to already existing laws, *e.g.*, whether previous laws are unaffected, referenced, absorbed or repealed. Often a chemical law exempts certain chemicals or chemical activities from coverage because they are already regulated. These kinds of provisions indirectly show how the new law affects the responsibilities of different chemical ministries.

60. In situations where more than one agency is assigned responsibility for implementing a chemical law, some countries have designated a lead agency for better coordination of efforts. This lead agency is given the task of consulting with other agencies or sectors and involving them in implementation of the law. In other instances, chemical legislation sets out the specific areas of authority for various agencies, *e.g.*, the roles of agencies responsible for overseeing chemical suppliers, the environment, occupational safety and public health, among others.

61. Many chemical laws elaborate the division of responsibilities among national, state and local authorities. Matters of policy, compliance standards and coordination usually are handled at the national level. Actual implementation, licensing, monitoring and some enforcement responsibilities are delegated to authorities at the state and local levels. Separate state or local legislation often is permitted, provided it is consistent with national legislative requirements.

62. Some chemical laws establish an inter-agency advisory body whose purpose is to evaluate chemical risks, make recommendations for control measures or generally help the lead agency implement the law. The chairman of such a group often represents the ministry with primary chemical authority. Members typically come from those ministries with some expertise or interest in the handling of chemicals, *e.g.*, Health, Agriculture, Environment, Industry, Labor, Trade/Customs or Transport. If further coordination is needed regarding specific issues such as chemical emergencies or the strengthening of enforcement efforts, other agency representatives, *e.g.*, from the Fire, Police or Justice ministries, might be included.

63. The effectiveness of an inter-agency advisory group depends largely upon the strength of its leadership, the clarity of its purpose, and its ability to make or affect decisions on chemicals. Regular meetings and a separate secretariat can help an inter-agency body's overall effectiveness. The body can provide different kinds of advice depending on the type of decisions being made and criteria being used. Decisions made about the gathering or evaluation of chemical data will differ from those about the prioritizing or controlling of chemical risks.

64. In addition to the use of an advisory body, some countries enhance inter-agency coordination by means of special task forces or working groups. They also use Memoranda of Understanding to improve agency cooperation in information sharing, implementation, enforcement or other matters. A chemical law can go so far as to require one agency to consult or negotiate with other agencies regarding particular chemical management issues.

#### Inter-sectoral

65. A number of countries make it possible for scientific institutes, academia, private industry, labor unions and public interest groups to participate in the chemical management process. This participation may include representation on an advisory body or the opportunity to address government decisionmakers on specific issues. Those countries which allow public comment on proposed legislation often receive important sectoral input regarding the potential costs or benefits of suggested regulatory measures.

66. Certain chemical laws authorize the creation of a scientific/technical advisory board or committee to assist the national authority in its chemical decisionmaking. These types of bodies usually are separate and different from the more policy-oriented inter-agency advisory bodies described in the previous section. Some laws also provide for the establishment of expert task forces or working groups to address specific chemical management needs or policy questions.

67. In addition to chemicals legislation, some countries have experimented with voluntary agreements between the chemical industry and government to better control chemicals. Under such agreements, chemical traders have promised to notify importing countries about the shipment of hazardous chemicals and chemical producers have guaranteed substantial reductions of chemical emissions into the environment. Voluntary initiatives by industry offer creative solutions to various chemical management problems. In addition, they often are implemented more quickly and effectively than government programs.

#### International

68. The transboundary health and environmental effects of poor chemicals management have prompted countries to work more closely with each other in reducing exposure to harmful chemicals. This is reflected in regional efforts to exchange information, experience and resources to improve chemicals management. Organizations such as the OECD allow groups of countries to share information and skilled personnel, so they make maximum use of limited resources and do not duplicate each other's chemical management activities. Member countries of a regional body like the EC have gone beyond mere sharing of ideas and gained substantial experience with actually coordinating their chemicals legislation. In the interest of free trade and economic development, developing countries in all regions have begun looking to the OECD and the EC as sources of harmonized chemical laws or programs.

69. As yet, there is no international treaty covering the comprehensive management of chemicals. Nevertheless, international agreements such as the ILO's Convention Concerning Safety in the Use of Chemicals at Work (1990) provide countries with widely accepted minimum standards for national chemicals legislation. Whether legally binding like the ILO Convention or voluntary like the FAO Code of Conduct on Pesticides or the U.N. Recommendations on the Transport of Dangerous Goods, international instruments help countries harmonize their chemical control efforts. Many international agreements, like UNEP's amended London Guidelines on Information Exchange permit countries to take advantage of others' knowledge and experience.

70. In particular, the Prior Informed Consent procedure contained in the amended London Guidelines provides countries with a formal means of obtaining chemicals information needed to take import decisions about

certain harmful chemicals in international trade. It further provides a means of disseminating those import decisions to other countries.

### **Practical Suggestions**

- \* establish an inter-sectoral task force or advisory group for chemicals involving government, industry, public interest groups and others*
- \* before drafting any legislation, do a realistic appraisal of chemical control needs and priorities (see Part 7 of this Overview)*
- \* identify all available or developable resources*
- \* identify an inter-ministerial or other body which can set chemical management policy, coordinate government action and resolve inter-agency conflicts*
- \* consider whether the regulation of more than one chemical category or chemical activity can be consolidated under a framework law*
- \* within the law, clarify the role of each agency and better link their setting of chemical priorities, occupational or environmental standards, etc.*
- \* ensure the law authorizes government to request/share information, to regulate/restrict chemical use and to monitor/enforce compliance*
- \* become more familiar with chemical management efforts in the region and ways of regularly sharing information/resources*

### **Useful Resources**

- \* funding for study of chemical control needs and implementation of resulting recommendations*
- \* any existing studies which identify and describe agencies and legislation involved with chemical control*
- \* personnel with administrative, technical or legal skills who can plan and implement an improved chemical control system*
- \* information network linking major actors in chemical control*

## **KNOWLEDGE BASE**

### **\* Collection/organization of information**

Identification of existing and new chemicals through listing, new chemical notification scheme or product register

Data-gathering through exposure monitoring or problem reporting network and organization of information in databases

### **\* Interpretation of information**

Hazard, risk and benefit assessment

Classification by hazard

Prioritization for study or regulation

### **\* Dissemination of information**

Risk communication, including labelling, material safety data sheets, training and education

Publication of chemical decisions and safety information in official gazette/journal

Provision of access to chemical records but protection of confidential business information

Information exchange

## KNOWLEDGE BASE

71. Before considering how chemicals should be controlled, it is helpful to know which chemicals are in need of control. To make this determination requires knowledge (organized information) about those chemicals produced, imported and used within a country's borders. Chemicals legislation obliges chemical producers/distributors and others to submit certain chemicals information to the proper government body. It further authorizes government to collect any additional information, including confidential business information, without justification. This power enables government to develop the knowledge base needed for evaluating chemical risks to health or environment and for taking appropriate decisions about the measures which can reduce those risks. Chemical laws also provide for the communication of important chemical safety information to all those who might come into contact with harmful chemicals.

### Collection/Organization of Chemicals Information

#### Generally

72. It has been difficult for countries to gather chemical data, if they lack the legal authority to compel chemical suppliers and users to submit such information. Therefore, chemicals legislation must provide government the authority to obtain any information it deems necessary and to punish those who fail to supply requested information. With or without this authority, agencies must be persistent and creative in locating sources of chemicals information.

73. Collecting chemicals information requires substantial time and effort. The costliness of the process in terms of human, technical and financial resources has led countries to set priorities for national data-gathering and to seek better access to international sources of chemical data. In terms of priorities, it is most important that countries generally know:

- (1) who is using
- (2) which chemicals
- (3) in what amounts and
- (4) for what purposes.

To assist their evaluation of chemical risks, countries also need basic information about the extent to which human health and the environment are exposed to chemicals. Such exposure data, unlike standard scientific information on chemical characteristics and effects, needs to be developed locally because the circumstances of chemical use vary from country to country.

74. In collecting chemicals information, a distinction can be made among agricultural, consumer and industrial chemicals. More information has been gathered on pesticides and pharmaceuticals than on industrial chemicals. This is due to the known hazardousness of pesticides and pharmaceuticals, their relatively small numbers and the great likelihood of human exposure. Later legislation on industrial chemicals has tried to correct this imbalance.

75. For purposes of gathering data, industrial chemicals have been further divided into (1) those chemical substances in use at a particular point in time (existing chemicals) and (2) "new" chemicals which are introduced after that point. This administrative separation between a large number of existing chemicals and a smaller number of new chemicals has enabled countries to subject new chemicals to more consistent information gathering and safety assessment. After instituting these controls on new chemicals, many countries began compiling additional health and environmental data on selected existing chemicals as well. To share the burden of this task, members of the OECD have agreed among themselves to identify and fill data gaps concerning 1,000 existing chemicals chosen on the basis of high production volume. Together these chemicals comprise the majority of world chemical production.

#### Identification of Existing Chemical Substances

76. General chemical laws authorize government to establish and maintain a list of all chemical substances domestically produced or distributed. The purpose of such a national list is to identify, *i.e.*, learn and make

known, which substances are being used in a country. This knowledge forms the basis for all further chemical management efforts on a national level. It also permits participation in international programs like Prior Informed Consent which require a country to know whether a particular hazardous chemical is in use. Mere inclusion of a substance on a national list of existing chemical substances does not mean the substance has been officially studied and approved for use. It simply means the substance exists in commerce. As discussed in the next section, however, chemical substances not on the list may be treated as "new" chemicals. This means they cannot be produced or marketed legally until they have been notified to the government.

77. A decision to list all existing chemical substances within the country should not be taken lightly as the chemical listing process takes a great deal of time and effort. An existing chemical substance list from another country or an international organization often serves as a useful reference point. The process of compiling a chemical list begins with the identification of chemical producers and importers who are asked to identify the chemicals they are making domestically or bringing into the country. Governments have requested this information by official letter and by newspaper advertisement. Some countries simply have required that chemical suppliers submit chemical safety data sheets (manufacturers' written summaries describing the chemical and its proper handling) for every chemical they supply to others.

78. If the anticipated number of chemicals is large, the government first can require information on high volume or extremely hazardous chemicals and later can obtain information on lower volume or less hazardous chemicals. Preparation of the list also can be based on information gathered from other government bodies, research institutes, industry associations, chemical retailers or users and public interest groups. After distribution of an initial list, a grace period of time (six months or more) might be provided for industry and others to fill in missed chemicals or nominate candidate chemicals.

79. Whether a country compiles a limited or complete list of chemicals, arrangements must be made for maintaining the list in some way and for publishing it in an official gazette or journal. Such maintenance and publication of the list is important because the list serves as the basis for future chemical actions, *e.g.*, the collection of additional information, the assessment of risks and the determination of chemical control priorities.

80. At least one country has created two separate lists of existing chemicals in its legislation: (1) a realistic list of chemicals used nationally (actual chemicals) and (2) a larger inventory of chemicals which may enter the national market (potential chemicals) based on inventories prepared by the European Community, Japan or the United States. By legislatively adopting one of these large inventories, countries can avoid trade obstacles which might be caused by treating any chemical not currently in the domestic market as a "new" chemical subject to notification provisions.

81. Inventories of existing (or new) chemicals compiled by Europe, Japan, the U.S. and other developed countries operate as the basis for extensive assessment schemes. These testing programs demand a large resource commitment which less wealthy countries may not be able to duplicate. If a country obtains access to scientific data or assessment results obtained by other countries, it can focus its attention on improving chemical knowledge in areas where there is insufficient data, *e.g.*, the effects of chemicals in tropical climates or at high altitudes. In this way, a national chemical list need not serve as the foundation for a comprehensive analytical program.

#### New chemical notification scheme

82. The distinction between "new" and "existing" chemicals has enabled countries to anticipate and prevent the introduction into commerce of new chemicals which present unacceptable risks to human health or the environment. A number of countries now have new chemical notification schemes which draw attention to the market entry of a new chemical and require that a minimum set of scientific data on the new chemical be submitted to the government before the chemical is manufactured or marketed.

83. There are two primary kinds of new chemical notification schemes: a pre-market scheme which ensures product safety by controlling the introduction of new chemicals into domestic commerce and a pre-manufacture scheme which further ensures occupational health during production of the chemical as well as the safety of any chemical exports.

84. Typical supporting data required for new chemical notification identify the chemical, suggest a hazard classification, describe any impact on human health and the environment, explain the chemical's proposed use and give the quantity to be produced or imported. Such data indicate whether the chemical is likely to cause health or environmental problems. In compiling the data, companies themselves can decide that a chemical should not be introduced because it presents too much risk of harm.

85. After receipt of a new chemical notification, the government generally has two or three months in which it can (1) request additional information and testing, (2) allow manufacture or marketing of the chemical to proceed, or (3) prohibit manufacture/marketing of the chemical. If the government decides the chemical poses no unreasonable risk, it incorporates the chemical into either a list of existing chemicals or a separate list for new chemicals. The chemical also is assigned a hazard classification, *e.g.*, flammable, toxic, environmentally harmful, etc..

86. Protective measures ranging from appropriate labelling to limitation of use may be imposed. If the government fails to respond within the given time period, the presumption is that the chemical may be manufactured or marketed as planned. The government's inaction during the notification period, however, does not preclude it from taking action later when better knowledge becomes available. Legislation generally provides that the government will send written notification of its decision to the applicant. Applicants also may be required to pay the government a fee to cover administrative expenses involved with assessment of the new chemical. Final decisions usually are published in an official gazette or journal. Appeals of adverse decisions often are permitted.

87. Notification of a new chemical and its inclusion on a chemical list does not mean the chemical has been thoroughly reviewed and approved for certain uses. In this sense, new chemical notification is different from the registration of a pesticide or pharmaceutical. The process of registering a pesticide or pharmaceutical involves the submission and careful evaluation of comprehensive scientific data. A registered chemical is one which has been governmentally approved as safe and effective for sale/use under certain conditions. Because the registration procedure takes much time and effort, it cannot be applied easily to large numbers of new chemicals. The less demanding process of notification allows the government to collect some basic data on all new chemicals and to single out those new chemicals which require more attention.

88. Nevertheless, new chemical notification schemes require significant resources and may simply duplicate assessments already conducted in another countries. Current efforts to standardize these assessments and to share them, therefore, should be supported.

#### Chemical trade product register

89. Although rare, some legislation requires that chemicals information be collected in national trade product registers. Unlike lists of existing/new chemical substances (raw ingredients), trade product registers collect data on finished products which contain chemicals. Trade product registers make no distinction between existing and new chemicals or between pesticides and other chemicals. Nevertheless, a trade product register can coexist with a pesticide registration scheme, which goes further than the product register and requires government approval of specific chemicals. A product register also may exclude food/feed additives, pharmaceuticals, explosives or radioactive materials.

90. Trade product registers require producers and importers every year to submit information on all potentially harmful chemical substances (regardless of use) which exist in any product made, distributed or used. Such registers are practical because they reflect the way chemicals usually are found, that is, in usable mixtures rather than as raw ingredients. Trade product registers can be administratively complex, however, because products often contain more than one chemical. Initial development of a product register is time-consuming and maintenance of the register requires constant updating. Product registers also collect large amounts of confidential business information which must be kept separate from other information and protected from complete, public disclosure.

91. The choice between legislatively establishing a chemical substance list or a trade product register depends on: (1) the number and types of chemicals used in a country and (2) the quantity and quality of chemical management resources available. Product registers offer a reasonable and somewhat less costly alternative to listing for countries with a small number of chemicals and adequate means to update the register regularly.

#### Chemical numbers and names

92. Whether chemicals are gathered into national lists, inventories or product registers, they often are identified by internationally-used chemical names and numbers. These "identifiers" are important in chemical listing because references to chemicals vary greatly. Standardized chemical identification allows data to be shared more easily and effectively. Knowledge of a chemical's C.A.S. (Chemical Abstracts Service Registry) number permits access to available information on that chemical virtually anywhere in the world. The C.A.S. numbering system has assigned numbers to more than nine million chemical substances. Another well-known numbering system, the United Nations Number (U.N. No.), generally is used for the uniform identification of hazardous chemicals during transport. Many countries also use an internationally standardized Customs numbering system which covers chemicals and other goods.

93. In addition to identifying numbers, each chemical often has a common name, one or more chemical names and many different trade names which are used interchangeably. For example, chloroform also is known as freon 20, methyl trichloride and trichloromethane. Proper identification of a chemical primarily is the manufacturer's or importer's responsibility, and they should be pressured to provide adequate information. If the manufacturer or importer supplies only one of the various trade names used for a chemical, useful cross-referencing information on alternative trade names and corresponding chemical numbers can be found in various national/international inventories and databases.

#### Exposure Monitoring/Regular and Problem Reporting

94. A number of countries have implemented systems which monitor (or measure) the presence of chemicals in human beings and the environment. For example, periodic sampling of workplace surroundings or medical examinations of workers enable government or employers to ensure a safe working environment, to track the effectiveness of chemical control measures and to identify any situations involving chemical exposure. Similarly, regular sampling of water sources or ambient air has been used to detect the concentration levels of various chemical contaminants. Although both sorts of monitoring require substantial resources, they help identify adverse chemical effects which may need to be controlled. In this sense, they provide useful data for chemical decisionmaking.

95. Certain chemical laws, largely occupational safety and health legislation, impose recording and reporting requirements for chemical accidents, injuries, diseases or other problems. This kind of information also identifies adverse chemical effects which government can use in setting chemical control priorities and making regulatory decisions. A broader reporting network might involve reporting of chemical problems by industries, hospitals, poison centers and emergency response centers, among others. In addition to problem reporting, certain laws require regular reporting of chemicals being produced, imported/exported, sold, used and disposed of. This information helps government keep track of which chemicals are in commercial circulation.

96. Involvement of public interest groups and industry in monitoring activities can strengthen a country's knowledge about harmful chemical exposure. To date, environmental and consumer groups have provided very useful statistics and case studies on chemical misuse. As industry becomes more responsible for tracking the life of its products, it has been obliged to report any possible adverse effects it uncovers.

#### Databases

97. Data collected on chemicals ordinarily is centralized, organized and maintained in one or more databases. Some countries have computerized their national databases and arranged for them to have access to each other. A database network like this enables one chemical regulatory agency (*e.g.*, Agriculture) to make use of specialized data kept by another agency (*e.g.*, Health). Use of a standardized or harmonized system for

keeping chemical data permits countries to more easily exchange information on chemicals. It also assists the provision of useful and complete information to national chemical decisionmakers.

98. Databases are one means of creating a national chemicals information system which facilitates and coordinates access to different kinds of data. Important categories or fields of data include: identity/characteristics/effects; distribution and availability patterns; emergency measures for spills or poisoning; existing regulatory measures; and proper waste disposal means. Ideally, countries should have information covering all phases of the chemical lifecycle. As countries identify and link various sources of chemicals information, they can obtain a more complete picture of their chemical management situation and can determine better their priorities for future action. Making use of data kept by industry, other countries and regional/international organizations can keep costs down and avoid duplication of effort. To help countries access this data, ILO, OECD, the EC and other organizations have collected information on existing databases related to chemicals.

### **Interpretation of Chemical Information**

#### Hazard, risk and benefit assessment

99. After the collection and organization of chemical data, countries evaluate (or assess) the information obtained. Based on this interpretation and weighing of the data's significance, government can determine a chemical's hazards, risks, benefits and safe conditions of use. The ultimate goal of the evaluation process is to identify which chemical uses present an unacceptable risk to human health and the environment. Assuming all chemicals pose some risk of harm, the risk becomes unacceptable if it cannot be managed by available safety measures.

100. As already mentioned, legislation commonly provides for the general evaluation of all new chemicals, more thorough evaluation of new or existing chemicals likely to cause harm and and the in-depth evaluation of pesticides or pharmaceuticals. To the extent possible, chemical evaluation should involve the consideration of a chemical's lifecycle (e.g., risks connected with its production, transportation, storage, distribution, use and disposal) as well as its possible misuse (e.g., misapplication of an agricultural pesticide as a medicine). Because the assessment of chemicals can be a lengthy, difficult process, countries have begun to prioritize their assessment needs, to standardize the assessment procedure and to share their scientific data. Some of the most significant efforts in this area are OECD's prioritization of high production volume chemicals for further study as well as OECD's work on chemical testing guidelines, good laboratory practices and the mutual acceptance of data. OECD now is considering the exchange of national chemical assessments performed on new chemicals, data profiles on existing chemicals and information on pesticides undergoing reregistration.

101. As mentioned earlier, the obligation for developing chemical data through testing generally is placed on the manufacturer or importer of the chemical. Manufacturers and importers should be in the best position to know their product. If they do not know it well enough, governments should not necessarily perform extensive testing. Nevertheless, government must have the means (skilled personnel and/or laboratory facilities) of verifying scientific information submitted to it and evaluating toxicological or other appropriate data. This burden can be lessened by requiring the use of standardized scientific methods as well as good laboratory practices for all chemical testing and by relying on data which has been reviewed (verified) elsewhere.

102. Complete chemical evaluation or assessment involves several phases:

1. Evaluation of the chemical's hazards

(i) Inherent physical or chemical properties, such as flammability, explosivity, or reactivity with other chemicals which can cause harm to health or the environment

(ii) Toxicity to human beings, including ability to cause irritation, damage to tissue, cancer, genetic changes or birth defects

(iii) Negative impact on the environment, including toxicity to animals or plants, non-biodegradability, tendency to accumulate and possibility of harmful chemical reactions.

2. Evaluation of the chemical's risks

Likelihood of human beings or the environment being exposed to and harmed by the chemical given the ways and quantities in which it is handled. This involves consideration of a chemical's lifecycle and the examination of direct/indirect as well as short/long term chemical effects.

3. Evaluation of the chemical's benefits

Importance of the chemical to agriculture, industry or other sectors of the economy; need of the chemical for public health purposes; effectiveness of the chemical for a particular purpose; or the unavailability of less harmful, similarly-priced alternative chemicals.

4. Evaluation of the relative risks and benefits from continued use

Overall acceptability of the chemical given its potential for harm balanced against the country's economic needs or policy priorities. The ability to control a chemical's hazards as well as the availability of chemical alternatives which pose less risk also are considered.

103. Recent national decisions to phase out the use of chlorofluorocarbons (CFCs) provide an example of the evaluation process: (1) CFCs react with ozone to form other chemicals and thereby destroy the ozone layer in the atmosphere, (2) Research shows portions of the ozone layer already have been destroyed and the destruction is continuing, (3) Without an ozone layer, human beings and the environment will not be adequately shielded from the sun whose rays can cause cataracts, skin cancer and other adverse effects and (4) Although CFCs have many beneficial uses, the risk that their continued use will harm health and environment outweighs their benefits and safer, economically feasible alternatives are available.

104. Chemical evaluation is a continuing process for both government and industry. Under some national legislation, both are required to track the usage of chemicals and record any problems (chemical accidents, injuries, diseases, pollution) which arise. Laws have obliged industry to advise government whenever (1) additional chemical information becomes available, (2) changes in the chemical product or its use are made, and (3) chemicals are withdrawn for health and environmental reasons. Chemical manufacturers have been obliged to voluntarily withdraw or recall chemicals from the market, if it is learned they cannot be used safely. Practices like these have been extremely helpful in reducing chemical hazards more promptly and effectively than when government is required to act alone.

105. As mentioned, evaluation of a chemical involves comparing its risks and benefits with those of an available alternative. The overall lack of information on chemical alternatives has prompted several countries to encourage more research on the identification and development of safer chemical substitutes. This type of information could prove useful as countries continue reregistering older pesticides, that is, evaluating again their safety and efficacy in light of new scientific or technical knowledge. Reregistration programs show that the evaluation process never ends.

### Classification

106. Evaluation of a chemical substance or mixture enables it to be classified or grouped with other similar chemicals for easier management. Legislation ordinarily authorizes the classification or grouping of chemicals according to their identified "hazards", that is, a chemical's ability to cause harm based on its physical/chemical characteristics, toxicological effects or impact on the environment. A substance might be given one or more classifications, depending on its properties and effects. Responsibility for a chemical's initial classification can rest with the manufacturer or importer and should be based on testing results.

107. Creation of a classification scheme requires government action and begins with the designation of specific hazards. Commonly identified hazards include the following: explosive, oxidizing, extremely flammable, flammable, very toxic, toxic, harmful, corrosive, irritant, dangerous for the environment, persistent, bioaccumulative, carcinogenic, teratogenic and mutagenic. Criteria for hazard classes are based on scientific testing results. For example, certain flashpoint levels (the temperature at which a chemical will catch fire) distinguish "extremely flammable" chemicals from those which are "flammable." Similarly, "very toxic" chemicals can poison test animals at lower dosage levels than "toxic" chemicals. Countries are not uniform in the hazard classifications they use. Neither do they agree on standard definitions or criteria for specific hazards.

108. WHO's Hazard Classifications are based primarily on toxicity. The classification scheme found within the United Nations Recommendations on the Transport of Dangerous Goods focuses on the physical/chemical and short-term exposure dangers of chemicals, *i.e.*, the likely effects of chemical accidents. By contrast, the classification scheme used within the European Community also incorporates long-term health effects and environmental hazards, *i.e.*, the likely effects of continued use of or exposure to a chemical. Regardless of the scheme used, hazard classification of chemicals has significance for packaging and labelling requirements and other safe use practices. Both the UNRTDG and European Community legislation closely link a chemical's classification to provisions for its proper packaging and labelling.

109. Efforts now are underway to internationally harmonize the various classification and labelling systems being used in the world. During this harmonization process, countries have recognized a need to provide improved classification categories for chemicals which pose environmental hazards as well as human health and safety hazards.

#### Prioritization

110. Legislation often separates out certain chemicals for special regulation because of the particular threat they pose to human health or the environment. For example, a law can direct that special attention be paid to chemicals which have carcinogenic (cancer-causing) effects. The prioritization process generally applies after a chemical has entered the market. Prioritization helps determine proper control measures and the most efficient use of regulatory resources. Priority chemicals can be identified within legislation through listing or the establishment of certain criteria (quantity produced, hazardousness, degree of exposure) to be applied to a list of chemicals in commerce. Alternatively, legislation can authorize a government agency, inter-agency group or technical committee to select chemical priorities. Some countries have developed elaborate means of scoring chemicals to determine priority, but the main point is to identify chemicals of concern.

111. Legislation often groups chemicals into general categories of priority depending on their toxicity or hazardousness. Existing schemes often establish three or four groupings of chemicals ranging from those of most concern to the those of least concern. Use of the most harmful chemicals might be either prohibited totally or subject to serious restriction. Use of the next most harmful chemicals might be subject to licensing or some other significant use limitation. Use of the least harmful chemicals might be subject to obligations for safe use.

112. In addition to priority categories, many laws establish priority lists of chemicals. Typical lists include: chemicals which require additional scientific data or testing, hazardous air or water pollutants with environmental emission controls, high production volume chemicals, workplace chemicals with occupational exposure limits and banned or severely restricted chemicals. Each list of priority chemicals serves a different purpose, is based on different criteria and contains different chemicals. Internationally, the Prior Informed Consent (PIC) procedure selects certain chemicals for priority action regarding trade because these chemicals have been banned or severely restricted for health or environmental reasons. Chemicals also can be included in the procedure, if they have been causing problems in developing countries.

### **Dissemination of Chemical Information**

#### Risk communication

113. A primary reason for collecting and interpreting chemical information is to then advise others of what has been learned. As discussed in more detail later, industry bears the primary responsibility for communicating risk information (*e.g.*, major hazards, safety precautions during use, emergency measures in the event of an accident and proper disposal means) in the form of labels or chemical safety data sheets. Nevertheless, government often sets minimum standards for the content and format of such materials. Labels are the primary means by which chemicals information is conveyed. Many incidents of chemical misuse are attributable to a missing or inadequate label.

114. Government and industry share an obligation to train chemical users and educate the public at large about important safe use information regarding chemicals. Language differences and illiteracy, however, have

created obstacles to effective risk communication and have prevented people from taking advantage of increased access to chemicals information. This situation has illustrated the need for pictograms, multi-lingual labels and translations of educational information. Countries also have noted a need to train health personnel in the proper diagnosis of and response to chemical injuries. Public interest groups play an important role in communicating chemical risks and safe practices.

#### Publication

115. Publication of proposed or final chemical regulatory actions in an official national gazette or journal offers another means by which industry and the general public can obtain useful information about chemicals. Some national governments publish detailed reasons for their actions and encourage public comment or questions. Government and other sectors also have published explanations of chemicals legislation as well as guidelines and advice about compliance.

#### Freedom of information/protection of confidential information

116. Various legislative procedures have been developed for providing public access to chemicals or environmental information kept in a national information system. These provisions allow anyone to demand information without having to show any legal interest or other justification. Access is not permitted, however, to information which is legally protected or related to national security and defense. Usually these procedures also protect from disclosure any confidential business information or trade secrets contained within the system. Disclosure protection generally is granted or refused based on government review of a written request for confidentiality. This request accompanies the submission of allegedly confidential information. Businesses commonly seek the protection of information which, if disclosed publicly, could be used by their competitors to achieve an economic advantage. Typical confidential business information includes product composition/formulation, process descriptions/diagrams and client lists.

117. In some laws, important health and safety information have been exempted from any requests for confidentiality. Such information includes: chemical names, names of the manufacturer or importer or exporter, country of destination, general data on the chemical's uses, safe handling precautions, recommended disposal methods, emergency response measures, certain physical or chemical data and summary results of testing related to the chemical's health effects. Public interest groups have sought access to this information so (1) members of the public will be better informed about chemical risks, (2) those exposed to chemicals can seek medical or other advice and (3) chemical users can make informed choices among the chemicals available to them.

118. Restrictions on access to confidential data often do not apply to chemicals information shared among government bodies. Nevertheless, the country receiving the information must apply the same degree of legal protection provided in the country supplying the information.

#### Information exchange

119. Improved coordination of chemical control efforts depends largely on improved information exchange among affected agencies, sectors and countries. This exchange can occur within a formal body/facility (e.g., national inter-agency advisory body or regional laboratory), a formal agreement (e.g., memorandum of understanding between Customs and the Health ministry), a funded project (e.g., bilateral aid to develop a new environmental agency), or a formal mechanism/procedure (e.g., required signature of several agencies for chemical authorization). Information exchange also occurs informally as when one party simply asks another for help regarding a particular chemical issue (e.g., a query submitted to UNEP from a nongovernmental organization) or two parties voluntarily agree to work together in lessening chemical emissions (e.g., government and industry voluntary agreements to reduce water pollution).

#### **Practical Suggestions**

*\* establish a national chemical information system to link existing sources of chemicals information*

*\* consider developing a product register or list of chemical substances as part of this system*

- \* begin the chemical listing process by identifying chemical suppliers (manufacturers, processors, formulators, importers and exporters) and having them supply chemical safety data sheets for chemicals they make, import, export or use*
- \* make an initial national list of those chemicals which present the greatest risks to health and environment because of high hazard or high volume or high exposure and later expand the list as resources become available*
- \* use C.A.S. numbers and common names as key identifiers*
- \* provide a means for screening chemicals before they enter the market, e.g., through registration or a new chemical notification scheme*
- \* ensure any chemical testing is done in accordance with standard guidelines and good laboratory practice*
- \* conduct field research or studies to determine chemical effects on health and environment*
- \* develop standard criteria for risk assessment*
- \* consider a chemical's lifecycle stages and possible misuse in assessing its risks and benefits*
- \* adopt a chemical classification, labelling and packaging system*
- \* select priorities for assessment and control, e.g., chemicals produced, imported or used in large quantities or which have caused specific health/environmental problems*
- \* use chemicals identified in the PIC procedure as an initial priority category for control and add other chemicals as infrastructure develops and resources become available*
- \* establish university courses related to skills needed for chemicals management*
- \* provide seminars for industry and other sectors on chemical alternatives and clean technology*
- \* develop manuals, codes or guidelines for chemical safety, e.g., transport of dangerous goods or preparedness for accidents*
- \* provide free access to chemicals information with protection for trade secrets*
- \* require immediate reporting by anyone who has information that a particular chemical presents a risk*
- \* fully implement the PIC procedure*

### **Useful Resources**

- \* domestic information on worker/public exposure, chemical poisoning, pollution incidents, chemical accidents or chemicals used in large quantities*
- \* UNECE lists of chemical products and producers in Eastern Europe and the Mediterranean*
- \* chemicals information included in the international Prior Informed Consent procedure, taking into account that new chemicals will be continually added to the procedure*
- \* IRPTC database and IRPTC Bulletin*
- \* ILO Chemical Information System and occupational exposure standards*
- \* chemical lists/inventories/registers and new chemical notification schemes from other countries*
- \* FAO guidelines on development of pesticide registration schemes*
- \* microfiche version of C.A.S. registry*
- \* CIRAD regional compilations of chemicals*
- \* 1-2 personnel with some background in chemistry who can prepare an initial list of existing chemicals*
- \* personnel with some knowledge of chemistry, toxicology, biology (also environmental chemistry and ecotoxicology, if possible) and occupational health who can assess chemical hazards and risks*
- \* a technical advisory body to assist the chemical assessment process*
- \* IPCS Environmental Health Criteria and Health and Safety Guides, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*
- \* OECD Council Decisions on the Mutual Acceptance of Data in the Assessment of Chemicals (1981) and the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals (1982), as well as OECD Recommendations regarding confidential data, a list of non-confidential data, the list of high production volume chemicals and the systematic evaluation of existing chemicals*

## **PROTECTIVE MEASURES**

### **\* Creation of general obligation**

Duty to handle chemicals safely throughout their lifecycle so as to minimize health or environmental exposure

### **\* Creation of specific obligations**

Production (including product quality, packaging, labelling/CSDSs and accident prevention/response)

Transport

Storage

Distribution (including domestic sale, advertising and import/export)

Use

Disposal (including environmental emissions, occupational exposure, siting of industry)

### **\* Restrictions**

Authorization/registration

Positive/negative lists

Limitations on use, method of use, concentration and quantity

Licensing or certification

Prohibiting most or all uses

### **\* Economic instruments**

## PROTECTIVE MEASURES

120. In addition to providing for the assessment of chemical risk, chemicals legislation also provides various means for managing chemical risk, that is, protecting human health and environment from harm. To do this, it imposes certain obligations and may offer certain incentives for chemicals to be handled properly. Recent legislative trends show an interest in balancing the two approaches. Because both types of actions usually focus on preventing or minimizing harm to health and the environment, they often are referred to as "risk reduction" measures. Creation of an elaborate but unenforceable control scheme is a waste of effort. Realistic assessment of chemical management needs and resources helps determine which protective measures are most appropriate and feasible.

121. The interest in taking protective measures varies according to a chemical's inherent hazards, the risk created by its use/exposure and its relationship to a country's priority concerns. Of course, other factors also play a part, *e.g.*, national environmental awareness, the ability to detect human poisoning or environmental contamination caused by chemicals, the availability of management resources and the cost of reducing chemical use. Countries concerned about the proper handling of all chemicals, may create a general obligation for safe use. Countries concerned about chemical accidents may place specific obligations on chemical production, transport and storage. Countries concerned about pollution of drinking water might require chemical facilities to obtain a license for operation or a permit which controls chemical discharges. Finally, countries concerned about a particular chemical's hazardousness might restrict it to public health use, gradually phase it out or immediately prohibit its use. Most national governments include a mixture of these and other protective measures in their legislation.

122. Virtually every provision in a chemicals law assists the management of chemicals. Chemical listing, evaluation, classification and prioritization are all measures which control chemicals. New chemical notification programs and pesticide or pharmaceutical registration schemes also regulate chemicals. Often measures are separated into pre-market controls (notification or registration schemes) and post-market controls (labelling, licensing or restrictions). Through the use of subsidies or other economic instruments, legislation can encourage the substitution of less harmful chemicals and the use of alternative technology.

### General obligations

123. Some chemical laws impose a general duty of care on anyone who handles a chemical covered by the law. This requires an individual to use whatever measures are necessary and appropriate to prevent or minimize any harm to human beings and the environment. Such a provision supplements more specific legal responsibilities. It also provides a basic standard against which various conduct can be measured. A general duty of care, among other things, expects people to obey the chemical law and follow chemical labels. Many problems associated with chemicals arise from the failure to do either. Although such general obligations are useful as broad statements of policy (*i.e.*, intended to cover those responsibilities not specifically described in the law), they at times have been found unenforceable because of their breadth. To correct this problem, some chemical laws now authorize a ministry to make these general obligations more concrete by issuing specific regulations.

124. Another general statement found in some laws requires the use of non-harmful or less harmful chemicals where possible. More specifically, manufacturers are encouraged or required to formulate less toxic chemicals, employers to substitute less harmful chemicals and consumers to use natural or biological agents in place of chemicals. These overall substitution obligations also have presented practical enforcement problems in the countries which impose them. Nevertheless, there is value in encouraging chemical suppliers and users to take steps which phase out unreasonable and unmanageable chemical risks to human health and the environment.

125. Industry initiatives on responsible care and product stewardship related to chemicals often contain general obligation statements. Ordinarily, these are supplemented by more specific industrial codes which address various aspects of chemical management.

### Specific Obligations

## Production

### Quality

126. Chemicals legislation sometimes requires chemical manufacturers or importers to provide chemicals of adequate quality. These are chemicals which conform to applicable specifications for purity, concentration, etc. Quality control requirements are one means of discouraging the provision of substandard, off-specification or adulterated chemicals. Such provisions most commonly are found in pharmaceutical, food additive and pesticide legislation.

### Packaging

127. Chemicals legislation, especially transportation of dangerous goods laws, generally require chemicals to be packaged in containers which are properly labelled, leakproof, non-reactive and sturdy. Other provisions might require that containers be resealable, childproof, distinguishable from non-hazardous containers and difficult to reuse. Some chemical management regulations limit the repackaging of chemicals to those who are licensed to perform the task properly. This helps ensure that repackaged chemicals are secure and appropriately labelled. Similar regulations entirely prohibit the repackaging of chemicals into food or beverage containers.

### Labelling

129. Chemical labelling requirements are the most common means used to control chemical risk. Labelling provides a warning to the user of a chemical and also acts as a broader source of information about the chemical. Depending on national practice, chemical products destined for an importer may be labelled differently than chemical products intended for users or consumers. Generally, though, labels are of two major kinds: transport labels and use labels. By comparison, transport labels usually contain less safe use information because they are not directed at the end user of the chemical. Transport labels also may use different numbers, symbols or words to identify or describe the same chemical. The dissimilarities between the two systems have led to more complicated labels and confusion. Therefore, efforts have been underway for some time to harmonize the two approaches.

130. Proper use labels adequately identify the chemical, describe its risks and give directions on its safe use, including proper disposal methods and first aid or other emergency procedures. To regulate labels, chemical legislation might simply require the placement of clear and concise labels on chemicals. More specific laws require labels to: (1) accurately reflect the testing results obtained on the chemical's effects, (2) use appropriate symbols or pictograms, which are not confusing, (3) be written in a language understandable to those handling the chemical, (4) warn about the reuse of containers, (5) provide a production batch number and expiration date, (6) be firmly affixed to the container and (7) adequately describe dangers to the environment. Countries which find it difficult to develop a national labelling scheme have found it useful to adopt one used elsewhere, *e.g.*, the EC labelling system which contains standard risk and safety phrases or the WHO color-coding system for toxicity.

131. Label harmonization efforts have addressed the need to control excessive labelling. The addition of eco-labels (identifying products less harmful to the environment) and other supplementary labelling to a chemical's primary labelling can distract a user from the most important safety information. Labels which contain too much information can confuse the chemical user. Similarly, countries which place severe warning labels on many different chemicals can lessen the significance of such a warning through overuse.

132. While seeking ways to improve chemical labels, some countries have developed different labels for harmful and less harmful chemicals. Other countries have considered providing more label information on chemicals which are more harmful. With regard to exported chemicals, several countries are taking steps to label them as they would domestic chemicals, unless the importing country imposes different requirements.

### Chemical safety data sheets

133. In addition to proper labels, many countries require chemical manufacturers to prepare written chemical summaries known as chemical safety data sheets (CSDSs). Such summaries contain information on the manufacturer, the chemical's identity, health hazards from exposure, first aid advice, precautions for use and safe handling information. Ordinarily CSDSs accompany shipments of a chemical from the manufacturer. They are most often used as a chemical information source for workers. Because CSDSs generally contain more detailed information than a chemical label, they can be used to communicate information which cannot be included easily on a label.

#### Accident prevention, preparedness and response

134. Chemical accidents most commonly occur during the production, transport or storage of chemicals. Accident management has both a preventive and a responsive aspect. To prevent chemical accidents, countries have set operational standards for industrial facilities which handle or store harmful chemicals and carriers which transport dangerous goods. To respond to chemical accidents, countries have required the preparation of emergency plans and established prompt notification and response procedures. Specific legal provisions addressing accident prevention and response during the transport of dangerous goods are discussed in more detail in the next section.

135. Legislation related to the prevention and handling of chemical accidents at industrial facilities ranges from strict licensing requirements to general notification obligations. Information required under these schemes helps identify specific facilities which produce, store or handle threshold quantities of listed hazardous chemicals. In addition to identifying the hazardous chemicals used or kept on site, legislation also might require the reporting of any hazardous chemical releases into the environment. Regulation of "major hazard facilities" generally forces them to be more diligent in handling hazardous chemicals. This diligence can include: (1) improved assessment of the risks posed by certain chemicals and the likely consequences of any accidents, (2) preparation of contingency plans, (3) better monitoring of chemical safety via proper maintenance operations and in-house inspections and (4) immediate reporting of and response to any chemical accident or incident which does occur.

136. Hazardous chemical information requirements, as well as other environmental requirements, have affected the construction of new industrial facilities. Knowledge about a proposed facility's handling of harmful chemicals (perhaps in the context of an environmental impact assessment) is critical to making sound decisions about its proper siting and operation.

137. Regardless whether existing legislation addresses chemical accidents, a number of national governments have established poison centers, telephone hotlines and local emergency response teams (with identified technical personnel, police and firefighters who have received chemicals training). These kinds of programs are designed to deal immediately with requests for chemical information and reports of any chemical accidents/injuries. In those countries which lack the capability to staff or fund such public programs, private companies must take responsibility for instituting adequate emergency response systems.

#### Transportation

138. Although the transport of chemical waste often is regulated by hazardous waste legislation, the transport of chemicals commonly is governed by a national transportation law for all dangerous goods. Countries without national transport legislation may follow various voluntary international standards which apply to the transport of dangerous goods by air, sea, road and rail, e.g., the United Nations Recommendations on the Transport of Dangerous Goods, the International Maritime Organization's Dangerous Goods Code and standards of the International Civil Aviation Organization.

139. Under both national and international transport provisions, hazardous chemicals can be transported only under specific conditions. Usually these conditions concern the packaging, labelling and stowing of chemicals, so they can be moved without accident. Additional legislative provisions might address the documentation required for transport and use of proper vehicles or equipment. Some laws also require the licensing of transporters, the use of certain safe routes (those which avoid water supplies and population centers) and driver training requirements. Regulations or guidelines may urge drivers to use TREMCARDS, written summaries of

emergency response procedures which should be followed in case of a transportation accident involving chemicals.

### Storage

140. Legislative requirements for chemical storage might be found in chemical marketing laws, occupational safety and health laws, accident prevention laws or transportation laws. These provisions usually focus on the manner in which chemicals are stored, including physical separation of chemical incompatibles (those chemicals which react with each other) as well as the physical separation of chemicals from foodstuffs, feedstuffs or medicine. The storage facility or premises are required to be controlled, secure (able to prevent access by children and others), physically sound in structure and well-ventilated. All sources of possible ignition must be kept away. Hazard statements or warning signs also may be required. More recent legislative provisions seek to minimize a facility's regular inventory of hazardous chemicals.

### Distribution

#### Domestic Sale

141. Pre-market controls like notification or registration determine whether a chemical ever is distributed domestically. Once a chemical is allowed to enter commerce, chemicals legislation controls the availability of chemicals for certain purposes (use restriction), to certain persons (licensing requirements), in certain forms or concentrations (production control) or at certain prices (subsidies or taxes). Chemical sellers also must comply with labelling, packaging, storage and other requirements. Recently, governments have shown increased interest in pricing mechanisms. For example, a tax placed on leaded gasoline seeks to reduce overall sale and consumption of a chemical product known to be harmful to health and environment. Generally, however, more harmful chemicals often are priced lower than less harmful chemicals. In several instances, countries have been given or donated substantial quantities of harmful chemicals. This has resulted in harmful chemicals being passed along to consumers free of cost and often without appropriate safety information. These situations point up the need for additional control of chemical distribution and sale.

#### Advertising

142. Chemical laws which regulate advertising generally prohibit the use of any false or misleading statements or visual presentations. In particular, legislation may prohibit statements and pictures which exaggerate or otherwise misrepresent a chemical's safety and effectiveness. Proper advertising is described as accurate, factual statements which can be substantiated by testing results or other technical information. In many countries, advertising has contributed to an overuse of chemicals, and promotional statements have not been balanced with adequate safety information. Efforts now are underway to supplement advertising statements which encourage a chemical's use with statements that stress the importance of reading the chemical label and following appropriate safety precautions.

#### Import/Export

143. Chemicals imported for illegal purposes, such as narcotics or chemical weapons, often are governed by special legislation and international instruments. The bulk of commercial chemical traffic, however, is regulated by both chemical laws and Customs laws. Under their chemicals legislation, a number of countries prohibit the import of unregistered pesticides and pharmaceuticals. Similarly, several countries do not permit new chemicals to enter the country until notification requirements have been met.

144. It is fairly common to require that chemical importers be licensed and that they display proof of this license or other documentation to national Customs inspectors, when bringing chemical shipments into the country. An importer may be required to certify in writing that a chemical shipment complies with national law. Effectiveness of chemical import control has been weakened by the loosening of import requirements to encourage development, inadequate legal authority for Customs to inspect chemical shipments and the lack of Customs inspectors trained to identify illegal chemical traffic. The international Prior Informed Consent procedure is intended to assist countries in strengthening inadequate import controls.

145. Historically, chemicals legislation has not regulated chemicals intended for export in the same manner as chemicals intended for domestic use. In fact, most laws give the government no or little power to control chemical exports. For this reason, domestically-imposed bans or severe restrictions on certain chemicals generally have had no legal effect on the export of those chemicals. Instead, exporting countries have left the task of regulating such chemicals to the importing country. The fact many of these importing countries have inadequate chemical control legislation has resulted in serious problems being caused by the misuse of exported harmful chemicals.

146. In recent years, some countries have begun to strengthen their control over chemical exports, particularly those chemicals subject to domestic restriction. Certain legislative provisions prohibit the export of any chemical which is domestically banned. Other legislation requires that importing countries be notified about the export of listed, harmful chemicals. Countries also have strengthened existing export policies to ensure more effective communication with importing countries, *e.g.*, direct notification of designated national authorities for chemicals and multi-lingual labelling. With the implementation of the Prior Informed Consent procedure, trade in banned and severely restricted chemicals is expected to become more "transparent" as importing countries obtain more information about the chemicals being exported to them.

#### Use

147. Some of the most common legislative controls on chemicals limit the way in which they are used. Use limitations can affect the purposes for which a chemical is used (*e.g.*, restrict use to agricultural, industrial, domestic or public health purposes), the method of its use (*e.g.*, restrict quantity, duration/frequency/type of application or technical aspects such as closed systems or protective equipment), the particular user of the chemical (*e.g.*, require license or certification) or the form of the chemical itself (*e.g.*, specific concentration or dry rather than liquid form).

148. Other legislative conditions for chemical use relate to the setting and monitoring of worker exposure limits or environmental emission standards. Occupational safety laws usually ensure the use of protective equipment or clothing, the accessibility of chemical risk information (such as CSDSs being kept on file or at a central work station) and adequate training or education regarding the proper ways to use chemicals. This can help reduce the incidence of misuse caused either by ignorance or carelessness. Without control over the conditions of chemical use, hazardous chemicals cannot be used safely.

149. Legislation which requires that safer chemicals be substituted for more harmful ones or that chemicals be reused and recycled where possible has a substantial impact on chemical use as well. Moreover, several European countries have developed national programs to reduce by 50% their overall use of pesticides within a multi-year period.

#### Disposal of chemical waste

150. Environmental pollution largely is caused by the emission of harmful chemicals into the atmosphere, water and soil. These chemical releases can be either the regular results of chemical production and use or the consequences of chemical accidents. Laws which regulate environmental pollution or hazardous waste often reflect an "end-of-the-pipe" approach to managing chemicals. In other words, they try to ensure that harmful chemicals are captured and neutralized before they are emitted from a smokestack or a wastewater discharge pipe. Examples of such legislation include waste treatment requirements and emission standards. Related laws oblige industrial polluters to pay for clean-up efforts at already-contaminated sites.

151. Dissatisfaction with the results of this approach and concern about ever-increasing amounts of hazardous wastes has led to increased interest in clean production and waste minimization. Necessary reductions in the quantity of waste generated are emphasized in the Basel Convention on the Transboundary Movements of Hazardous and Other Wastes (1989). The agreement shows a shared desire to lessen international traffic in hazardous wastes intended for recycling or disposal. Another means of encouraging reductions in chemical waste can be found in national "right-to-know" legislation. Such legislation requires enterprises to report to government

certain releases of toxic chemicals into the environment. Members of the public then have the right to learn about the information collected regarding hazardous chemicals in their community.

152. Chemical laws which focus on earlier lifecycle phases help prevent the creation of chemical waste in the first instance. For example, requiring the reuse and recycling of chemicals as well as the substitution of less harmful chemicals during production can reduce substantially the amount of hazardous waste produced. The identification and listing of chemicals producers/products helps monitor and control the environmental impact of chemicals. Chemical assessment procedures ensure that a chemical's impact on the environment is considered during a risk-benefit evaluation. Safe handling procedures during chemical production and use lessen the release of waste chemicals into the environment. In general, better management before disposal means less waste to manage at the time of disposal. Countries' recognition of this fact has prompted the development of pollution prevention programs and legislation.

#### Siting

153. The physical location of facilities which produce, formulate and process chemicals has become a significant concern of many countries because of the likelihood they will regularly or accidentally emit chemicals into surrounding water sources or human communities. Legislation regarding major hazard facilities or environmental impact assessments addresses this concern by better controlling the placement of chemical facilities. Under such laws, state or local officials can be given authority to make siting decisions and information surrounding their decision can be made publicly available. At the international level, a new European Convention on Environmental Impact Assessment in a Transboundary Context (1991) applies to the proposed construction of oil refineries, power stations, paper mills, waste disposal facilities and other major installations.

### **Restrictions**

#### Authorization/Registration

154. Legislation commonly requires government authorization, approval or registration of a chemical before its production or distribution can occur. Registration requirements also can be applied to facilities or persons who wish to engage in particular chemical activities, *e.g.*, chemical repackaging or export. Registration can mean anything from the simple notification of a facility's existence to a thorough review of a proposed pesticide.

#### Positive/negative lists

155. Another basic form of chemical restriction is the creation of a positive list, that is, a list of chemicals approved for use. Any chemical which has not been placed on a such a list is prohibited from use. Examples of positive lists include lists of approved food/feed additives, cosmetic ingredients or registered pesticides. In the reverse, legislation may create a negative list, that is, a list of chemicals disapproved for use. Any chemical which has been placed on such a list is prohibited from use. Examples of negative lists include lists of controlled substances in ozone protection laws, lists of pesticides which have been refused registration or lists of banned chemicals. In addition to listing chemicals, some laws also provide positive or negative lists of specific chemical uses (approved for use as a food stabilizer) and methods of use (disapproved for aerial spraying).

#### Limitations on uses/methods of use/concentration/quantity

156. Chemical laws commonly restrict the use of certain substances to specific purposes and qualified users. Pesticides legislation in particular may restrict the method of use by forbidding hand or ground spraying or limiting pesticide application to certain quantities in a given area, a certain number of times within a growing season or certain geographical areas where the water table is less shallow. Some laws authorize the national government to restrict the production, import and use of a chemical to particular or lower concentrations so as to reduce the risk it will cause harm. Government might also be authorized to limit production, import or use of a chemical to specific quantities. As ozone protection laws show, continued reductions in these amounts eventually will result in the total phasing out of a chemical.

## Licensing

157. Although demanding in terms of administrative resources, licensing (or permitting schemes) often are used in chemicals legislation to limit the availability of chemicals to certain persons, uses or activities. Licenses and permits are generally equivalent means by which government can positively authorize an individual or business or facility to handle chemicals under prescribed conditions. For example, a person may be licensed to import only certain chemicals in certain quantities. Another license might be required to operate a particular facility.

158. Issuance of a license or permit usually is based on an application which shows that the applicant meets specific criteria required by law. Common license application requirements concern an individual's personal qualifications (e.g., over 18 years of age), possession of certain equipment or technology (e.g., closed system), or proof of insurance against harm to human health and the environment (e.g., security bond with a certain monetary value). Possession of a license does not mean the licensee is exempted from any additional chemical regulations.

159. Licenses or permits have been required for chemical manufacture, import/export, transport, storage, distribution, sale, use and disposal. Some countries have required a different license for each of these lifecycle stages. More detailed or stricter licenses have been required for extremely harmful chemicals or particularly dangerous activities. Chemical licenses generally are limited to a particular time period, which may be reduced depending on the harmfulness of the chemical being handled (this has the effect of requiring more frequent renewal for those who handle very toxic chemicals). Legislation often requires government to keep a register of licenses issued and establish a system by which compliance with their provisions can be monitored.

160. As mentioned, licensing places huge demands on available resources. Therefore, a number of countries have chosen to replace such a system with one which places more emphasis on training, education and other measures which promote good selection and use of chemicals.

## Certification

161. Some persons are authorized to handle chemicals by means of professional certification. This process usually requires an individual to obtain certain training or education. After attending the required number of classes and/or passing an examination, he is awarded a document certifying that he has acquired special knowledge regarding chemicals. Examples of chemical certifications include those for asbestos removal experts and pesticide applicators. Certificates may need to be renewed periodically and could require the successful completion of continuing education courses.

162. In 1987 the International Standards Organization issued a certification procedure for overall production quality of various goods (ISO 9000). This kind of broad certification scheme could remove the need for a chemical production license because it certifies compliance with a certain level of competence. Efforts have been underway to incorporate environmental considerations in this scheme, as it is elaborated. These could include standards on environmental management systems, environmental auditing, environmental labelling, environmental performance, lifecycle analysis and environmental guidance for production.

## **Prohibitions**

163. When moderate restrictions are insufficient to reduce a chemical's risks to an acceptable level, government must consider prohibiting all or virtually all uses of a chemical. Decisions to substantially restrict a chemical's use (as well as to impose other lesser restrictions) generally are published in an official gazette or journal, together with the reasons for the decision. The actual content of these published notices may vary, depending on national practice. Additionally, affected manufacturers or importers ordinarily are given written notification of the decision. Bans and severe restrictions which conform to the PIC procedure must sent to UNEP and FAO.

164. DDT, mercury compounds, polychlorinated biphenyls (PCBs), chlorofluorocarbons (CFCs), and crocidolite asbestos are examples of chemicals which have been substantially restricted for use in several

countries. Prohibiting all of a chemical's uses ordinarily prevents its presence and use in the country entirely, with the possible exception of any remaining unused stock which must be properly disposed of and chemicals produced or processed solely for export. Total removal of a pesticide from domestic use involves cancellation of its registration or other approval for use. Although rare, national legislation does exist which prohibits the export of any chemical that is prohibited for domestic use. For reasons of fair trade, any decision to prohibit the import of a chemical must be applied equally to all foreign sources and must also prohibit all local production of the same chemical for domestic use.

165. In response to the imposition of strict controls on their chemical products, manufacturers occasionally have filed lawsuits in national courts seeking to overturn regulatory decisions. Some of these legal challenges have been successful, forcing the national chemical authority to reconsider or provide a better basis for its action. Depending on a country's legal system and the rights accorded private citizens under legislation, public interest groups also have brought suit against the government for failing to regulate strongly enough.

### **Economic instruments**

166. Because chemical producers, distributors and users are motivated by economic interests, governments have been experimenting with the use of economic instruments to achieve chemical management goals. These instruments must be chosen and applied with care, however, as they can affect broad market forces and their results are not entirely predictable. It also is not clear whether countries with poor financial conditions can make use of these instruments. If effective, economic instruments can reduce the need for and costs of enforcement. They also could lead to creative initiatives from the private sector to reduce chemical hazards even further.

167. As mentioned earlier, some chemical laws require chemical producers and users to substitute less harmful chemicals where possible. Such legislative provisions are intended to encourage the development and use of less harmful, alternative chemicals to replace substances like asbestos. Economic instruments stimulate industry to research and introduce "clean" (environmentally sound) chemicals, technology or processes. For example, government monetary grants to interested companies have enabled the identification of less toxic chemicals for use on certain agricultural crops or in certain industrial processes.

168. Economic instruments must be applied equally to all those who handle certain chemicals, e.g., both domestic and foreign businesses. Instruments can be negative or positive in nature. Examples of negative economic incentives include charges or taxes for using or emitting certain harmful chemicals. In addition to taxes on leaded gasoline, serious consideration has been given to imposing a carbon tax on the use of fossil fuels. Governments also have placed levies on certain products to fund research. Industry has suggested creation of a pollution-added tax similar to a value-added tax. Others have urged the use of security bonds for enterprises which handle hazardous chemicals.

169. Examples of positive incentives include tax or Customs duty reductions for the purchase of clean technology. Companies have obtained full loans and interest rate subsidies for the purchase of clean equipment or the remodeling of a facility. A national investment code can award bonuses for environmentally sound chemical management. Use advantages for enterprises can allow chemicals to be applied in ways which generally are prohibited. Marketable permits to use lead in gasoline or to emit sulfur dioxide can be obtained by using less than the legally allowed quota or ceiling on pollution emissions. Deposit-refund systems which return money deposited when pollution is avoided have been applied to tires, batteries and used oil. Businesses can be given protection from competition for 5 years, if they properly notify a new chemical. (Other trade restraints, however, cannot conflict with the General Agreement on Tariffs and Trade.) Governments have transferred technology developed in the public sector and have provided monetary grants for the development or use of technology which prevents pollution by reducing the source of harmful contaminants.

### **Practical Suggestions**

*\* because many options exist for the regulation of chemicals, countries should select those which are most appropriate and feasible given national needs and resources*

- \* in particular, the selection of regulatory measures should be based on their ultimate enforceability as many countries lack substantial enforcement resources*
- \* government should encourage industry to regulate itself as much as possible and should work with industry in controlling chemicals*
- \* effects of economic liberalization on chemicals management should be evaluated*
- \* if possible, government should include both conventional regulations and economic instruments in legislation*
- \* Customs and other authorities should be trained to stop entry of obsolete, mislabelled or prohibited chemicals*

### **Useful Resources**

- \* existing domestic legislation on chemicals or other products which contains examples of regulatory measures*
- \* FAO Guidelines on the Retail Distribution of Pesticides with Particular Reference to Storage and Handling at the Point of Supply in Developing Countries (1988), FAO Pictograms for Pesticide Labels (1988), FAO Guidelines for Good Labelling Practice for Pesticides (1985), FAO Guidelines for the Packaging and Storage of Pesticides (1985), FAO Guidelines on Protective Clothing in Tropical Climates (1992)*
- \* OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response (1992)*
- \* UNEP and UNIDO programs on clean production*
- \* industry publications on responsible care and product stewardship*
- \* UN Consolidated List has examples of regulatory measures taken by various countries*
- \* ILO Code of Practice on Prevention of Major Accidents (also manual and draft convention?)*
- \* IRPTC's Legal File contains national regulations from a number of countries which control specific chemicals*

## COMPLIANCE SCHEME

### \* **Monitoring of compliance**

Recordkeeping/reporting

Sampling/monitoring

Inspections

### \* **Compelling of compliance**

Warnings, citations, orders

Investigations

Prosecutable offenses

Penalties for violation

### \* **Promotes compliance with**

Field support, training, education

Industry self-regulation

Increased public participation

## COMPLIANCE PROGRAM

170. Without a sensible program for encouraging and ensuring compliance, even the best chemical law is a "paper tiger". People will not change their usual behavior, if they do not see a benefit or a cost associated with obeying the law. The health, safety and environmental consequences of inadequate compliance with chemicals legislation are enormous. Accordingly, countries have had to pay serious attention to establishing adequate means of promoting/monitoring compliance with and punishing violations of chemicals legislation. This means national governments have had to designate substantial resources for these tasks, improve relevant inter-agency coordination and constantly encourage industry to regulate itself.

171. The collection of fees for various administrative services helps fund government monitoring and enforcement efforts. Improved coordination with other agencies or local authorities facilitates the sharing of limited human and other resources. For example, inter-agency coordination is crucial where an agricultural agency implements a pesticides law and the customs service enforces it. Overall enforcement costs can be reduced by actively assisting chemical users to comply with the law. For example, community-based or field service personnel have contributed to the successful operation of integrated pest management (IPM) schemes which promote the safer and more effective use of chemicals.

172. Most countries use administrative or civil means to ensure compliance with chemicals legislation. Nevertheless, serious violations of law have been made punishable as crimes.

### Monitoring Compliance

#### Generally

173. Proper enforcement of chemicals legislation depends largely on monitoring compliance to detect problems or violations. Monitoring involves both routine and spontaneous checks on people's behavior to see whether it comports with the law. Because these efforts are resource intensive, governments have had to establish monitoring priorities based on risk of harm. They also have considered means by which industry, public interest groups and other sectors can share the burden. In particular, public interest groups often serve a useful "watch-dog" function. They have been very effective in observing and reporting instances of noncompliance.

174. Monitoring efforts often are directed at those persons whose chemical activities present the highest risk to health and the environment. Different monitoring techniques may be applied to the activities of chemical producers, distributors and end-users. For example, monitoring which occurs in response to a complaint allows government to uncover violations of the law. Spot checks of chemical transporters can help avoid accidents or illegal hazardous waste movements. Required renewal of licenses or other documentation gives government an opportunity to inspect the records, activities and facilities of those authorized to handle extremely harmful chemicals.

175. These focused monitoring actions are complemented by more regular efforts such as the health monitoring of workers who use chemicals. Regular visits to chemical users by community-based personnel help monitor compliance with pesticides and poisons laws. All of these programs rely on related activities which train workers and others in good industrial or agricultural practices. Other regular monitoring programs can involve the taking and analysis of samples by Customs to check for the illegal presence of a particular chemical substance. Sampling also can occur during the self-monitoring required of industries for product quality control or for compliance with occupational exposure or effluent/emission standards. Self-monitoring efforts usually are verified by follow-up government sampling.

#### Recordkeeping/reporting/requests for information

176. Some chemicals legislation places general recordkeeping responsibilities on chemical producers, traders, distributors, transporters, storers, disposers or others who handle chemicals. Inspection of these records can help government track the movement of harmful chemicals for compliance purposes as well as economic or

statistical reasons. Records might be kept on (1) chemical testing performed, (2) sampling results obtained, (3) kinds/quantities of chemicals handled, (4) chemical problems which have been uncovered or reported and (5) communications with government or others which concern the handling of chemicals. Records which contain information on the quantities of chemicals being handled and any accidents or adverse effects involving a chemical are of particular importance for establishing future chemical control priorities. Legislative provisions usually require that chemical records be maintained in a certain manner (in a logbook at the facility), kept for a certain period of time and made available for inspection. Such records also help the preparation of periodic reports which might be required.

177. The required reporting of certain information (1) under special circumstances (accident, release or injury), (2) on a regular basis or (3) in response to a specific, direct government request can be an effective monitoring tool. Some chemical laws require immediate reporting of chemical spills or releases which exceed a certain threshold. Other laws require yearly reports of the types and quantities of chemicals sold. Government requests for the submission of particular information or answers to specific questions both encourage compliance and uncover violations. Unfortunately, reporting requirements can be administratively burdensome because of the need to review and evaluate the information submitted. If the amount and complexity of written material is kept to a minimum, the reporting process still can prove useful.

### Inspections

178. Many chemical laws authorize the appointment of inspectors and describe their specific powers. National governments vary in the number of inspectors they fund but all seem to agree the number is inadequate. Recognizing that inspections require a significant commitment of human and other resources, they still are one of the most effective means of achieving compliance with the law. This is especially true, if they are conducted regularly and thoroughly by properly trained inspectors. Comprehensive inspection programs cover large, medium and small industry. They also ensure the inspection of producers, sellers and users. Some countries defray inspection costs by requiring private enterprises to pay for government inspections.

179. Occasional unannounced inspections (or spot checks) are extremely useful in ensuring compliance and uncovering noncompliance. Surprise inspections, together with regular reporting by enterprises, allow government to make maximum use of limited resources. At the very least, inspections need to be conducted in response to reported problems, *e.g.*, a chemical accident, environmental pollution or adverse health effects.

180. Within the law, inspectors usually are authorized to enter both public and private property (residences may be excluded) on giving proof of their identity. They often have additional authority to inspect records, processes or activities and all premises. They commonly are authorized to take samples, conduct field tests, use monitoring equipment, confiscate certain items, take photographs and interview concerned persons. Legal procedures in some countries require that notice be given if the inspection may result in criminal charges. This notice differs from the search warrant required for a criminal investigation designed to collect evidence of suspected illegal conduct.

## **Compelling Compliance**

### Warnings/Citations/Orders

181. Some laws authorize government officials to issue warnings of any violations they find during the review of reports or the conducting of inspections. Agency inspectors or other representatives also have been authorized to issue citations (or tickets) on discovering a more serious violation of law. In an emergency situation which endangers health or environment, inspectors may be able to order that certain action be taken or certain improper action stop. Written administrative orders also might be used to recall unsafe products, require more information/testing or prohibit a certain activity. Procedures regarding the appeal of such orders often are provided in legislation as well.

### Investigations

182. Stronger compliance measures often used by countries include the subpoenaing of people, documents or items to an administrative or judicial hearing. Most chemical laws also provide for the obtaining and use of search warrants which authorize law enforcement officials to search for and seize evidence of the law's violation.

### Violations

183. Legislative sections governing the prosecution of violations usually can be found either in the chemical law itself or more general legislation on civil and criminal offenses. Regardless of their location, these sections list the unlawful conduct (or offenses) punishable under the law and the penalties which can be imposed for committing an offense. Aspects of procedure such as the right to appeal adverse decisions also might be discussed.

#### Noncompliance

184. The law might generally state that noncompliance with any of its provisions is an offense or it might list specific instances of noncompliance. Both acts and omissions to act can violate a law. Depending on the type of chemical law involved, typical violations include: use of an unregistered chemical, import of a prohibited chemical, misleading advertising, mislabelling, failure to submit chemicals information, failure to keep required records, obstruction of any government inspector in the performance of his duties, failure or refusal to obtain the necessary license, failure to comply with license conditions, failure to obey an administrative/judicial order, etc.

#### Fraudulent behavior

185. Many laws punish the making of a false statement or omitting of material information in license/permit applications and other required documents. Similar false statements or omissions made in response to the oral/written question of a government official and broader misrepresentations by fraudulent conduct also may be made punishable.

#### Creating harm or threat of harm

186. Some chemical laws make punishable the endangerment or injuring of people, animals and the environment by unjustified releases of chemicals. Knowing endangerment of human beings during the commission of another illegal act has been subjected to more severe punishment than is provided for the underlying illegal act. Many countries have accepted the "polluter pays principle" which places civil liability for environmental harm on the one who causes it, regardless of his intent. A proposed European Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment will strengthen the application of this principle. It is intended to impose strict responsibility on companies which produce hazardous substances, waste treatment facilities and anyone using dangerous chemicals.

#### Disclosure of confidential information

187. A number of chemical laws provide for the punishment of those who improperly disclose protected confidential information. Though seemingly less significant than other offenses, punishing these kinds of violations is viewed as necessary to obtain the proper respect for confidential information.

### Penalties

188. National practice with regard to legislating punishment provisions usually is quite well-established and particular to the country. Therefore, a detailed discussion of administrative/judicial procedures and penalties might not be useful here. It may be sufficient to say that violations of law are often subject to administrative, civil or criminal penalties. In civil law countries, however, the distinction between administrative and civil sanctions does not exist.

189. Examples of common penalties include: (1) citations for violations; (2) fines; (3) revocation, suspension, or modification of a license or permit, (4) barring of an individual or company from future government contracts,

(5) agency or court orders to do or refrain from doing something, (6) obligation to rectify any damage caused by the wrongful conduct, (7) imprisonment, and (8) forfeiture of property used to commit an offense.

190. Occasionally, private citizens have the legal right to sue the government for failing to adequately implement or enforce a chemical law. Individual citizens also may be allowed to file lawsuits against an individual or company which violates a chemical law. Several chemical laws punish corporations and corporate officials for the acts of their employees which violate the law. Criminal sanctions may not commonly be used in enforcing chemical legislation, but they do provide a means of punishing or preventing certain extremely harmful behavior and drawing more attention to the serious need for chemicals to be managed safely. For example, they have been used to punish the intentional use of a banned chemical, illegal export of hazardous waste, failure to report a chemical spill, the emission of a hazardous pollutant and falsification of laboratory test results.

### **Promoting Compliance**

191. Although government "command and control" measures can be effective in regulating chemicals, many countries have found the schemes difficult to enforce. Accordingly, they have developed means of encouraging as well as ordering people to handle chemicals properly.

#### Field support/training/education

192. Agricultural extension services, occupational safety and health services and health care services do much to promote the safe use of chemicals because they have personal contact with the producers, importers and end-users of chemicals. Field support staff can consult with regulated parties about how to comply with legislation. They can provide technical information and conduct or arrange for chemical risk training or education for those most affected by chemical usage. They often provide advice for specific situations and help respond to emergency situations arising from chemical poisonings or spills. Seminars on chemical substitution and clean technology/processes provide useful assistance in preventing chemical injuries or pollution.

#### Industry self-regulation

193. To obtain a personal commitment to preventing pollution and immediate action, some national, state or local level governments have entered into agreements with specific industries or facilities to control chemical emissions. Larger programs have urged industry overall to substantially reduce its use or emissions of certain chemicals over a particular time period. Similar negotiations have occurred between local public interest groups and local businesses.

194. The threat of government enforcement or a negative public image has caused a number of chemical companies to conduct environmental audits on their facilities and operations. These audits usually are performed by outside experts, who check a company's compliance with legal requirements and write a report summarizing their findings. Companies then can use the audit report to bring themselves into compliance with legislative provisions. Chemicals legislation requiring the monitoring and reporting of noncompliance with government-established standards also allows companies to correct their own behavior. Low government emission standards based on best available technology have encouraged the installation of closed engineering systems designed to prevent chemical releases. Through chemical reuse, such systems also reduce the quantity of chemicals used and chemical waste generated. They also can improve the management of any chemical waste which is produced.

195. Even without the prompting or pressure of other sectors, the chemical industry has taken steps to regulate itself. A number of national chemical manufacturing associations have developed "Responsible Care" or "Product Stewardship" programs regarding chemicals. Under Responsible Care, chemical companies make formal commitments to improve their protection of health, safety and the environment. Each national program includes a set of guiding principles, implementing codes, performance indicators, communication with outside parties and a sharing of views/experiences with other companies. Some associations have made the commitment to Responsible Care a condition to membership. Consideration also has been given to refusing to do business with those companies which fail to adopt or comply with the program.

196. Product stewardship programs require the responsible and ethical management of a chemical product throughout its lifecycle. They incorporate management principles concerning risk assessment, risk communication and risk reduction. In addition to these activities, the international agrochemical industry has actively been engaged in following and promoting the FAO Code of Conduct on the Distribution and Use of Pesticides. Chemical manufacturing associations from major chemical-producing countries also have shown support for the Prior Informed Consent procedure.

#### Increased Public Participation

197. Many countries have recognized the effectiveness of using public opinion to influence private sector behavior. Publication of industrial noncompliance in the newspaper has shamed many enterprises into changing their ways. Generally providing the public better access to chemicals information has encouraged companies to act more responsibly. If members of the public know government will listen to them and they will be protected from retaliatory action, they also are more likely to "blow the whistle" on illegal conduct.

198. In addition to supplying members of the public with more information, countries have solicited their views on proposed legislation or other government actions related to chemicals. This enables government officials to weigh better the opinions of industry representatives, who have an economic interest in a particular outcome. Moreover, members of the public are those most affected by chemical management decisions. It is their health and environment which chemicals legislation seeks to protect.

#### Practical Suggestions

- \* if monitoring or inspection resources are limited, use them to respond to specific complaints or problems and to conduct unannounced spot checks within a self-regulation program*
- \* if specialized chemical inspectors do not exist, train existing agricultural, health, labor and Customs inspectors to recognize chemical violations*
- \* establish compliance priorities and enforce highest priority matters strictly*
- \* encourage workers or public to report violations, through education, hotlines and legislatively protecting workers from employer retaliation*
- \* urge industry and public to do business only with those who comply with chemical law*
- \* consider imposing criminal penalties for serious offenses*
- \* support industry codes of conduct*
- \* establish mechanisms for increased public involvement*

#### Useful Resources

- \* Canadian publication on Enforcement and Compliance Policy (?)*
- \* OECD Regulation on the Use of Economic Instruments in Environmental Policy (1991)*
- \* FAO Guidelines on Post-Registration Surveillance and Other Activities in the Field of Pesticides (1988)*
- \* IE/PAC publication on compliance*
- \* funding for health or environmental monitoring projects*

## PHASED APPROACH TO CHEMICALS LEGISLATION

199. The development or strengthening of national chemicals legislation can be compared to treatment of an illness. The first step--examination of the patient--is to assess the chemical situation. The second step--diagnosis--determines the health and environmental problems being caused by chemicals and identifies priority needs. The third and final step--treatment--involves reviewing the legislative options and prescribing the legislative components which will solve the problem. These steps will lead to different legislative results depending on whether a country has no chemicals legislation, some chemicals legislation or extensive chemicals legislation.

### Phase I--Examination

Which chemicals are present (agricultural, consumer, industrial)?  
Where do they come from (production/import)?  
Where do they go (export/disposal)?  
Which aspects are controlled (lifecycle)?  
Which agencies and which laws regulate chemicals?  
How are other sectors involved in chemicals management?  
Are there any chemical management obligations under international agreements?

### Phase II--Diagnosis

Pollution (air or water or soil)  
Poisoning (workers or consumers)  
Accidents (production, transport or storage)  
Which chemicals, chemical uses or chemical activities are causing the problems and how?

### Phase III--Treatment

How will other laws be linked to this one?  
Is this national, state or local legislation?  
Is this primary or secondary legislation?  
Should it be broad or narrow in scope?  
Will it be similar to laws in other countries, especially in the region?  
Which specific provisions are needed for organizational structure, knowledge base, protective measures and compliance scheme?

## LIST OF SELECTED REFERENCES

139. The following references are intended to give readers a sampling of current, available publications and legislation which address chemical management. This list is not a complete compendium of everything written about chemical management. Instead, the list of international references has been kept to a minimum. An attempt also has been made to provide examples of recent national legislation from different regions of the world. The selections offer a variety of languages and a variety of approaches to chemical management.

### International

1. **(UN)** United Nations Conference on Environment and Development, Agenda 21, Chapter 19--"Environmentally Sound Management of Toxic Chemicals (including prevention of illegal international traffic in toxic and dangerous products)" (June 1992) (Arabic, Chinese, English, French, Russian, Spanish?)
2. **(UN)** Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments (4th ed, 1991)
3. **(UN)** Recommendations on the Transport of Dangerous Goods (7th ed. 1991)
4. **(UNEP)** Register of International Treaties and Other Agreements in the Field of the Environment (1991)
5. **(UNEP)** London Guidelines for the Exchange of Information on Chemicals in International Trade (1987, amended 1989) (Arabic, Chinese, English, French, Russian, Spanish)
6. **(UNEP)** IRPTC Bulletin (issued bimonthly? since 19\_\_ ) (languages?); IRPTC Legal File (19\_\_)
7. **(UNEP)** IE/PAC Publications on APELL, Storage, Compliance, Clean Production
8. **(FAO)** International Code of Conduct on the Distribution and Use of Pesticides (1985, amended 1989) (Arabic, Chinese, English, French and Spanish)
9. **(FAO)** Guidelines for Legislation on the Control of Pesticides (1989); Guidelines for the Registration and Control of Pesticides (1985)(English, others?)
10. **(FAO)** Food and Agriculture Legislation (December 1990, yearly publication series) (English, French, Spanish)
11. **(ILO)** Convention No. 170 and Recommendation No. 177 Concerning Safety in the Use of Chemicals at Work (1990) (English, French, Spanish, German, Chinese, Arabic and Russian); also Code of Practice (1992) and training manual (1993)
12. **(ILO)** International Occupational Safety and Health Information Centre (CIS) Bibliography on Laws, Regulations and Directives in the CIS database (1989 version) (English, others?)
13. **(ILO)** Code of Practice on Prevention of Major Industrial Accidents (\_\_\_)
14. **(IPCS)** Environmental Health Criteria series, Health and Safety Guides series
15. **(WHO)** Model List of Essential Drugs
16. **(WHO)** International Digest of Health Legislation (quarterly, English)
17. **(WHO)** African Workshop on Technological Disasters (Addis Abba, 26-30 November 1990) (English, others?)

18. **(WHO Western Pacific Regional Centre for the Promotion of Environmental Planning and Applied Studies)** Regional Workshop on Chemical Safety Legislation (Kuala Lumpur, 7-11 October 1991)
19. **(WHO Regional Office for Europe)** Legislative and Administrative Procedures for the Control of Chemicals (1984)
20. **(OECD)** Council Decision on the Mutual Acceptance of Data in the Assessment of Chemicals (1981) (including Guidelines for the Testing of Chemicals and GLP; Council Decision on the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals (1982), use of economic instruments in environmental policy; Guidelines on Accidents (1992); recommendations re confid data; integrated pollution prevention and control, list of non-confidential data, risk reduction of chemicals, systematic investigation of existing chemicals
21. Rune Lonngren, International Approaches to Chemicals Control: A Historical Overview (KemI 1992)

National

22. **Austria** Chemicals Act (1987, amended 1989); Environmental Information Act (1993) (German, English-unofficial)
23. **Australia** Industrial Chemicals (Notification and Assessment) Act (1989, amended 1992) (English)
24. **Canada** Environmental Protection Act (1988) (English, French)
25. **Colombia** Regulations on the Use and Handling (Management) of Pesticides (1991) issued under the Pesticides Law of 1979 (Spanish)
26. **Costa Rica** Regulations on Registration and Control of Toxic Substances and Products and Dangerous Substances, Products and Articles (1992) authorized under General Law on Health
27. **Denmark** Consolidation Act on Chemical Substances and Products (1987, amended 1989) (Danish, English-unofficial)
28. **European Community** Regulation No. 67/548 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (seventh amendment Directive 92/32/EEC, 30 April 1992, O.J. No. L154 p. 1) (English, French); also Directives on Seveso, ozone, freedom of information, PIC
29. **Finland** Chemicals Act (1989) (Finnish, English-unofficial)
30. **France** Chemical Products Control Law (1977, amended 1982) (French)
31. **Germany** Chemicals Act (1980, amended 1990) (German, English-unofficial)
32. **India** Manufacture, Storage and Import of Hazardous Substances Rules (1989) and Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms and Cells (1989) issued under Environmental Act of 1986 (Hindi, English)[get 3d set of regs]
33. **Japan** Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances (1973, amended 1986) (Japanese, English-unofficial)
34. **Kenya** Food, Drugs and Chemical Substances Act (1965, rev.ed. 1980) and Regulations (1975); Pest Control Products Act (1983, rev. ed. 1985) (Swahili, English)
35. **Netherlands** Chemical Substances Act (1985) (Dutch, English-unofficial)
36. **New South Wales (Australia)** Environmentally Hazardous Chemicals Act, 1985
37. **New Zealand** Toxic Substances Act (1979) and Regs (1983) and Ozone Protection Layer Act (1990) (English)
38. **Papua New Guinea** Pesticide Regulations (1988) and Guidelines (\_\_\_) issued under the Environmental Contaminants Act (1978) (local language?, English)
39. **Philippines** Toxic Substances and Hazardous and Nuclear Waste Act (1990) and Regs? (English)
40. **Singapore** Poisons Act (1939, amended 1989) with the Poisons (Hazardous Substances) Rules (1986) (Chinese, English)
41. **South Korea** Toxic Chemical Control Act (1990)

42. **Sweden** Act on Chemical Products (1985, amended 1991) (Swedish, English-unofficial)
43. **Switzerland** Federal Law on Trade in Toxic Substances (1969) and Ordinance relating to Environmentally Hazardous Substances (1986) issued under Federal Law relating to Protection of the Environment (\_\_\_\_) (German, French, Italian, English-unofficial)
44. **Thailand** [title]
45. **Tonga** Pesticides Act (1975, amended 1981) and Regulations (1989) (Tongan, English-unofficial)
46. **United Kingdom** Regulations for the Control of Substances Hazardous to Health (1988, amended 1991) issued under the Health and Safety at Work Act of 1974 (English) [also new Fertilisers Act?]others?
47. **United States** Toxic Substances Control Act (1976); Emergency Planning and Community Right-to-Know Act (1986) Pollution Prevention Act (1990)(English)