



## INTERNATIONAL EXPERIENCE WITH TOXIC CHEMICAL MANAGEMENT

### *Abstract*

*This note provides an overview of international experience with toxic chemical management. Such experience is drawn from practice in the United States, the European Union and its member nations, Japan, Canada, and certain developing countries. The key legal, policy, and technical measures discussed in the note include chemical inventory management, reporting requirements and procedures, chemical evaluation and registration focusing on new chemicals and existing chemicals, priority and toxic chemical controls, chemical hazard communications (particularly labeling and material safety data sheets), and industry voluntary programs. The note also discusses some on-going efforts to take a comprehensive approach toward chemical management, and specifically the Strategic Approach to International Chemicals Management. Key conclusions are summarized at the end of the note.*

### **Introduction**

Chemicals, in particular toxic chemicals, impose significant health, safety and environmental risks to human beings. For this reason, almost every nation in the world, has heavily regulated the manufacturing, distribution, usage, transportation and storage of various types of chemicals, in one way or another. However, environmentally sound management of toxic chemicals is still a serious challenge for many nations and the international community. Gross chemical contamination, with grave damage to human health, genetic structures and

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reproductive outcomes and the environment in general, has been continuing within some of the world's most important industrial areas, and restoration will require major investment, massive regulatory and policy efforts as well as the development of new technologies.

A number of national and international collaborative efforts to improve chemical management are either in place or are on-going. This brief note is prepared with the purpose of outlining the major existing and proposed legal, policy and technical measures for chemical management in the world, in particular for a number of selected developed and developing countries.

The key legal, policy and technical measures discussed in this note focus on chemical inventory management, reporting requirements and procedures, chemical evaluation and registration, priority and toxic chemical controls, chemical hazard communications (in particular of labeling and material safety data sheets), industry voluntary programs, and the on-going efforts of the Strategic Approach to International Chemicals Management.

## **Inventory Management and Reporting**

Many countries find that it is important to establish an inventory of existing chemicals. Existing chemicals are defined differently under each country's chemical control laws. In the United States, existing chemicals are defined as those chemicals listed in the Inventory of Toxic Substances Control Act (TSCA). Current EU legislation defines existing chemicals as those listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). By creating and managing the chemical inventory, and the related reporting requirements, governmental authorities can obtain necessary information about the chemicals that are being manufactured and imported into the countries.

The United States Toxic Substance Control Act (TSCA) is perhaps the first regulatory regime in the world to create a chemical inventory. TSCA was enacted by the US Congress to give the Environmental Protection Agency (EPA) the ability to track the 75,000 industrial chemicals currently produced or imported into the United States. The EPA repeatedly screens these chemicals and can require reporting or testing of those that may pose an environmental or human health hazard.

TSCA gives the EPA broad authority to regulate the manufacture, use, distribution in commerce, and disposal of chemical substances. TSCA is a federally-managed law and is not delegated to states. A major objective of TSCA is to characterize and evaluate the risks posed by a chemical to humans and the environment before the chemical is introduced into commerce. TSCA accomplishes this through the requirement that manufacturers perform various kinds of health and environmental testing, use quality control in their production processes, and notify EPA of information they gain on possible adverse health effects from use of their products.

Under TSCA, the Inventory Update Rule (IUR) and the Preliminary Assessment Information Rule (PAIR) are set forth for the reporting requirements.

Under the IUR, companies that manufacture or import more than 10,000 lbs. of certain chemicals that are included on the TSCA Chemical Substance Inventory, which are primarily organic chemicals, are required to report current data on the production or import volume, plant site, and site-limited status of these chemicals.

Under PAIR, companies must report site-specific information on the manufacture or importing for commercial purposes of any chemicals listed at 40 CFR 712.30 (which are generally toxic chemicals). The information includes quantity of chemical, amount lost to the environment during production or importation, quantity of releases (controlled and non-controlled) of the chemical, and per release worker exposure information.

Another inventory in the US is the Toxics Release Inventory (TRI). TRI collects information about chemical releases and waste management reported by major industrial facilities in the U.S. The TRI database was established by the Emergency Planning and Community Right-To-Know Act (EPCRA) of 1986. Under EPCRA, industrial facilities in specific sectors are required to report their environmental releases and waste management practices annually to the EPA. Covered facilities must disclose their releases of approximately 650 toxic chemicals to air, water, and land, as well as the quantities of chemicals they recycle, treat, burn, or otherwise dispose of on-site and off-site.

Through inventory management and reporting requirements, the US government can effectively track the flow of manufacturing and distribution of chemicals, in particular toxic chemicals. This management mechanism can provide the necessary information for quick and effective response if any accident happens.

Similar to the US inventory and reporting management requirements for chemicals, many other countries in the world have also established an inventory and reporting system to manage and control chemicals. The major chemical inventories in the world include those of the US, Canada, the EU, Japan, and Korea. Some developing nations have also made efforts to establish an inventory and reporting system in the recent years.

## **Evaluation and Registration**

Many countries, such as the European Union nations, the United States, Japan, Korea, and Canada, have introduced and implemented evaluation and registration systems for chemicals. While the evaluation and registration system is generally applicable to the new chemicals, some advanced proposals extend the scope of evaluation and registration requirements to include existing chemicals.

The United States, Canada, the EU, and many other countries in the world review the risks of new chemicals, although they do so at different times. For example, TSCA requires chemical companies to notify the EPA before beginning the manufacture of new chemicals, while in Canada and the EU chemical companies must notify regulatory authorities only after the new chemical has reached certain levels of manufacture or importation amount.

While the chemical evaluation and registration requirements and procedures vary from one nation to another, governmental authorities around the world generally require chemical companies to submit the physical chemical properties, as well as basic toxicological and health effects data for evaluation and registration of new chemicals.

The proposed EU Registration, Evaluation and Authorization of Chemicals (REACH), if approved by the European Parliament, will become the most comprehensive chemical evaluation and registration system in the world.

Under the proposed rules, any company that manufactures or imports more than one metric ton of an existing substance is required to register the chemical in a central database. Registration includes information about the properties of the substance, its uses and safe ways of handling it. A new European Chemicals Agency will be responsible for reviewing registrations and providing non-confidential information to the public.

The directive does not require that each chemical be tested. Indeed, it is tailored to reduce the expense of testing and minimize animal testing. Each registered chemical's dossier is examined to evaluate compliance with registration requirements and existing test data related to the substance. If a human health or environmental risk is suspected, further testing may be required. It is expected that around 80 percent of existing substances will require no more than a dossier evaluation.

Official authorization would be required to continue to use substances determined to pose serious and irreversible risks. The EU estimates that the cost of implementing REACH will be \$3.5 to \$6.5 billion over the next 15 years, but that \$60 billion will be saved in chemical-related health costs. In addition, business costs will be offset by profits from new, safer alternative substances.

The proposed EU REACH will have significant compliance implications for the producers who manufacture chemicals in or import chemicals into EU. In addition, it is possible some other nations in the world may look into the EU experience and introduce similar regimes into their own chemical management systems.

## **Priority and Toxic Chemical Control**

For human health and environment, most chemicals pose little, if any, danger. In contrast, a limited number of certain chemicals may cause serious health, safety and environmental problems. To manage chemicals in the most cost-effective way, many nations list chemicals that may potentially cause serious health, safety and environmental damage as "priority chemicals" or "toxic chemicals". For the chemicals included in these lists, the most stringent management and control requirements are applicable.

Priority and toxic chemicals make up a fairly limited proportion of the total volume of the stream of waste, while still being the potentially most hazardous component. Regulatory authorities throughout the world try to eliminate or reduce priority chemicals and other chemicals of national concern from commercial products, waste streams, and industrial releases through pollution prevention, waste minimization, and recycling and reuse.

The US EPA lists 31 chemicals as "priority chemicals". These chemicals are priorities because they are persistent, bio-accumulative, and highly toxic. The US EPA has worked together with industry in recent years, with a focus on reducing priority and toxic chemicals to better protect human health and the environment.

By substituting or eliminating certain chemicals in manufacturing processes, companies may produce less waste and thus lower their waste disposal costs. The major approach of priority and toxic chemical control in the US is to substantially reduce the volume and toxicity of priority chemicals in waste. The key measures include asking companies to voluntarily substitute safer alternatives; minimizing the amount of priority chemicals they use, if they cannot find substitutes for them; maximizing recycling efforts; practicing cradle-to-cradle chemical management; and designing products to minimize exposure to, and release of, priority chemicals during manufacturing and use. Through these measures, the US EPA wishes to reduce priority chemicals in waste by 10% by 2008 (using 2001 data as the baseline).

Many other countries, including developing countries, have also established their priority or toxic chemical lists and set forth more stringent requirements for manufacturing, importation, distribution, use, transport, treatment and disposal of these chemicals.

For example, the Philippines has developed the Philippine Priority Chemicals List (PCL). It is a short list of chemicals that have been determined to potentially pose unreasonable risks to public health, workplaces and the environment. At present, there are 28 toxic chemicals enumerated in the PCL. The inclusion in the PCL is primarily based on the selection criteria used by industrialized countries, such as persistence, toxicity and bioaccumulation.

The Taiwan EPA has listed 252 types of toxic chemicals to guard against the potential dangers posed by these substances. The chemicals listed as toxic chemicals are subject to requirements of classification, quantity control, permit, registration, pollution prevention and

emergency planning and response. Violations related to toxic chemicals are also subject to much stronger fine and other penalties.

Worldwide, the management of priority and toxic chemicals is still evolving. Future management policies will focus on formulating a total-quantity-control system for priority and toxic chemical release, expanding the priority and toxic chemical toxicology database, establishing environmental background data, and assessing any potential environmental exposure. In addition, efforts will also likely be made to build disaster prevention and mitigation skills for all priority and toxic substances and to establish mechanisms for disaster recovery and remediation.

### **Hazard Communications**

Hazard communication is a mechanism of chemical information communication in order to ensure chemical safety in the workplace. Through labeling and material safety data sheets (MSDS), government authorities require chemical manufacturers and importers to provide chemical information to their employees and customers. By doing so, employees at workplaces and customers can readily access chemical information and therefore prevent chemical exposure and accidents.

In the United States and many other countries, information must be available about the identities and hazards of the chemicals. For example, in the US, the Hazard Communication Standard (HCS) under the Occupational Safety and Health Act requires chemical manufacturers and importers to evaluate the hazards of the chemicals they produce or import, and prepare labels and MSDSs to convey the hazard information to their downstream customers. In addition, all employers with hazardous chemicals in their workplaces must have labels and MSDSs for their exposed workers, and train them to handle the chemicals appropriately.

The Occupational Safety & Health Administration (OSHA) is the executive agency responsible for chemical hazard communication in the United States. Over the years, OSHA has developed various enforcement initiatives for compliance officers to review and evaluate the adequacy of MSDSs. Under these programs, OSHA chooses a certain number of chemicals, and follows the requirements in the HCS, to identify some critical elements (phrases, words, etc.) that should appear on an accurate MSDS. Compliance officers use this information as they encounter these chemicals at worksites. Where MSDSs are found that do not contain these critical elements, OSHA will notify the manufacturer in writing of the deficiencies or inaccuracies. Manufacturers will be required to correct and update their MSDS. They will then have to respond to OSHA and inform the Agency of the steps taken to correct and update their data sheets. Those manufacturers that fail to respond or do not update their MSDS can potentially be cited or penalized under the HCS.

Similar to the United States, many other nations have also developed hazard communication systems, including labeling and MSDS. In such efforts, detailed requirements for labeling and MSDS vary from one country to another. Such variations result in different labels and material safety data sheets for the same chemicals. The missing or incomplete information on chemicals may lead to reduced protection for human beings. In addition, the large number of varying requirements around the world may create potential barriers to trade in chemicals, particularly for small businesses.

For the above reason, a harmonized and consistent approach would have benefits both in terms of protection and trade. For countries that do not have existing systems, and may not have the resources to develop and maintain one, availability of a globally harmonized approach will allow them to provide necessary protection for their citizens while enabling them to participate in international trade. In 1992, an international mandate to develop a globally harmonized system for hazard classification and labeling was adopted at the United Nations Conference on Environment and Development (UNCED).

The Globally Harmonized System for Classification and Labeling (GHS) was initiated with this background. GHS includes harmonized criteria for classification of physical and health hazards, labeling elements, including harmonized symbols, hazard warning statements, and signal words for each type of hazard, and a harmonized format for safety data sheets. Within the United Nations, the Subcommittee of Experts on the Globally Harmonized System for Classification and Labeling was established to implement and maintain the GHS.

Because of political, technical and other reasons, GHS has not been widely adopted by many countries, although a number of countries have adopted GHS as their national regulation. While it may take time for the majority of nations to take GHS as an international standard or national legislation, such a trend seems likely.

## **Industry Initiatives**

While chemical management efforts are generally government initiatives, in recent years industry has initiated various programs to implement sound management planning for chemicals. Such programs were created by industry companies and associations for various reasons, including better marketing image, public relations, as well as environmental, health and safety concerns.

Responsible Care is one of such programs that have created global impacts. This is the chemical industry's global voluntary initiative under which companies, through their national associations, work together to continuously improve their health, safety and environmental performance, and to communicate with stakeholders about their products and processes. The Responsible Care ethic helps industry to operate safely, profitably and with due care for future generations, and was commended by UNEP as making a significant contribution to sustainable development.

Responsible Care is currently practiced in 52 countries, which share a common commitment to advancing the safe and secure management of chemical products and processes. Specific Responsible Care practices may vary from country to country as they are determined by each country's laws and national industry association.

Responsible Care programs have significantly improved the environmental, health, safety and security performance of US chemical companies. Participation in Responsible Care is mandatory for member companies of some associations. The key elements of Responsible Care in the United States include measuring and publicly reporting performance, implementing the Responsible Care Security Code, applying the modern Responsible Care Management System to achieve and verify results, and obtaining independent certification that a management system is in place and functions according to professional standards.

In the U.S., Responsible Care has resulted in reduced emissions by 75 percent and an employee safety record that is four and a half times better than the average of the U.S. manufacturing sector. Responsible Care helps America's leading chemical companies go above and beyond government requirements and openly communicate their results to the public. Responsible Care require companies to consider the practice of making health, safety and environmental protection an integral part of the development, manufacture, handling and use of chemical products.

As part of their commitment to product stewardship, Responsible Care suggests that companies conduct systematic and rigorous evaluations of their chemical products to ensure that these products deliver their intended benefits, while protecting public health and the environment. These evaluations include characterization of any risk associated with the use of the products and a determination of risk management activities needed to address that risk. Reporting on these activities is intended to provide a greater understanding of how product safety and management decisions are made.

### **Comprehensive Approaches**

Over years, governments, academia, industries, citizens and other stakeholders have recognized that the goals of sound chemical management cannot be achieved without comprehensive approaches, although individual legal, policy and technical measures are also required to achieve such goals. Such comprehensive approaches should be carefully designed and effectively implemented.

In recent years, the international community has been trying to develop and negotiate such comprehensive approaches, including the Strategic Approach to International Chemicals Management (SAICM). Adopted by the International Conference on Chemicals Management (ICCM) on 6 February 2006 in Dubai, United Arab Emirates, the SAICM is a policy framework

for international action on chemical hazards. The SAICM was developed by a multi-stakeholder and multi-sectoral Preparatory Committee. The SAICM supports the achievement of the goal agreed at the 2002 Johannesburg World Summit on Sustainable Development of ensuring that, by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.

Currently, the SAICM includes three major elements: the Dubai Declaration, the Overarching Policy Strategy, and the Global Plan of Action.

The Dubai Declaration expresses commitment to the SAICM by Ministers, heads of delegations, and representatives of civil society and the private sector.

The Overarching Policy Strategy sets out the scope of the SAICM, the needs it addresses and objectives of risk reduction, knowledge and information, governance, capacity-building and technical cooperation and illegal international traffic, as well as underlying principles and financial and institutional arrangements. The ICCM adopted the Overarching Policy Strategy which together with the Dubai Declaration constitutes a firm commitment to the SAICM and its implementation.

The Global Plan of Action sets out proposed work areas and activities for implementation of the Strategic Approach. The ICCM recommended the use and further development of the Global Plan of Action as a working tool and guidance document.

It is too early to comment on the effectiveness of the SAICM; and many details are still required to ensure its meaningful implementation. Nevertheless, the SAICM signals the start of more comprehensive approach toward chemical management.

## **Conclusion**

Reviewing the efforts to improve toxic chemical management around the world, some basic conclusions can be reached. Many governments have established chemical inventories to obtain and maintain information about the manufacture and importation of chemicals, as well as information about major producers of toxic chemicals. Evaluation and registration systems are introduced to review the health, safety and environmental risks of new chemicals and existing chemicals. Nations select priority or toxic chemicals for which the more stringent controls are imposed. Chemical information is required to be communicated to employees and customers to prevent and respond to any potential accidents. In addition to government regulatory and enforcement efforts, industry voluntary programs are encouraged to better manage and use chemicals. The international community has recognized that more comprehensive and collective approaches are called for future.

Though the international experience and practice discussed in this note were largely drawn from developed nations, many developing including countries have adopted these measures to some extent, and have achieved some success. So the developed country experience has been shown to be generally applicable to developing nations. Designing a comprehensive regulatory regime that draws upon this experience, together with the effective implementation, is now perhaps the most important task for developing nations.

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