Global Environmental Health in the 21st Century: From Governmental Regulation to Corporate Social Responsibility

Myron Harrison and Christine Coussens, Editors, Roundtable on Environmental Health Sciences, Research, and Medicine

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GLOBAL ENVIRONMENTAL HEALTH IN THE 21ST CENTURY

FROM GOVERNMENTAL REGULATION TO CORPORATE SOCIAL RESPONSIBILITY

WORKSHOP SUMMARY

Myron Harrison and Christine Coussens, *Rapporteurs*

Roundtable on Environmental Health Sciences, Research, and Medicine

Board on Population Health and Public Health Practice

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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the final draft of the report before its release. The review of this report was overseen by **Melvin H. Worth, M.D.**, Scholar-in-Residence, Institute of Medicine, who was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.report rests entirely with the authoring committee and the institution.

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Preface

The Institute of Medicine's Roundtable on Environmental Health Sciences, Research, and Medicine was established in 1988 as a mechanism for bringing various stakeholders together to discuss environmental health issues in a neutral setting. The members of the Roundtable on Environmental Health Sciences, Research, and Medicine come from academia, industry, and government. Their perspectives range widely and represent the diverse viewpoints of researchers, federal officials, and consumers. They meet to discuss environmental health issues that are of mutual interest (though sometimes very sensitive). The basis of these discussions illuminates both current and emerging issues for the field of environmental health.

There is a growing awareness of significant environmental health issues, both domestically and worldwide. Scientists and policy makers are grappling with complex issues such as climate change, sustainability, and obesity—a diverse set of challenges that continue to have health impacts. Meeting these challenges requires dialogue from a number of stakeholders. The problems did not come from one activity, and the solutions are not going to come from one source (e.g., government or academia). Government alone clearly does not have the financial and other resources to solve all the health-related problems. Further gains in environmental health are going to be met through collaborations and partnerships. This does not mean that each stakeholder group needs to play a role in every problem, but we need to move forward collectively. This has been more apparent as disasters such as the tsunami in Indonesia, hurricanes Katrina and Rita in the Gulf Coast, and SARS. There is a need for stakeholders to bring their expertise to the table.

In this workshop, the Institute of Medicine's Roundtable on Environmental Health Sciences, Research, and Medicine discussed the role of industry in environmental health. The workshop looked at programs that work in concert with governmental regulations and tried to focus on how these programs can improve environmental health. One point that was made a number of times during the workshop is that we are going to need these programs at the global level. They are

needed because of the complexity of the societal problems; and in order to begin to address these issues, we are going to need input from all stakeholders.

During the workshop, the Roundtable members, speakers, and participants focused some of their attention on the complexity of the management of chemicals. Each stakeholder group echoed the need for a sound management system, but the discussion focused on the details of the current and proposed systems for managing the use of chemicals in commerce. The challenge for any government entity is that over 70,000 chemicals are in use today. Understanding the potential health and environmental effects is a challenge for a developed country and not possible for developing countries that lack financial resources.

As one speaker noted, regulations can spawn innovation. Thus it is clear that regulations are an important and necessary part of the plan to improve environmental health. However, regulations are only one part of the picture. There are many limitations to relying solely on governments and regulations. First, governments are limited to their own jurisdiction. On an international arena, there is reliance on treaties and agreements, but they are often difficult to enforce. Second, many governments lack the resources to continue to make gains in environmental health. Developing countries often do not have a stable government or tax base. Even developed countries have competing interest for the tax funding that makes funding of health projects infeasible. Finally, regulations take time to implement and do not incentivize companies to exceed the regulatory standards.

This is especially true for the business community which has a global reach that transcends political boundaries. In this workshop, the Roundtable on Environmental Health Sciences, Research, and Medicine looked at some of the programs and challenges for engaging industry through the shareholders' call for social responsibility.

This summary captures the presentations and discussions of the workshop. The views expressed in this report are those of individual speakers and participants, and do not necessary reflect the views of the Institute of Medicine, the members of the Roundtable on Environmental Health Sciences, Research, and Medicine, or the sponsors of this activity.

Paul G. Rogers
Roundtable Chair

Summary

WHAT ARE ENVIRONMENTAL MANAGEMENT SYSTEMS?

Environmental management systems (EMSs) are tools that corporations and some government agencies use to manage environmental issues. These systems may vary from facility (or agency) to facility but the basic premise is to implement the broader concept of sound and proactive environmental management. In recent years, EMS has evolved further to respond to increasing stakeholder pressure to improve social responsibility. As more companies, federal agencies, and organizations choose to implement EMSs, such as ISO 14001, it is important to consider the current state of the research concerning the relative successes and obstacles associated with existing systems in practice and what impact it will have, if any, on environmental health.

Despite wide implementation, EMSs are frameworks, or a tool, noted Edward Pinero of the Office of the Federal Environmental Executive. They vary in their content, coverage, and spectrum. EMSs have both operational and general benefits, remarked Pinero. EMSs can be used to improve the organization at large by facilitating the achievement of mission goals by systematically and operationally capturing environmental issues. In addition to increasing the awareness of impacts, consistency in operations, and promoting a more effective corrective action when problems occur, successful EMSs ultimately improve the condition of the surrounding environment.

Although the benefits of EMSs suggest improved performance, researchers are beginning to understand where, when, and how improvements are achieved. Deanna Matthews of Carnegie Mellon University has conducted research concerning the link between EMSs and improvement in environmental performance. From her research she learned that successful management systems support decision makers, evaluate and select projects based upon an organization's goals, and

The roundtable's role was limited to planning the workshop, and the workshop summary has been prepared by the workshop rapporteurs as a factual summary of what occurred at the workshop.

reduce liability or risk to the organization. They also support the general goals of a successful management system through proactive and cost-effective methods to improve operations to achieve better overall performance. There remains a need to bridge the information gap between the leadership and management system components of the organization and for EMSs to address potential problems, especially non-regulated public health needs. In addition, a better communication between firms and stakeholders is needed, concluded Matthews. Some meeting participants suggested that EMSs cannot be generalized and that we need to move forward toward a more sustainable approach to governing. We need to recognize that organizations need a wide range of incentives and disincentives, and they need to be given every possible tool to assist them toward their goals. A combination of approaches coupled with command and control regulation, insurance and supply chain incentives, and community pressure will lead to sustainable improvement after a few years, noted general discussion participants.

The Environmental Impact of Environmental Management Systems

Environmental performance is defined by the reduction of pollution or other kinds of resource uses, whether it is water or energy use, said Cary Coglianese of the Kennedy School of Government, Harvard University. Although EMSs are initially implemented to maintain compliance with regulations, they often have implications for lowering environmental costs, training employees, and developing indicators for environmental impact. An effective EMS enables an organization's officials and stakeholders to examine its values, priorities, policies, strategies, objectives, methods for allocating resources for delivering performance, and learning. Some research suggests that EMSs can manage risks, gain competitive advantages, and achieve environmental improvements at lower costs. During the workshop the speakers, Roundtable members, and participants considered how companies could use EMSs and other tools and policies to achieve greater impact beyond regulatory compliance. Coglianese suggests that required EMSs can and do make environmental improvements, but one must use caution in distinguishing how much comes from the system and how much comes from the commitment.

USING ENVIRONMENTAL MANAGEMENT SYSTEMS TO IMPROVE PERFORMANCE IN THE CHEMICAL INDUSTRY

Being a $450 billion-a-year enterprise, the chemical industry in the United States is a key element of the country's economy and nation's largest exporter, accounting for 10 cents out of every dollar in the U.S. exports, said Gregory Bond of Dow Chemical Company. The chemical industry is critical to a wide variety of markets essential to human needs, such as food, transportation, electronics, health and medicine, personal and home care, and building and construction. In

addition, chemistry companies invest more in research and development than any other business sector.

The industry has had a long history of conducting testing, exposure, and risk assessment in practicing product stewardship. It has recognized for a long time that some of its products are inherently hazardous and is therefore continuing its commitment to evaluate risk responsibly. The industry is participating in developing sound public policy and trying to improve its communications; however, there is room for improvement, said Bond. Sixteen years ago, the industry recognized the importance of improving environmental health and safety performance and their dialogue with the public and launched Responsible Care, which evolved into an environmental health and safety management systems approach.

Today's chemical industry is very sensitive and responsive to the growing number of public concerns regarding the use of chemical products, said Terry Yosie of the American Chemistry Council. The chemical industry attempts to design programs that focus on product safety and health. One of the programs adopted in the United States in 1988 is Responsible Care. Responsible Care focuses on outreach, dialogue, and interaction of stakeholders and connects the initiative with the actual business operations within chemical companies as well as their business partners.

Other companies, such as Xerox, are trying to minimize their contribution to pollution by discovering ways to use their products responsibly. Xerox does not manufacture paper; it buys finished and already packaged paper and distributes it, said Jack Azar of Xerox. Therefore, the company has certain environmental requirements to the company's various suppliers and encourages them to be more environmentally responsible. Xerox's suppliers have to meet the following requirements: (1) compliance, wherever the supplier is operating; (2) effective paper mill EMSs; (3) manufacturers that control their own forests must have those forests third-party certified; (4) manufacturers that buy fiber and convert it through their mills into finished paper have to receive a third-party chain of custody certification. Today, 82 percent of the 60 suppliers worldwide that Xerox uses for paper are in compliance with the requirements.

Green Chemistry

According to the *Wall Street Journal*, the pharmaceutical industry spends $90 billion a year to manufacture drugs (Abboud and Hensley, 2003). Many companies in the pharmaceutical industry are using green chemistry principles at commercial scale, but possibly hundreds of millions of kilos of waste could still be prevented by broadly adopting green chemistry, said Berkeley Cue of the Green Chemistry Institute. The pharmaceutical industry is devoted to discovering and developing new medicines that will enable patients to live longer, healthier, and more productive lives. Sustainability and environmental health are important to the industry for its environmental, economic, and social performance. The

pharmaceutical industry is exploring the possibilities to make existing commercial manufacturing processes more environmentally friendly. According to Cue, the real battle yet to be fought is going to be in the laboratories, especially with the discovery of chemicals and start to set the strategy for how chemicals are going to be synthesized throughout the life-cycle.

Industry Volunteerism

Industry plays an essential role in the generation of hazard data, but there are limitations to that role, and there are very important roles that government needs to play, said John Balbus of Environmental Defense. Industry volunteerism does not include the need for substantial government resources. The voluntary programs are very beneficial, but they still require substantial government resources for monitoring, tracking, third-party validation, and dissemination. There is an inevitable conflict of interest in the voluntary programs, and that may be putting some limitations on the products of these programs. Thus, voluntary programs seem to work best where there is a good regulatory backstop, noted Balbus. Industry volunteers in a number of programs that are not required by the government regulations. Such programs include the High Production Volume (HPV) Challenge, the Organization for Economic Cooperation and Development Screening Information Data Set (OECD-SIDS) program, and the Voluntary Children's Chemical Evaluation Program (VCCEP).

GLOBAL IMPLICATION OF ENVIRONMENTAL STANDARDS

Central to any country's environmental program is their management of the tens of thousands of chemicals used daily in commerce. Although a sound chemical management program is the keystone for ensuring both public health and healthy environments, determining which chemicals to monitor and how to implement the program provides a challenge for all countries, whether they are developing or developed. During the workshop, Roundtable members, speakers, and participants discussed the management approaches in Europe, the United States, and Canada and the implications for improving management of chemicals around the world.

The challenges of risk and risk assessment in protecting public health through regulation of chemicals requires looking at the changes in Europe, according to Bernard Goldstein, Graduate School of Public Health, University of Pittsburgh. Central to the current debate about environmental control in the European Union is the precautionary principle. The Rio Declaration defined the precautionary principle as: "Nations shall use the precautionary approach to protect the environment where there are threats of serious or irreversible damage. Scientific uncertainty shall not be used to postpone cost-effective measures to prevent environmental degradation" (United Nations Conference on Environment and Development, 1992). According to Goldstein, the precautionary principle is one

of those positive statements with which, in principle, everyone can agree. It is similar to the idea of sustainable development—something that is loosely defined. However, he noted that the use of the precautionary principle in a legal framework suggests the need for further scrutiny.

Invoking the precautionary principle requires some degree of scientific uncertainty about the worst case. If there was scientific certainty, there would be no need to invoke the precautionary principle. Further, the precautionary action needs to have significant economic or social costs. If the costs were trivial, the action would be taken without the need to invoke the precautionary principle. In essence, the precautionary principle is used for situations in which resources are to be invested, despite there being no surety that adverse consequences will occur. Thus, the more precautionary a country is, the more often that it is going to spend money, resources, and social capital for the wrong reason. Goldstein argued that one needs to build in an evaluation to determine if the precautionary approach is warranted.

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>
> *—Bernard Goldstein*

Global Corporate Policies on Health, Safety, and the Environment

Voluntary corporate policies can provide improved protection of human health and the environment, particularly in poor countries, noted Barry Castleman, Environmental Consultant. The vacuum of regulation and liability in many countries has allowed global corporations to operate without applying safeguards required of them in Europe and the United States.

The tragedy in Bhopal, India, in 1984 brought the issue of corporate "double standards" to the world's attention. Numerous safeguards in effect in the United States, such as plant design, safety systems, and maintenance, had been neglected at the company's plant in India, noted Castleman.

After the tragedy in Bhopal, multinational corporations began to issue global corporate policy statements based on the premise that there was no justification for operating a chemical process under less strict conditions of pollution control and worker protection in one country than another. In order to be successful, these company standards have to be applied to all aspects of production and marketing, stated Castleman. Some corporations assert responsibility for not only their subsidiaries but also their suppliers by auditing the occupational and environmental conditions of these suppliers and requiring conformity with corporate standards. On the other hand, companies that transfer environmentally dangerous production to other ones, where they appear as the customer but not the manufacturer, can make no claim to corporate social responsibility.

Further, the same care needs to be applied in marketing of the products. "Double standards" issues arise in labeling, worker training, and product stewardship. For example, pesticides withdrawn for uses in the United States should be withdrawn for those uses worldwide, asserted Castleman. Another example is hazardous waste disposal in countries that do not have the proper facilities set up by the government or under some governmental regulation. In such countries, a responsible company should practice same policies of hazardous waste disposal as required in the United States.

In addition, there needs to be public disclosure of toxic releases worldwide, stressed Castleman. Corporations in the United States often have policies not to sell chemicals to companies that do not use them in a reasonably sound manner. This practice needs to be corporate policy in other areas of the world, regardless of liability considerations, asserted Castleman.

The REACH Initiative

The European Union has the same issues as the United States but in a much more crowded situation, noted Robert Donkers of the delegation of the European Commission to the United States. The European Union has more than 450 million people in an area half the size of the United States. REACH is a response to the opinion in the EU that the burden of proof of what chemicals are not safe is no longer on the authorities. Rather, it is on industry to prove that its chemicals can be used safely. Currently, the burden lies with the government, which needs to spend enormous resources to ensure that the chemicals can be used safely, noted Donkers. The European Union is looking at REACH as an opportunity to ensure that industry is doing what they promised for years—responsible care and product stewardship.

The REACH initiative, according to Donkers, will be based on information and science provided by industry and checked by authorities to determine if the EU needs to take management action. The precautionary principle will be invoked when industry will not play its role and does not deliver the information necessary; and, on the basis of information available, it would be irresponsible to wait to take action. In the European Union, measures enacted on the basis of the precautionary principle are not permanent, and are regularly reviewed on a case-to-case basis as more scientific information comes available.

Working with REACH: Practical Observations

James Bus of Dow Chemical Company suggested that industry should not be viewed as pushing back on the REACH initiative in the context that it should not move forward. Rather, he noted that the initiative is a complex new piece of regulation that affects the marketing of chemicals in the European environment. It is reasonable to have a robust dialogue between the government agencies, affected

parties, industry groups, and other stakeholders to ensure that ultimately there is a legislative outcome that achieves the purpose that was originally intended.

Bus suggested that the need for reform is real—both in Europe and the United States—where there is a distinction between new and existing chemicals. Dow does have an extensive database that has information on where their chemicals are being utilized. However, it is not a perfect system. There is an opportunity for improvement. Any system that gives a greater degree of confidence of the full (breadth) of uses of the chemical helps to elucidate the potential risks, acknowledged Bus.

In conclusion, Bus suggested that as the REACH program moves forward, there is a need to have a productive dialogue between industry and the European Union authorities. This continued dialogue can help to achieve REACH's objectives by putting in place a chemical management program that achieves improvements and refinements in understanding human health and risk.

Canadian Environmental Protection Act

The Canadian Environmental Protection Act (CEPA) is the primary federal legislation in Canada that is used to protect human health from environmental risks. As broadly defined, substances of concern are both organic and inorganic matter and include almost anything in the environment that could be a potential hazard to human health, noted Daniel Krewski, Institute of Population Health, University of Ottawa.

CEPA was introduced in 1988 and is required by law to be reviewed periodically. CEPA is focused on national issues, but done in cooperation with the provinces. Primarily, the provinces are responsible for health protection; but trends, boundary issues, issues of national concern such as air quality are implicit in the scope of CEPA. The provinces and the federal government work jointly to implement the intent of CEPA through a series of federal provincial committees (e.g., the committee on environmental health, the committee on drinking water). The act contains a number of key features, including jurisdiction and management. There is a shared jurisdiction of implementing CEPA between the federal Department of Health and the federal Department of the Environment. Primarily, Health Canada oversees the health assessments, and Environmental Canada oversees the environmental assessments. However, decisions on control measures are determined jointly by the two ministers of those departments following consultation with a broad range of stakeholders, according to Krewski. CEPA differs from the U.S. Toxic Substance Control Act (TSCA). Krewski suggested that one of the main differences is that under CEPA, there is a broader scope for looking at non-regulatory options, such as the use of multi-stakeholder issue tables, and allowing industry and the public to participate in the development of proposed risk management activities.

U.S. Approach to Regulation: The Toxic Substance Control Act and Public Health

It is important to note that when discussing chemical management that some of the management is outside of chemical statutes and that their management occurs in media-specific statutes, noted Lynn Goldman, Bloomberg School of Public Health, Johns Hopkins University. One example would be certain air pollutants covered by the Clean Air Act. These chemicals are interpreted through specific approaches that are often based on an engineering approach and are not usually a risk-based approach. Media-specific approaches are not very conducive to looking at a chemical from cradle to grave, which considers the entire life cycle of the chemical or a process. Media approaches can push a chemical from one medium to another, but never quite address the life cycle and what the alternatives might be, noted Goldman.

The life cycle of a chemical starts with research and development, through production, and then use by workers. The use of the chemical can often be just as important as the production. However, often a regulator of a chemical does not have information about use. It is difficult to do a risk assessment without knowing about use and exposure, she noted.

The standard for TSCA for all chemicals is the unreasonable risk standard. This standard is more than a common denominator—it doesn't differentiate between the types of exposure, the quantities of exposures, or the scenarios for exposures. In addition to the factor of risk, it also includes whether the risk is reasonable in proportion to the costs that are required to control it.

A significant burden on the government to prove that a standard has been met has rendered much of TSCA ineffective, noted Goldman. One of the challenges under TSCA is new chemical approvals. New chemicals and existing chemicals are treated differently by the regulators, thus creating a bias in the law against bringing new chemicals into the market. It is easier to continue to use existing chemicals because there is little likelihood that they will be evaluated. Under the Pesticides Act, a company cannot bring a new chemical on the market without testing and approval; however the EPA can establish categories of exemptions. TSCA does not require a testing prior to submitting a new chemical to the EPA.

A second challenge under TSCA is existing chemicals. At the time that TSCA went into effect, approximately 70,000 chemicals were grandfathered into use and placed on the inventory. This is not a true list as some of the chemicals are mixtures and some chemicals have overlapping structures. However, the point is that there is a volume of chemicals in commerce, and primarily the focus has been on high-production chemicals. This again is a limitation of TSCA as it has not been very beneficial in producing data. Every year, there are a few chemicals that undergo testing through the use of test rules; however, to get a test rule written, the government needs to make a proof of unreasonable risk in order to have the chemical tested. Without any data on hazard and exposure, it is difficult to have a test rule written, observed Goldman.

There is very little rule making and risk management out of the EPA as a result of TSCA. This means that all the risk management for chemicals occurs under statues like the Clean Air Act and does not occur under the laws covering chemicals. The result is that the government focuses on end-of-the-pipe solutions rather than pollution prevention-related solutions. It further creates problem with shifting pollutants between media as discussed earlier. TSCA does not reward efforts to develop safer processes of resource reduction, and it does not replace media by media-specific regulations.

International Cooperation on Regulatory Issues

In 1990 as preparations were underway for the UN Conference on Environment and Development (UNCED), there was a heightened interest and activity in addressing toxic chemical issues. There have been some international mechanisms established to coordinate the efforts of international government organizations and other international stakeholders in addressing the UNCED's goals. Currently, there are at least 52 global and regional agreements that address the use of chemicals. There were 7 agreements in the 1970s, 13 in the 1980s, and since 1990, there have been 30. These agreements cover air pollution, water pollution, biodiversity, specific toxic chemicals, chemical weapons, industrial accidents, storage and transportation, trade in chemicals, and trans-boundary waste.

The problem facing the international arena is how to work with the plethora of agreements. At the World Summit on Sustainable Development in Johannesburg in 2002, the world leaders were "aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment" (Johannesburg, 2002). It was noted in the specific recommendations that both technical and financial assistance will be needed for developing countries and economies in transition to build their capacity.

INDUSTRY'S CONTRIBUTION TO IMPROVING THE GLOBAL COMMUNITY'S HEALTH

We are living in a fragile, complex, and dangerous world, said Djordjija Petkoski of the World Bank. Imbalances in the world, such as the wealth gap, generational gap, and poverty, have direct impact on environment and health. Poverty has a substantial impact on the environment because the poor have less access to information and services; less formal or non-relevant education is associated with risk behaviors, especially by youth; and economic need forces poor women and migrants into risky work environment that poses high risk in communicable diseases. Furthermore, poor neighborhoods tend to have fewer doctors and pharmacies, inadequate transportation and recreation facilities, and lower availability of healthy food and clean water. Without these services it is difficult, if not impossible, to provide access to basic public health systems.

The lack of institutional capacity and sound governance contributes to many of our global community health concerns. If a country's energy capacity is developed, we have the potential to enhance a community's access to economic, social, and health resources, said Brian Flannery of ExxonMobil. Capacity building is therefore a necessary step toward improving community health.

Energy companies such as ExxonMobil Corporation have the potential to develop capacity and, consequently, alleviate poverty. Issues of global community health can be examined from a number of perspectives, including EMSs, policy implementation, and CSR. The ExxonMobil Chad-Cameroon oil pipeline project illustrates the principles of community health management. This project involved the construction of an oil pipeline from ExxonMobil's oil production facility in Chad through neighboring Cameroon to the African Coast. This large-scale project had numerous environmental, health, and economic impacts. The strategies for managing these impacts were sometimes cited as examples of successful implementation; however, there were weaknesses in these strategies and methods for filling in the health gaps left by ExxonMobil's pipeline project, noted Flannery. Before construction could begin, ExxonMobil had to develop a strategy to address the social, economic, community, and structural challenges that such a large-scale project would pose, said Andre Madec of ExxonMobil.

In both Chad and Cameroon, ExxonMobil created health management plans to protect the health of pipeline workers and communities neighboring the pipeline. One of the major public health initiatives established by ExxonMobil during oil pipeline construction was the Community Health Outreach Program (CHOP), noted Burton Singer of Princeton University. The general objective of CHOP was to target selected health issues in communities potentially affected by the oil pipeline project while specifically focusing on locations in the vicinity of permanently staffed project field facilities. Strategies for the implementation of CHOP included (1) focusing on specific diseases and public health conditions most likely to affect the oil pipeline workforce or the larger community affected by the project; (2) initiating the program during construction and operation phases; (3) adapting support projects to varying socio-cultural settings; and (4) targeting education and other preventive and curative project-related health issues.

CHOP's successful programs have application potential throughout Chad and Cameroon. By collecting health and environmental data on ExxonMobil's programs, regional health plans can be developed to incorporate CHOP's successful techniques.

CORPORATE SOCIAL RESPONSIBILITY

CSR has gained more interest in the past decade, however it is not a new idea; it dates back to the 1930s, said Eric Orts of the University of Pennsylvania. Just before World War II, a German industrialist Walter Rathenau claimed that business corporations have become very large and that they had grown to be a

significant part of the society. According to Rathenau, even though fundamentally a corporation's intent is the pursuit of private interests and profits for owners of the company, they increasingly are bearing the marks of an undertaking and, to an increasing degree, have been serving the public interest (Kessler, 1930). Further, philosophers John Dewey and James H. Tufts in their book *Ethics,* published in 1908, raised the concept that it is not sufficient to view companies as purely economic machines, and that companies should be involved in public duty as well (Dewey and Tufts, 1908).

CSR is not a static concept—it is a moving, evolving target, said Norine Kennedy of the U.S. Council on International Business. According to Kennedy, there is no solid definition of CSR; however, it is not a replacement for the governmental role and responsibility in meeting challenges of sustainable development.

The scope of corporate responsibility varies country by country, region by region, interest group by interest group. At a minimum, it includes environmental issues, but it also takes on social, ethical, governance, health, and other issues. Potentially, it is a very broad concept to cover, and it is a challenge for the business community.

The phenomenon of CSR emerged because of globalization, stated Kernaghan Webb of Carleton University in Ottawa. Globalization increased movement of people, goods, ideas, and corporate activity across borders. The underlying premise of CSR is that organizations should behave with equal respect to people and the world, wherever they are. Advances in telecommunications (e.g. the introduction of the Internet), NGO activity, and media scrutiny mean that an organization's activities can be critically tracked and followed more easily than ever before, regardless of their location. CSR is largely a phenomenon that is resulting from lack of state capacity, stated Webb.

The result of the phenomenon is a growing expectation that firms should be economically, environmentally, and socially responsible. At the same time, these expectations apply to small, medium, and large firms, and all sectors: pharmaceutical, mining, refineries, chemicals, and so on, wherever they operate.

Many initiatives are attempting to develop flexible, practical, standardized approaches for a global economy. Intergovernmental-level initiatives include such initiatives as Global Compact, the International Labour Organization declarations, OECD guidelines, the World Bank, and others. Individual governments such as the United Kingdom are taking lead roles as well. Other initiatives include investment, standards, industry, and NGO-driven and faith-based initiatives. Although all the initiatives indicate considerable engagement, there is a big challenge with content, comprehensiveness, interoperability, and take-up, said Webb.

Introduction

The Institute of Medicine's Roundtable on Environmental Health Sciences, Research, and Medicine was established in 1998 as a convening mechanism to discuss both timely and sensitive environmental health issues in a neutral environment. Members come from academia, industry, and government and their discussions serve to facilitate dialogue on various topics in environmental health. This summary report has been prepared by the workshop rapporteurs to convey the essentials of the 2-day workshop. It should not be construed as a statement of the Roundtable, which can illuminate issues but cannot actually resolve them, or as a study of the Institute of Medicine (IOM).

CHARGE TO SPEAKERS AND PARTICIPANTS

Samuel Wilson

The field of environmental health has evolved during the last several years as scientists and others have worked toward better ways to understand linkages between human health and environmental factors. This is a challenge in the United States and around the world as our understanding of the impact of the environment on human health continues to evolve. As we move forward, scientists and policy makers realize that new paradigms and partnerships are needed to address the complex environmental health challenges facing society.

Traditional View and Evolving Definition of Environmental Health

Traditionally, the field of public health has developed a working model of the relationship to health and disease that takes into account the role of such features such as genetic susceptibility, biology, and behaviors in determining health. As illustrated in Figure I–1, these features can interact and converge to result in disease. Environmental health builds on this model by identifying those

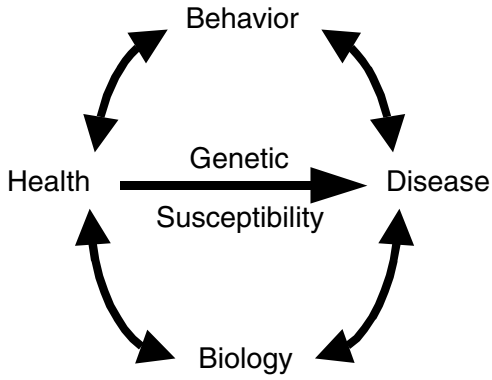

FIGURE I-1 When taking into consideration the relationship of health and disease we need to take into account the role of multiple contributing factors. SOURCE: Wilson, unpublished.

environmental factors that can interact with the features in this primary model (see Figure I-1) to influence the disease state.

The definition of environmental health continues to change. In recent years, the field has evolved toward a more holistic view of the effect of environment on health and has recognized the challenges and the opportunities inherent in this broader view in advancing the field. The World Health Organization defines environmental health as the direct pathological effects on health of chemical, physical, and biological agent and of the effects of the broad physical and social environment on human health (World Health Organization, 1986). This definition is one of many examples that not only apply to air, water, and soil, but in the broadest sense to the pathological effect on health of the broad physical and social environment. Considering these and other definitions, the Roundtable began to define environmental health as the human health impact of the holistic environment—one comprised of the natural, built, and social environments. This view superimposes a holistic view of the influence of various environments in which we live, play, and work. The Roundtable continues to look at how socioeconomic factors, the natural environment, and the built environment can interact to impact human health.

Environmental Health: New Challenges, New Strategies

Medical science is advancing and developing new and far more precise tools to investigate the linkages between health and the environment. One example is

advances in the field of genetics due to the work under the aegis of the Human Genome Project. With sequence of the 20,000–25,000 genes in human genome DNA, we are beginning a new age from the standpoint of research opportunities on gene-environment interactions. In environmental health, this will have tremendous implication. We will be able to better understand the complex question, Why does one individual when exposed to a toxicant develop disease, while another with the same exposure does not?

With the adoption of a broader view of environmental health, environmental health scientists' strategies for addressing issues have changed. In a speech in 1997, then President of MIT, Charles Vest, suggested that "For the past 30 years, environmental concerns in this country have been dominated by a mentality of government regulation and remediation." He further noted that, "In the future, industry and academia must instead play an increasingly important role in exercising environmental responsibility. We must educate engineers, managers, scientists, economics and policy experts to analyze environmental issues and synthesize sound solutions. Sound thinking about and commitment to sustainable development and environmental stewardship must be an integral part of the general education and practice of engineering management. Proactive environmentalism is good business in the growing commitment to a healthy environment on the part of both industry and academia in setting the stage for new partnerships between the public and private sectors," (Vest, 1997). His remarks frame an important concept for industry, for the field of engineering, and for this workshop, in the sense of exploring environmental stewardship.

This workshop was planned to examine some of the issues surrounding international regulations and concept of corporate social responsibility (CSR) and to understand the impact they will have for environmental health. Currently, there are pressures from shareholders and environmentally-minded individuals to encourage or require the adoption of "environment-friendly" practices, standards, and policies. Although it is clear that global regulatory standards will always be a major driver in the field of environmental health, there is growing understanding of the value of voluntary standards to fill in gaps or to work in concert with formal regulations.

Overall, this workshop was planned to help define the term corporate social responsibility, identify best practices, and consider cost-benefit issues. The workshop planning group hopes to challenge the industry to identify ways that best practices can be more efficiently shared and to address issues of privacy or trade secrets, which will allow for data to be more transparent. Federal research agencies also have roles to play, meaning that research needs to help reduce risk, especially up front, before the harm is introduced into the environment. Finally, the planning group would like to see the workshop define needs for strategic partnerships in global environmental health. This Roundtable has done an excellent job in the past on this point of identifying new partnership opportunities, and this is also a priority as we begin this exciting workshop today.

FIVE WORKSHOP OBJECTIVES

Myron Harrison

Environmental health is an extremely democratic and non-elitist issue. Anyone can be a player in environmental health, and anyone and everyone has legitimate contributions to make. The planning group reflected this in the diversity of the speakers on this program. By sponsoring the workshop, the Roundtable wanted to explore the following:

- Better understand the systems approach, that is, understanding the bidirectional contributions of individual components in environmental health by understanding the linkages and interactions of the elements from a holistic view.
- Better understand the diversity and inconsistency of global health and environmental issues and regulations.
- Better understand the challenges of operating responsibly in the absence of either health infrastructure or regulation.
- Discuss the respective roles of voluntary actions and regulation.
- Capture learnings that might promote more rapid progress toward a better environment for human health.

It is hoped everyone will better understand the challenges of operating responsibly in the absence of regulations. Sometimes from the perspective of corporations, there is too much regulation, but sometimes there is not enough, noted Harrison of ExxonMobil. There are parts of the world where there is no such thing as direction, essentially no government effectiveness of any type; and that makes it very difficult to ensure that company employees and the communities where they work have adequate health infrastructure.

1

Tools for Monitoring Environmental Health[1]

Environmental management systems (EMSs) are tools that corporations and some government agencies use to manage environmental issues. These systems may vary from facility (or agency) to facility but the basic premise is to implement the broader concept of sound and proactive environmental management. In recent years, EMSs have evolved further to respond to increasing stakeholder pressure to improve social responsibility. As more companies, federal agencies, and organizations choose to implement EMSs, such as that established by the International Standards Organization (ISO) and known as ISO 14001, it is important to consider the current state of the research concerning the relative successes and obstacles associated with existing systems in what impact it will have, if any, on environmental health. This chapter gives an overview of EMSs, their characteristics, focuses, and benefits.

ENVIRONMENTAL MANAGEMENT SYSTEMS

The environmental management concept, using the EMS as the platform, is a highly productive strategy to achieve sustainable environmental stewardship promotion throughout the federal community, said Edwin Pinero, Federal Environmental Executive. EMS provides a structured, systematic approach to negotiate environmental issues and have two key components: integration of management of environmental issues in daily operations and improvement-oriented practices. EMSs seek to bridge the gap between the environmental and business or operational sides of an organization. According to Pinero, the basic components of an EMS include:

[1]The views expressed here do not necessarily reflect the views of the Institute of Medicine, the Roundtable, or its sponsors. This chapter was prepared by Jenners Foe-Parker from the transcript of the meeting. The discussions were edited and organized around major themes to provide a more readable summary and to eliminate duplication of topics.

- A policy
- Identification and prioritization of environmental attributes (aspects and impacts)
- Goals or objectives or targets
- Implementation plans, milestones, and timelines to meet goals
- Definitions of roles and responsibilities
- Training and competency needs of workforce
- Operational controls and work procedures to manage environmental attributes
- Communications procedures and document controls
- Emergency planning and response
- Monitoring and measurement, that includes regulatory compliance and EMS auditing, and corrective action mechanisms
- Senior management reviews leading to continual improvement

While these basic components define a framework, environmental management is a broader term that also encompasses the organization's overall culture, commitment, and approach to achieve performance goal, said Pinero. For this to happen, management needs to identify the appropriate measurements to achieve goals and, at the same time, ensure that the organizational culture, leadership, and corporation's mission and operation are in step with environmental management.

The management system model is built on the premise that senior management is consistently participating or otherwise involved in management system implementation. The role of management is critical, not only for the specific responsibility of providing resources and accountability, but also for providing the leadership message and the commitment to stewardship. There are key points where senior management has a defined role and where their ongoing support is critical; for example, organization's policy, management review, the mission, vision, and support for improved environmental procedures, noted Pinero.

However, understanding why procedures are performed will produce more responsible action in the future, because the individual will appreciate the implications of their actions. Thus at all organizational levels, individuals must share the commitment to achieve company goals for sustainable environmental practices.

Best Practices

Despite wide implementation of the overall framework, EMSs are quite varied across organizations, noted Pinero. They vary in their content, coverage, and spectrum. In general, an effective EMS has three characteristics that lead to the benefits of sustainable practices. First, an EMS directs and facilitates relevant

measurements to analyze information for environmental improvement. Measurements can include environmental conditions, status of programs, compliance, and the EMS itself. Interestingly, this very point of using appropriate measurements as a management tool poses a new challenge as Executive Order 13148 goes into practice in 2006, noted Pinero. The order required the federal community to have EMSs in place by the end of 2005. As the agencies begin to implement their EMSs, the task at hand will be to measure how environmental management systems help improve agency performance rather than simply measuring progress of implementing the system.

Second, an efficient EMS focuses on measuring the aspects of, rather than the impact of, a company's environmental interaction. An EMS is built around the capacity to identify, prioritize, control, and improve upon elements of the organization that interact with the environment. Policies that promote prevention, rather than reaction, are integral to sustaining limited resources.

Third, a successful EMS utilizes a corrective action process by understanding and solving root causes. An EMS is designed to first identify the root causes of nonconformance and then initiate corrective and preventive action. In this regard, the EMS seeks to solve, rather than to control, existing environmental problems. If we do not drill down into the systemic reason for a problem, we are only treating the surface of the wound and applying bandages to the same problem over and over again, said Pinero.

EMSs have both operational and general benefits, remarked Pinero. EMSs can be used to improve the organization at large by facilitating the achievement of mission goals by systematically and operationally capturing environmental issues. In addition to increasing the awareness of impacts, consistency in operations, and promoting a more effective corrective action when problems occur, successful EMSs ultimately improve the condition of the surrounding environment. A compliance management system embedded within the broader EMS addresses compliance. Compliance is demonstrated throughout the plan-do-check-act elements of an EMS, including periodic compliance audits that continually manage the management system in place.

> Environmental management systems in both the federal and private sectors can be proactive mediums to achieve sustainable environmental stewardship.
>
> *—Edwin Pinero*

EMSs in both the federal and private sectors can be proactive mediums to achieve sustainable environmental stewardship. After 10 years of EMS applications throughout the world, there is hard data illustrating that every one of these benefits can be realized by a properly developed, implemented, and maintained EMS, concluded Pinero.

ENVIRONMENTAL MANAGEMENT SYSTEMS IN PRACTICE

Although the benefits of EMSs suggest improved performance, researchers are beginning to understand where, when, and how improvements are achieved. Deanna Matthews, of Carnegie Mellon University, has conducted research concerning the link between EMSs and improvement in environmental performance. Within a firm, the EMS and related information systems provide information on the status and progress of environmental activities. Decision makers use this information to change operations and technology to improve environmental performance. External to a firm, one can judge environmental performance by examining publicly reported data. Trends in these data guide policy makers to develop regulations regarding the use of EMS (Figure 1-1). One aspect of her research concentrates on the internal information flow and operations within firms. In general, she found that there is a lack of information flow from EMS departments to leadership positions, which led Matthews to question the probability of significant environmental performance improvement within each corporation.

The second aspect of Matthews' research examined the relationship between facility performance and EMSs using several different environmental perfor-

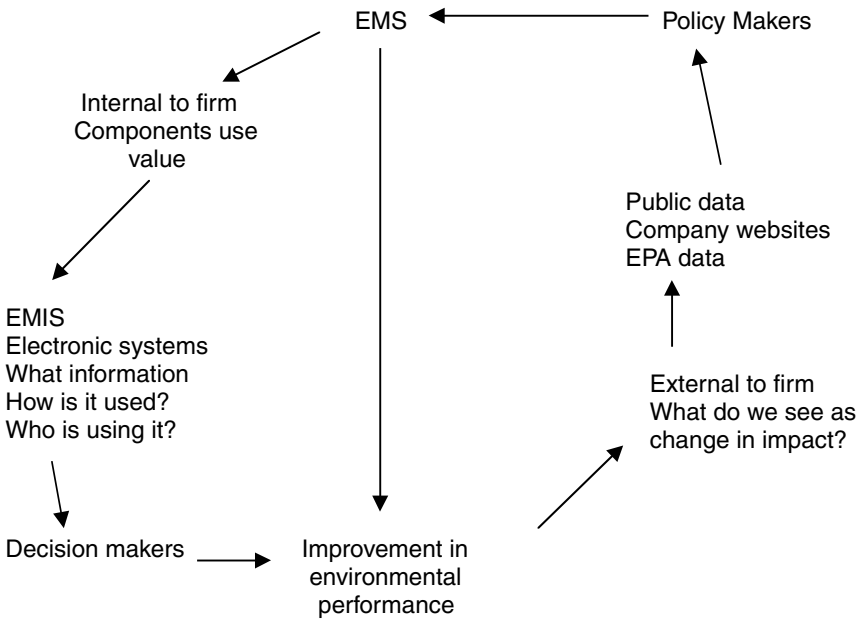

FIGURE 1-1 Overview of research. EMS and regulatory compliance are related and influenced by multiple factors. This figure illustrates the interrelation between different factors. SOURCE: Matthews, unpublished.

mance metrics—toxic release inventory releases, hazardous wastes, air emissions, and compliance history—to analyze facility performance in approximately 50 U.S. automobile assembly facilities. Overall, the results demonstrated little difference in performance between firms with and without ISO 14001 certification. This was irrespective of the length of certification or the date each company was certified.

Matthews examined regulatory compliance results to measure how EMSs and compliance relate. The study examined compliance, enforcement actions, violations, and inspections within three separate, 2-year periods (Table 1-1). The inspection rate was consistent across time. From 1996 to 1998, none of these facilities had any type of EMS certified; from 1998 to 2000, the facilities with a certified EMS had a much higher occurrence of noncompliance violations. Matthews suggested that typical regulation issues were pushed to the wayside as secondarily important to the new management systems, as management was preoccupied with implementing and operating under a compliance management system. An alternative perspective is that via EMS implementation, additional regulatory issues are uncovered or that better recordkeeping identifies issues more readily. From 2001 to 2003, as all facilities in the sample are operating under EMS, over half the facilities have a significant non-compliance event, compared to only one-third of facilities prior to implementing such a system. She suggests that the compliance record indicates that the existing environmental management system is not sufficient to ensure regulatory compliance.

Matthews' studies led to five conclusions: (1) EMS components typically relate to regulatory requirements; (2) environmental information is rarely widely disseminated internally, to decision makers; (3) EMSs have low value for communicating with stakeholders; (4) the data does not support improved environmental performance, and (5) available data suggests that while ISO 14001-certified facilities may understand and manage impacts better, they may not have better operations.

Lessons Learned

Successful management systems support decision makers to evaluate and select projects based upon an organization's goals, and to reduce liability or risk to the organization. They also support the general goals of a successful management system through proactive and cost-effective methods to improve operations to achieve better overall performance, said Matthews.

As a result of the preceding studies, Matthews developed the following five elements for cost-effective and lasting EMSs:

1. Develop process diagrams to identify material and energy inputs and outputs.

TABLE 1-1 Compliance, Enforcement, and Violations from 1996–2003 as EMS Are Implemented

	1996–1998	1998–2000		2001–2003	
	No EMS Certified	EMS Certified	No EMS Certified	Existing Certified EMS	EMS Certified
Total number of facilities	50	22	28	30	20
Facilities that have been inspected	46	20	26	26	17
Percent of facilities inspected	92%	91%	93%	87%	85%
Facilities w/violation or noncompliance event	38	20	19	23	16
Percent w/violation or noncompliance event	76%	91%	68%	77%	80%
Quarterly periods w/1 or more violation or noncompliance event	240	115	112	159	96
Average quarterly periods with violation or noncompliance event per facility	6	6	6	7	6
Facilities w/significant noncompliance	13	4	1	12	10
Percent w/significant noncompliance event	34%	20%	5%	52%	63%
Facilities where enforcement actions taken	9	9	3	18	5
Number of facilities assessed penalties	4	5	1	17	5
Total penalties assessed ($million)	0.144	0.490	0.056	1.650	0.176
Total number of enforcement actions taken	15	14	5	24	6
Average enforcement actions taken per facility	1.7	1.6	1.7	1.3	1.2
Percent of facilities where enforcement actions taken	18%	41%	11%	60%	25%

NOTE: Between 2001 to 2003, there is differentiation between firms that have been operating under an ISO 14001 EMS for a few years, and those that are just getting certified. In that period of time, 80 percent violation or non-compliance was observed at the facilities going through compliance. The compliance record indicates that the existing environmental management systems were not effective processes to ensure regulatory compliance. SOURCE: Matthews, unpublished.

2. Quantify goals for short- and long-term performance consistent with the organization strategic plan.

3. Have reliable methods for collecting and disseminating environmental information to leadership and decision makers within a corporation.

4. Use risk assessment tools for emerging environmental risks and their potential impacts.

5. Collaboration and education for environmental professions both within and external to the firm could lead to integrated and committed environmental systems.

Matthews suggested that some of the most effective lessons of the companies in her case studies came from rotating the environmental personnel from one facility to another to collaborate, check, and audit internally.

Promise for the Future

The regulatory-based nature of EMSs suggests that they have limited potential to reach beyond compliance. However, as EMSs and ISO 14001 evolve as tools for corporate-based management of environmental issues, they hold implications relevant to policy makers, management, and public health. ISO 14001 certification or EMS implementation should not be used as a proxy for continuous improvement of compliance, warned Matthews. There remains a need to bridge the information gap between the leadership and management system components of the organization and for EMS to address potential problems, especially non-regulated public health needs. In addition, a better communication between firms and stakeholders is needed, concluded Matthews. Some meeting participants suggested in the discussion that EMSs cannot be generalized, and that we need to move forward toward a more sustainable approach to governing. We need to recognize that organizations need a wide range of incentives and disincentives, and they need to be given every possible tool to assist them toward their goals. A combination of approaches coupled with command and control regulation, insurance and supply chain incentives, and community pressure can lead to sustainable improvement after a few years, noted general discussion participants.

THE ENVIRONMENTAL IMPACT OF ENVIRONMENTAL MANAGEMENT SYSTEMS: FINDINGS FROM THE LITERATURE

Environmental performance is defined as the reduction of pollution or resource uses, whether it is water or energy use, said Cary Coglianese of the Kennedy School of Government, Harvard University. The EMS is defined broadly as any kind of systematic management approach to identify environmental problems and to take action to respond to their plans.

According to Coglianese, a number of case studies suggest that EMSs can act as responsive tools to use fewer resources and generate less waste and pollution. For example, a Louisiana Pacific facility developed a corporate-wide environmental management system and, as a result, its facilities began to recognize new ways to recycle wood chips, causing a reduction in overall waste and company expenses (Coglianese and Nash, 2001). An Alcoa Corporation subsidiary in South Carolina cut waste generation in half after implementing an EMS, and in some of their facilities, they have been able to reduce the amount of waste that they generated by 50 percent (Rondinelli and Vastag, 2000).

> The environmental management system is defined broadly as any kind of systematic management approach to identify environmental problems and to take action to respond to those problems.
>
> *—Cary Coglianese*

Another study focused on manufacturing facilities in Pennsylvania where 214 manufacturing facilities were asked whether they had implemented an EMS or a pollution prevention program within the company. Also, each facility was asked to report any progress in managing their environmental affairs. With this sample, statistically significant differences were found in achieved improvements in environmental management between the companies that had adopted an EMS and those that had not. For example, approximately 75 percent of the companies with an EMS had reported making reductions in air emissions, compared with about 40 percent of the facilities that had not implemented an EMS. Similar trends were reported for water pollution and for energy use (Florida and Davison, 2001). There were significant differences between what companies with an EMS were reporting, compared with companies without an EMS.

A second large study at the University of Oregon studied 247 facilities in the electronic sector. A log of an index based upon toxic release inventory emissions was used to study the impact of the American Chemistry Council's Responsible Care program. Two statistically significant results were found: (1) older facilities had higher toxic release inventory emissions; (2) facilities with EMSs had lower toxic release inventory emissions, compared with facilities that did not (Russo and Harrison, 2004).

The large and the small studies present suggestive, but mixed, evidence that EMSs may make a difference. However, selection bias may affect results because each facility voluntarily chose to implement an EMS, perhaps making it unrepresentative of a typical firm. For example, facilities adopting an EMS voluntarily are likely to have managers committed to improving environmental performance, noted Coglianese. In this case, an EMS is a tool to be used to achieve that goal. The EMS may just be a representation or proxy for that underlying commitment. Firms with equal levels of commitment but that haven't adopted an ISO 14001 system might nevertheless manage their operations in

ways that achieve their commitment to an improved environmental performance, suggested Coglianese.

In seeking to understand why some companies performed better than others in their ability to reduce pollution, Coglianese examined management commitment to improving environmental performance. One study showed that leadership commitment played an important role in performance (Kagan, 2005). A survey of 617 facilities in the automobile sector—some of which have been required by General Motors and Ford to adopt an EMS—further tested the management commitment hypothesis. The survey found that firms with an EMS did not make substantial strides in reducing regulated air or water pollution (Andrews et al., 2005). However, they did make improvements in energy efficiency and managing spills. Further, a 2004 study analyzed facilities in states that had mandatory pollution prevention planning laws. The study found that facilities in states with pollution prevention programs reduced toxic release inventory releases by 62,000 pounds, or about an average of a 30 percent reduction (Bennear and Coglianese, 2004). However, studies also report diminishing environmental progress approximately 5–10 years after implementing planning processes. Overall, Coglianese is wary to suggest that an EMS is guaranteed to be an effective method for producing positive long-term environmental effects.

In conclusion, Coglianese suggests that a required EMS can and does make environmental improvements, but one must use caution in distinguishing how much comes from the system and how much comes from the commitment. Systems don't necessarily lead to improvements, but people and their commitment can. Nevertheless, even facilities that are required to adopt management systems or pollution prevention programs do demonstrate some performance improvements.

2

Moving Beyond Compliance: Can Industry Get Ahead of the Curve?[1]

Although environmental management systems (EMSs) are initially implemented to maintain compliance with regulations, they often have implications for lowering environmental costs, training employees, and developing indicators to measure and reduce environmental impact. An effective EMS enables an organization's officials and stakeholders to examine its values, priorities, policies, strategies, objectives, methods for allocating resources for delivering performance, and also learning. Some research suggests that EMSs can manage risks, gain competitive advantages, and achieve environmental improvements at lower costs. During the workshop the speakers, Roundtable members, and participants considered how companies could use EMSs and other tools and policies to achieve greater impact beyond regulatory compliance.

USING MANAGEMENT SYSTEMS TO IMPROVE PERFORMANCE IN THE CHEMICAL INDUSTRY

Today the chemical industry is increasingly sensitive and responsive to the growing number of public concerns regarding the use of chemical products, said Terry F. Yosie, formerly of the American Chemistry Council (ACC). The chemical industry attempts to design programs that focus on product safety and health. One of the programs that was adopted in the United States in 1988 was Responsible Care®. At the time when the program was created, it focused largely on environmental health and safety issues of manufacturing facilities. During more recent years, this program has undergone some significant changes and today Responsible Care® also addresses the need to integrate the initiative with

[1]The views expressed here do not necessarily reflect the views of the Institute of Medicine, the Roundtable, or its sponsors. This chapter was prepared by Dalia Gilbert from the transcript of the meeting. The discussions were edited and organized around major themes to provide a more readable summary and to eliminate duplication of topics.

the actual business operations, not only within chemical companies but also their business partners.

Yosie noted that all chemical companies who are members of the ACC—ACC members represent about 90 percent of the manufacturing capacity of chemicals in the United States—are required, as an obligation of membership, to participate in Responsible Care®. The scope of Responsible Care® is tailored specifically to the chemical industry and includes such aspects as continuous environmental, health, and safety performance improvement, enhanced security, increased product stewardship, improved performance across the value chain, communication with stakeholders, integration with sustainable development, and improved chemical industry reputation. ACC members are required to obtain a management system certification from independent third party auditors, and they provided the leadership to getting the industry as a whole to adopt this approach. Certification is one of the tools that can help promote cross-integration among government, industry, and non-government organizations (NGOs). The chemical industry is an industry that exists in a global market. Customer expectations have to be met and the industry is expecting its service providers and suppliers to adopt internationally recognized management systems with certification.

Responsible Care® is tailored specifically to the chemical industry and includes such aspects as: continuous performance improvement, enhanced security, increased product stewardship, improved performance across the value chain, communication with stakeholders, integration with sustainable development, and improved chemical industry reputation.

—Terry F. Yosie

Also, ACC is exploring the opportunities to integrate Responsible Care® with other business partners such as the suppliers and logistics providers. There are many opportunities to achieve efficiency across the entire business supply chain, said Yosie. The benefits of this approach are that customers are going to prefer to work with companies that can demonstrate better performance along with competitive costs. ACC collaborates with outside parties such as the U.S. Coast Guard, the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration, and the insurance industry to incorporate elements of Responsible Care® in their decision making. In May 2004, the ACC began publishing a set of performance measures and the performance of all its members against these measures. This transparency creates a dynamic where the academic community, the media, NGOs, and the government can look directly in the Responsible Care® website to determine the performance of ACC members. Also, this initiative provides a good incentive to drive performance because the whole world is watching, said Yosie.

Relationship Between ISO 14001 and Responsible Care®

Responsible Care®'s management system includes environmental health, safety, and security elements. Unlike Responsible Care®, ISO 14001 focuses on environmental issues and does not have fixed metrics nor does it require public reporting. The ISO 14001 standard does not explicitly encourage stakeholder dialog and interaction, whereas Responsible Care® includes it as an auditable function within its management system. Further, ISO-accredited auditors who conduct the certification must obtain additional training to ensure their competency in safety, health, and security issues. Finally, ISO 14001 is facility-based, and Responsible Care® is both facility- and headquarters-based.

Responsible Care® on the Global Stage

Responsible Care® is currently implemented in 52 countries. Its implementation area includes most of Latin America, Southeast Asia, Western Europe, and major North American countries. The number of participating countries is expected to grow in the future to include China, the Middle East, and Russia. In February 2006, the leaders of the major chemical industry trade associations and global chemical companies endorsed a document called the Responsible Care® Global Charter (ICCA, 2006). The charter adds new performance commitments for chemical operations around the world. It also harmonizes and makes the 52 national programs more consistent as a singular set of commitments and obligations to perform the following:

1. Adopt global Responsible Care® core principles.
2. Implement fundamental features.
3. Advance sustainable development.
4. Continuously improve and report performance.
5. Enhance product stewardship.
6. Extend Responsible Care® through the value chain.
7. Support national and global Responsible Care® governance processes.
8. Address stakeholder expectations.
9. Provide appropriate resources.

Extending Responsible Care® through the business process globally is important because, when the industry operates in a developing country, industry standards and practices are frequently well beyond existing national or local standards. With the aid of Responsible Care®, developing countries will be able to build capacity and institutions that will increase the level of skills within their population and help develop regulatory processes. For example, countries such as Latvia, Poland, and the Czech Republic were using Responsible Care® to meet the European Union entry requirements. Responsible Care® enables countries to track and influence not only how major companies perform but also how they

interact and meet societal expectations. This process facilitates the ability to track and influence how companies set their own objectives and how they participate as constructive members of civil society, concluded Yosie.

THE IMPLICATION OF TECHNOLOGY FOR ENVIRONMENTAL HEALTH

Technological advances have the potential to significantly impact how businesses operate. Although not specifically intended to reduce waste, these advances and practices can affect health and the environment. One of the advantages of technology is that it enables companies to allow their employees to telework. There are many social, economic, health, and cultural benefits of telework. Telework significantly increases employees' productivity. It increases efficiency and use of real estate. It also increases retention of personnel, reduces stress, and the employee families are happier because they can spend more time together, noted Braden Allenby of Arizona State University. However, the concept of teleworking brings out many issues that need to be addressed, said Allenby.

Environmental Impact of Telework

Due to virtual office activities, a company may no longer need excess real estate; therefore, it can consolidate its holdings, which is good for the environment and is also cost effective. When Allenby was head of health and safety at AT&T, the company did some calculations of the impact of telework. They found that because the employees did not have to commute, they cut back 100 million miles of unnecessary commuting, which came out to 5 million gallons of gasoline, which equals 50,000 tons of CO_2 that was not emitted into the atmosphere. Also, most of transportation infrastructure is designed for rush hour period; thus when people telework, rush hour period is shaved, and the demand for infrastructure is reduced.

Challenges of Telework

Despite the advantages that telework offers to employees, there are many challenges. Today, we do not know what the long-term impact of telework is going to be, said Allenby. Telework is a fundamental change in the way people behave, and it may take many years to understand what the impacts of those behaviors are. It is possible that urban sprawl may increase because, due to technological opportunities, people will not be compelled to live close to where they work. From the social perspective, a significant number of parameters are changing in the way people think about work. When the distance between family and work is collapsed, the impacts on the family and the worker are not known. When the worker's computer is on all the time, it may be difficult to divide between

work, play, education, and family—or the divide may become obsolete. Even today, vacations are becoming obsolete, said Allenby, because when people go on vacation they take their laptops, palmtops, and cell phones to be able to keep up with their work. Otherwise, if they don't do that, they will be overwhelmed with the amount of information they will have to process when they get back from their vacation.

Telework changes the pattern of life profoundly. It enables older persons and disabled people to come and work as equals in an organization. It changes the concept of retirement and the pension system. Taxation of teleworkers is also challenging. The tax system in the United States is place-based, meaning one gets taxed where they live or work. The challenge is to determine where one works if one is virtual. Another challenge is legal issues. Most of the workplace law today is based upon a manufacturing assumption; therefore, lawmakers need to face the challenge of working out new workplace law that is applicable to telework.

The challenges of telework are more profound than just environmental impact, said Allenby. It is also important to understand the operation of the institutional organization well enough to identify the opportunities to make strategic advances that also benefit the environment and the society, concluded Allenby.

CRADLE TO GRAVE: UPSTREAM SOURCES

Xerox Corporation has a waste-free strategy that has been in development for approximately 13 years, said Jack Azar of Xerox Corporation. The strategy started out with waste-free facilities, expanded into waste-free products, and, ideally, it plans to allow its customers to be waste free as well. In the past 10 years, Xerox avoided approximately 1.5 billion pounds of landfill waste. The calculations on the amount of hazardous materials (solid waste such as lead, chromium, mercury, and cadmium after it is separated from recyclable waste) are about 0.3 percent. Avoiding landfill and the use of raw material is energy efficient and helps reduce CO_2 emissions.

The most important factors to make the product life cycle work, with respect to hardware, equipment, and information technology, is to design up front for the product life cycle, observed Azar. Developing environmental benefits works better if it is done in segments, noted Azar. If a company just takes a product, introduces it as the identical product back to commerce, the approach can only go so far. Xerox found that product conversion developed for remanufacturing, reuse, and parts commonality right up front is a better approach. This process leads to significant waste reduction, extends the life cycle of products, and brings out new features and qualities in a product set, said Azar (Figure 2-1).

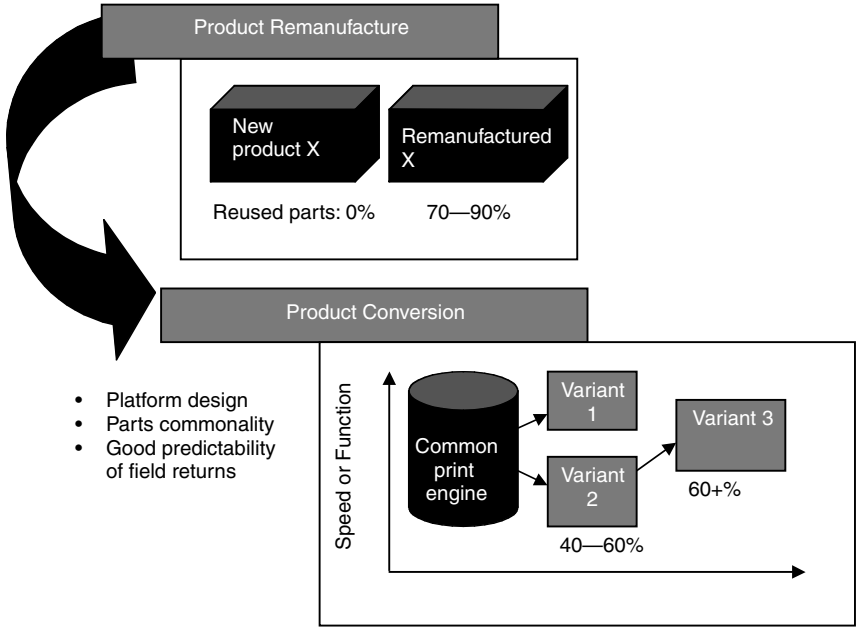

FIGURE 2-1 Xerox Corporation's approach to product conversion developed for remanufacturing, reuse, and parts commonality. This process leads to significant waste reduction, extends the life cycle of products, and brings out new features and qualities in a product set. SOURCE: Azar, unpublished.

Outsourcing of Manufacturing

Xerox is trying to discover a way to use paper responsibly. Xerox does not manufacture paper; it buys finished and already packaged paper and distributes it. Manufacture of paper is a highly energy-intensive industry; it takes 10 watts to produce every sheet of paper; creating that energy contributes to pollution. Even though the manufacturing of the paper is technically not in the company's control, Xerox requires that various paper suppliers' operating policies and manufacturing procedures are consistent with the company's reputation of its brand and environmental values and encourages them to be more environmentally responsible. Therefore, Xerox's suppliers have to meet the following requirements: (1) compliance, wherever the supplier is operating; (2) effective paper mill EMS; (3) manufacturers that control their own forests have to have those forests third-party certified; and (4) manufacturers that buy fiber and convert it through their

mills into finished paper have to receive a third-party chain of custody certification. For example, if the wood came from Brazil, Canada, Indonesia, or Finland, Xerox needs to know its origin and that the supplier is certified by a third party.

Today, 82 percent of the 60 suppliers worldwide that Xerox uses for paper are in compliance with the requirements. Cultural and trade barriers around the world may make this approach challenging; however, the company is trying to do what it can to minimize the risks and conduct its business appropriately, concluded Azar.

EMBRACING SUSTAINABLE DEVELOPMENT: GREEN CHEMISTRY

The pharmaceutical industry is devoted to discovering and developing new medicines that enable patients to live longer, healthier, and more productive lives. Sustainability and environmental health are important to the industry for its environmental, economic, and social performance, said Berkeley Cue of the Green Chemistry Institute's Governing Board. Sustainability indexes measure the performance of chemical industry cohorts that manage large sums of investment capital on the order of hundreds of billions of dollars a year.

Green Chemistry

Green chemistry was created by Paul Anastas from the EPA and John Warner from the University of Massachusetts as a set of principles that reduces or eliminates the generation of hazardous substances in the design, manufacture, and application of chemical products (Anastas and Warner, 1998). By looking at the companies who are performing well and identifying what attributes they exhibit in the design of their chemical products or their chemical manufacturing processes, Anastas and Warner described 12 principles that encompass the framework of green chemistry:

1. Prevention
2. Atom economy
3. Less hazardous chemical synthesis
4. Design safer chemicals
5. Safety solvents and auxiliaries
6. Design for energy efficiency
7. Use renewable feed stocks
8. Reduce derivatives
9. Catalysis
10. Design for degradation
11. Real-time analysis for pollution prevention
12. Inherently safer chemistry for accident prevention

Design for degradation is very challenging for the pharmaceutical industry, noted Cue. The industry would like to have the molecules that they produce go out into the environment completely degraded to innocuous entities, and must have them stable in the dosage form and in the patient's body until they get to the site of biological activity without degrading.

GlaxoSmithKline found that about 80 percent of the waste that is generated in a production process is solvent, and 20 percent is solid waste. Sometimes the solvent can be recycled and recovered, but it is a very inefficient process with only 40 to 50 percent yield recoveries, and it is very energy intensive. Sometimes solvents can be burned as a coadditive to fuel oil to generate energy; however, burning creates greenhouse gases. Further, the pharmaceutical industry pays twice for the solvent: when they buy it and when they dispose of it, observed Cue. In many cases, the disposal costs from the hazardous solvents are substantially greater than the purchase costs of the solvent. Thus adopting green chemistry at all phases of research and development could have a tremendous impact on the economic bottom line and the environmental bottom line for the industry, said Cue.

The pharmaceutical industry is exploring the possibilities to make existing commercial manufacturing processes more environment-friendly. According to Cue, the real battle yet to be fought is going to be in the laboratories, especially for the chemists who design the molecules; the chemists will be the ones to set the strategy for how the molecules will be synthesized throughout the entire life of the product.

In 1996, the EPA Presidential Green Chemistry Board created an initiative to promulgate the practices of green chemistry by giving industries an award in five categories: (1) alternate synthetic pathways; (2) alternate reaction conditions; (3) design of safer chemicals; (4) small business focus, which can be any of the focus areas above; and (5) an academic investigator award. Since 1996, four pharmaceutical companies won the award: Lilly Research Laboratories in 1999, Roche Colorado Corporation for alternative synthetic pathways in 2000, Pfizer Inc. in 2002, and Bristol-Myers Squibb Company in 2004. Lilly's award was given to the company for chemistry work they did developing a candidate for a non-competitive alpha-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid (AMPA) antagonist for treating epilepsy and neurodegenerative diseases. The new process consisted of seven manufacturing steps with only three isolations. It eliminated 34,000 liters of solvent, 300 kilos of chromium waste per 100 kilos of the active pharmaceutical ingredient, more than tripled the overall yield, and used an innovative bioreduction. Interestingly, this drug candidate did not make it to the marketplace. Cue noted that less than 5 percent of the drugs that start out in development make it all the way to the market. Therefore, there is a disincentive to work on the commercial manufacturing process too soon. However, companies need to establish their manufacturing process early on to meet their business and regulatory requirement, and green chemistry allows them to do this.

According to the *Wall Street Journal* and the Consortium for the Advancement of Manufacturing in Pharmaceuticals (CAMP) the pharmaceutical industry members spend $90 billion to manufacture drugs (Scherzer, 2003 and CAMP, 2002). Cue noted that Roche Colorado targets and achieves a 25 percent reduction in the manufacturing parts of their processes using green chemistry. Not all companies meet the same target as Roche, but Cue noted that if other companies achieve a 10 percent reduction of the process, it would save $9 billion a year that would be available to the pharmaceutical industry for reinvestment in research and development to bring new products along. Thus according to Cue, green chemistry makes good business sense.

Cue noted the multiple opportunities for the pharmaceutical industry:

- The industry needs to adopt a "benign first time" mind-set, with no exemptions for lab chemists.
- The industry needs to move from fossil fuel–based raw materials and start looking at biomass-based raw materials (organic material such as crops, crop wastes, trees, wood waste, and animal waste).
- The industry needs to measure and publish the pertinent environmental factors as a way of establishing metrics and setting improvement goals.
- The industry needs to apply a more extensive use of benign solvents such as water, supercritical CO_2, ionic liquids, and solvent-free chemistry.
- The industry needs to collaborate more closely with academia, government, and NGOs through more industrial seminars, communication, participation in workshops, and by recruiting and hiring chemists who are trained in green chemistry.
- The industry needs to integrate chemical synthesis and chemical engineering concepts.

Cue pointed out that many companies in the pharmaceutical industry are using green chemistry principles at commercial scale, but possibly hundreds of millions of kilograms of waste could still be prevented by broadly adopting green chemistry. Some examples are making their way into the research and development process, especially in development. Discovery labs are the next great opportunity for us. Emerging technologies are largely untapped in this industry, which could revolutionize how active pharmaceutical ingredients are manufactured at every scale. He noted that Einstein once said, "Significant problems we face today cannot be solved at the same level of thinking we were at when we created them." This is true for industry as sustainability continues to evolve.

ANALYZING RISK PRIOR TO PRODUCTION

Being a $450 billion-a-year enterprise, the chemical industry in the United States is a key element of the country's economy and nation's largest exporter,

accounting for 10 cents out of every dollar in the U.S. exports, said Gregory Bond of Dow Chemical Company. The chemical industry is critical to a wide variety of markets essential to human needs, such as food, transportation, electronics, health and medicine, personal and home care, and building and construction. In addition, chemistry companies invest more in research and development than any other business sector.

The industry has had a long history of conducting testing, exposure, and risk assessment in practicing product stewardship. It is aware of and has recognized for a long time that some of their products are inherently hazardous; therefore, is continuing its commitment to evaluate risk responsibly. The industry is participating in developing sound public policy and trying to improve its communications; however, there is room for improvement, said Bond. Sixteen years ago, the industry recognized the importance of improving environmental health and safety performance and their dialogue with the public, and launched Responsible Care® which evolved into an environmental health and safety management systems approach.

Milestones of Environmental Health and Safety Management in the Chemical Industry

The industry has recognized that its product intermediates and wastes are inherently hazardous and must be responsibly managed. In 1934, Dow Chemical Company's leadership recognized the importance of safety evaluation of products' intermediates and wastes. Dow's contribution to the field of toxicology has come a long way since that time when the first toxicology studies were conducted in modified 55-gallon drums, said Bond.

> Being a $450 billion a year enterprise, the chemical business in the United States is a key element of the country's economy and nation's largest exporter, accounting for 10 cents out of every dollar in the U.S. exports.
>
> *—Greg Bond*

In 2004, the company celebrated the 70th anniversary of its toxicology and environmental fate laboratories. In the late 1970s, the leading companies in the chemical industry founded the Chemical Industry Institute of Technology (CIIT) to conduct fundamental toxicology research to improve testing methods and their basic understanding of mechanisms of toxicity. In 1999, this effort evolved into a global initiative called the Long-Range Research Initiative (LRI), which funds CIIT and research at university to conduct independent research into the interaction between chemicals, human health, and the environment.

Other significant environmental health and safety milestones in the chemical industry include formalization of industrial hygiene in 1930s, epidemiology studies that began in the 1960s, emissions reduction starting in 1980s, the Product

Stewardship Code adopted in early 1990s, and finally, industry metrics adopted in 2002.

From the very beginning there has been an emphasis by the companies on publishing the results of their studies in peer-reviewed literature. However, in spite of the efforts, environmental health and safety programs in companies have been far from perfect, said Bond. They were not of uniform quality across the industry, and there have been notable incidents that have occurred in the industry that have led to some important and useful regulations.

Federal Regulations That Help Ensure Chemical Safety

In the United States, there is a strict comprehensive set of rules that is found in more than a dozen federal laws, said Bond. Similar laws exist in other developed countries and are being rapidly promulgated in the developing countries around the world. The Toxic Substances and Control Act (TSCA) is the primary piece of legislation that governs industrial chemistry. It gives the EPA broad authority to screen and regulate new and existing chemicals. The EPA has the authority to prohibit manufacture and distribution of a substance if it is found to pose an unreasonable risk, noted Bond. A company must notify the EPA prior to bringing any new chemical to market and must provide the EPA with the new chemical's identity, properties, available hazard data, anticipated production volume, by-products, use, environmental release, disposal practices, and human exposure limits. EPA scientists then determine if the chemical poses an unacceptable risk.

According to the EPA's data, the agency screened more than 30,000 new chemicals between 1979 and 2001 (EPA, 2004a). More than 1,200 of those were subject to legal restrictions imposed by EPA (EPA, 2004a). The EPA has prohibited certain uses of more than 900 additional substances, using tools such as significant new use rules, consent orders, and other TSCA authorities. In more than 300 cases, companies have voluntarily agreed to conduct additional testing in response to the EPA's informal requests, and for more than 1,500 chemicals, companies have voluntarily withdrawn their request to manufacture in the face of EPA concerns (EPA, 2004a).

TSCA mandates that every four years companies need to report to the EPA their updated product volume and other detailed information on existing chemicals. Newly enacted rules require companies to submit to the EPA a significantly larger amount of use and exposure information on these chemicals. The EPA has the authority to request even more detailed information and has exercised this request for more than 1,500 chemicals.

The TSCA requires manufacturers and importers to submit within 30 days any information that reasonably supports the conclusion of risk to human health and the environment. Failure to comply is subject to criminal or civil penalties of $25,000 to $50,000 per day and imprisonment.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires more than 120 scientific tests on any new product, and only after the information has been rigorously reviewed by the EPA can the product be approved for use to protect crops or public health. The process can take as long as 8 to 10 years and cost in excess of $30 million per product, noted Bond. Only about one in 20,000 chemicals that are screened and developed for potential use actually makes it from discovery to commercial use as a pesticide. Biocidal products are also regulated under FIFRA and must undergo a rigorous evaluation before they are approved for use.

The Federal Food, Drug, and Cosmetic Act establishes safety parameters for chemical content of various products and premarket approval of new chemicals, food additives, materials intended for contact with food, and coloring agents. The federal government has also developed stringent regulations for how chemical tests are conducted to ensure that the methods are consistent, reliable, and credible no matter who conducts the testing.

EPA data indicate that there are approximately 9,000 to 15,000 chemicals in U.S. commerce, about 2,800 of which are produced or imported in quantities of a million pounds per year and which account for more than 90 percent of the volume of chemicals in commerce (EPA, 2004a). Although the regulations described above are an important backstop to assure the public of the safety of chemical products, many companies in the industry go well above and beyond what is required by law to assure the safety of their products, said Bond.

Chemical Industry's Product Stewardship and Trends of Public Expectations

Dow and many leading companies have publicly committed to operate according to local standards or company standards, whichever are stricter, around the globe (Figure 2-2). It prevents costly employee illness and injuries, increases customer loyalty, and helps to avoid costly litigation, noted Bond.

According to Bond, in the past decade, the chemical industry has witnessed a successful shift in attention away from its operations toward its products. The focus on the toxic release inventory (TRI) and emissions reduction has lowered many point source pollution sites and has shifted focus to nonpoint sources. However, the industry still faces challenges.

> The lack of transparency in the past has caused people to assume the worst about the chemical industry.
>
> *—Greg Bond*

First, the lack of transparency in the past has caused people to assume the worst about the chemical industry. Demands for more product testing continue, and legislation now being promulgated in the European Union will make this a reality, said Bond.

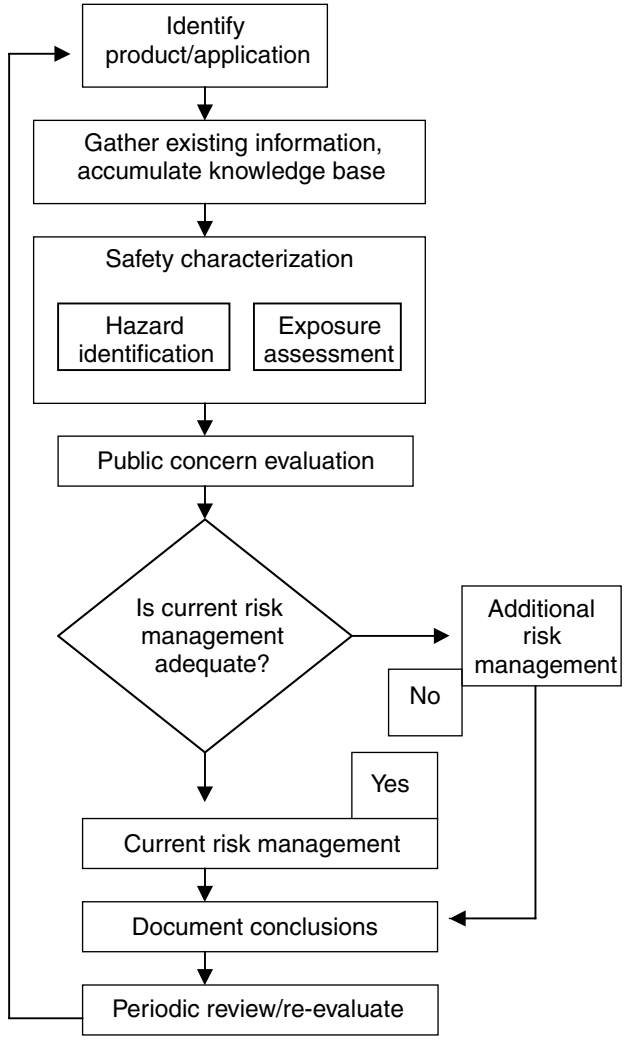

FIGURE 2-2 Among many leading chemical companies, Dow is committed to operate according to the environmental standards. The figure illustrates the general approach to product safety taken at Dow. SOURCE: The Dow Chemical Company, 2004.

In addition, the industry has to add new end points such as endocrine screening and testing to its repertoire. At the same time, there is a highly visible and vocal animal rights community demanding that the industry reduce the use of or ban all animal testing, making for a difficult balancing of competing demands.

Second, there are concerns that the existing safety margins already built into the safety assessment and risk management processes are not adequate to protect children, elderly people, or other vulnerable populations who may have special susceptibility. The public continues to raise questions about chemicals in the environment that are responsible for many human diseases, particularly cancer, asthma, and developmental disabilities such as attention deficit disorder and autism. The causes of such diseases are typically not known, and epidemiologists doubt whether existing tools can answer one way or the other if chemicals are the cause.

Finally, the industry's risk assessment paradigm is also under discussion, with some opponents arguing for a purely hazard-based approach. Some question if industry-sponsored scientists are inherently conflicted and not trustworthy, while others want to exclude industry-sponsored scientists from scientific panels and federal advisory panels. All the stakeholders need to be less divisive, urged Bond.

Industry's Response to Challenges

The industry continues to base its efforts on improving its performance and research. Transparency, developing and promoting credible science-based policy, and more outreach to stakeholders continues to be important, too, noted Bond.

In 1998 the chemical industry, working with the EPA, Environmental Defense, and others, launched the High Production Volume (HPV) chemical challenge program, which was an unprecedented voluntary initiative through which industry will make uniform hazard screening information on about 2,200 HPV chemicals available to the EPA and the public by 2005. The latest report, current as of January 31, 2005, is available on the EPA's website. (EPA, 2004b).

The industry has also has been participating in a voluntary EPA program called the Voluntary Children's Chemical Evaluation Program (VCCEP) (EPA, 2004c), and is sponsoring 20 chemicals in this assessment. In 2001, the American Chemistry Council (ACC) and the International Council of Chemical Associations both adopted a global chemicals management policy. The intent is to take industry product stewardship to the next level of performance, noted Bond. The policy lays out basic obligations of members to conduct product risk characterizations, to engage partners in the value chain, to understand uses and exposure, and to inform about risk characterizations. Many companies, including Dow, are building these obligations into their websites. Eventually, one will be able to go to www.dow.com and learn about their process for conducting product safety evaluations and get a summary and a layered look at the results of those product safety evaluations.

To summarize, Bond noted that the challenges that we are likely to face in the future continue to grow, even as we witness improved environmental health and safety protection. To meet these challenges requires all stakeholders to work

together in new ways. He called for the need for more collaboration and cooperation and less confrontation. He challenged that we need to get beyond the labels and the rhetoric to find practical solutions that are based on balancing sustainable economic, social, and environmental development. Just as the public is demanding more transparency and accountability from industry, the industry also needs to demand more transparency and accountability from all stakeholders in the process. The industry needs to set its priorities carefully and ground its decisions in risk assessment and science, concluded Bond.

VOLUNTARY PROGRAMS: CHALLENGES AND NEEDS

Industry plays an essential but limited role in the generation of hazard data, and there are very important roles that government needs to play in conjunction, said John Balbus of Environmental Defense. Industry volunteerism does not preclude the need for government oversight, monitoring, tracking, validation, and dissemination of results, all of which require significant government resources. Moreover, voluntary programs only work well when there is a good regulatory backstop, noted Balbus. The chemical industry has volunteered to develop hazard and exposure data in a number of programs. Such programs include the High Production Volume (HPV) Challenge, the Organization for Economic Cooperation and Development Screening Information Data Set (OECD-SIDS) program, and the Voluntary Children's Chemical Evaluation Program (VCCEP).

Overview of High Production Volume (HPV) Program

The realities of chemical safety and regulation are daunting, said Balbus. The first reality is that under the Toxic Substances Control Act, EPA must be able to demonstrate that an existing chemical poses a potential risk in order to require that its producer perform any toxicity testing—a true Catch 22, since making the risk finding is exceedingly difficult in the absence of toxicity data. As a result, over the 30-year history of TSCA, EPA has required testing for fewer than 200 of the tens of thousands of chemicals in commerce. It has turned to voluntary programs to try to bridge the gap.

According to analyses by the EPA and by the American Chemistry Council in the late 1990s, there was a striking lack of publicly available basic toxicity data for the approximately 3,000 chemicals (excluding polymers and inorganic chemicals) that were produced or imported in the highest quantities (over 1 million pounds per year) in the United States. The EPA documented that 43 percent of these high production volume (HPV) chemicals had no publicly available basic toxicity data, and that 93 percent of them were missing data for one or more of these basic tests (EPA, HPV). This situation led EPA to challenge the industry

to fill the gaps which led to the launch of the High Production Volume (HPV) Chemical Challenge in 1998. EPA indicated its intent to develop test rules for any HPV chemicals that were not voluntarily sponsored by their producers. This regulatory backstop helped motivate companies to volunteer their chemicals initially, but to date, EPA has issued only one test rule covering 17 of the nearly 300 unsponsored HPV chemicals.

Another challenge is that there are a lot of unassessed chemicals on the market, but due to limited resources, government is progressing very slowly in assessing them, noted Balbus. Therefore, it is essential for the manufacturers of those products to participate in generating the hazard information about them. The HPV program included options to reduce the cost burden on industry in generating basic screening toxicity information on their products. These options included sponsorship through consortia of producers to pool data and resources, and the encouragement of the use of quantitative structure activity relationship (QSAR) models and interpolation between members of categories of chemicals grouped together based on structural similarities, as a means of estimating rather than directly measuring toxicity data.

There are a lot of unassessed chemicals on the market, but due to limited resources, government is progressing very slowly in assessing them.

—John Balbus

Additionally, the HPV program has focused solely on generating hazard data. At that time, it was purposely set up not to include exposure data, in part because there were no adequate guidelines for how extensive that exposure data should be. Moreover, in contrast to the OECD SIDS process, there was no requirement to do any kind of prioritization or hazard assessment based on the information generated. It was strictly a hazard data generation and public dissemination exercise.

Today, about 1,900 of the original 2,800 chemicals have been sponsored, said Balbus; however, there are still nearly 300 chemicals that remain unsponsored, and some 700 have been shifted out of the US HPV program and into the OECD SIDS program, which is slower-paced (Environmental Defense, 2004). Nonetheless, the program is generating an unprecedented amount of publicly available toxicity information. A key lesson learned from the HPV Challenge is that while industry can deliver data relatively quickly, the quality of test plans and toxicity data is uneven and requires careful review by government. Public access to such data should also be provided promptly, to ensure accountability of both industry and government in such a voluntary initiative. Unfortunately, declining resources at EPA have meant long delays in making data publicly accessible. Ironically, one reason for the lack of resources for a voluntary program like the HPV is that it has to compete with regulatory programs.

Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) Program

According to the EPA, the Screening Information Data Set (SIDS) program, operated under the auspices of the Organization for Economic Cooperation and Development (OECD), is a voluntary cooperative international testing program that began in 1989. Like the HPV Challenge, the SIDS program is focused on developing screening-level toxicity information on HPV chemicals. The SIDS data are used to screen the chemicals and set priorities for further testing or risk assessment/management activities (EPA, HPV). However, unlike the HPV Challenge, the OECD SIDS program allows use of exposure information in formulating its recommendations as to whether a chemical is a priority for further work or not.

Unfortunately, there have been some serious deficiencies in many of the exposure analyses that have been done in this program, according to Balbus. While the OECD prescribes that exposure analyses must include all manufacturing facilities, at least within the sponsoring country, sweeping generalizations about low exposure potential are made based on incomplete data from just one or two facilities. Often the exposure analyses are based on unpublished data generated by the company, and in some cases, even the sponsoring government has not reviewed the data. Because the prioritization of the chemical is based on both exposure and hazard data, there have been several situations where very questionable exposure analyses have been allowed to trump clear evidence of hazard, Balbus said.

Voluntary Children's Chemical Evaluation Program (VCCEP)

VCCEP was designed to provide data to enable the public to understand the potential health risks to children from chemical exposures. For the pilot phase of the VCCEP, the EPA asked companies that manufactured or imported 23 chemicals, including acetone, benzene, ethylene dibromide, and others that have been found in children's bodies or their environments, to volunteer to sponsor a Tier 1 evaluation. The hazard evaluation part of VCCEP consists of three tiers shown in Table 2-1. One complication of the VCCEP pilot program has been that all of the chemicals evaluated thus far have had data from all three hazard tiers available and considered in the program. While the tiers for hazard data are clearly defined, the different tiers for exposure data are less clear; the result is some confusion as to what truly constitutes a Tier 1 evaluation under the VCCEP. In fact, it is unclear whether an evaluation of children's risk should even go forward based on limited first tier hazard data.

Under the VCCEP, the sponsoring company produces a document that reviews all of the exposure and all of the hazard data, models children's potential exposures, combines them in a risk assessment, and then makes a judgment as to whether or not there is sufficient information available to adequately judge risks

TABLE 2-1 Three Tiers of Voluntary Children's Chemical Evaluation Program

Tier 1	Tier 2	Tier 3
Acute toxicity	Subchronic toxicity	Neurotoxicity screening battery
Repeated dose toxicity with reproductive and developmental toxicity screens	Prenatal developmental toxicity	Carcinogenicity
	Reproductive and fertility effects	Developmental neurotoxicity
Bacterial reverse mutation assay	Immunotoxicity	
In vitro or *in vivo* chromosomal aberrations or *in vivo* micronucleus test	*In vivo* chromosomal aberrations or *in vivo* micronucleus test	
	Metabolism and pharmacokinetics	

SOURCE: EPA, 2004c.

to children, said Balbus. He noted that this is a situation that creates a potential conflict of interest, since the sponsoring company would have strong disincentives to write in a public document that their product was posing risks to children. Some of the expert peer consultation panelists reviewing the VCCEP studies have questioned several of the assumptions within the risk assessment documents, as well as some of the interpretations of the toxicity studies, observed Balbus. Furthermore, the pace of the VCCEP pilot has been very slow. Of 23 chemicals identified for this pilot back in 1999, the first chemical was evaluated in January of 2003, and the EPA did not finalize their review of that first chemical until late in 2005.

In conclusion, Balbus said that Environmental Defense feels strongly that well-designed voluntary programs can have an important role in speeding the pace of data generation, but they are not able to completely replace regulatory frameworks, and they demand dedication of government resources to ensure proper oversight and quality of the output.

3

Global Implication of Environmental Standards[1]

Central to any country's environmental program is their management of the tens of thousands of chemicals used daily in commerce. Although a sound chemical management program is the keystone for ensuring both public health and healthy environments, determining which chemicals to monitor and how to implement the program provides a challenge for all countries. This is true whether they are developing or developed. During the workshop, Roundtable members, speakers, and participants discussed the management approaches in Europe, the United States, and Canada and the implications for improving management of chemicals around the world.

BALANCING RISK ASSESSMENT WITH THE REALITIES OF UNCERTAINTY

The challenges of risk and risk assessment in protecting public health through regulation of chemicals requires looking at the changes in Europe, according to Bernard Goldstein, Graduate School of Public Health, University of Pittsburgh. Central to the current debate about environmental control in the European Union is the precautionary principle. The Rio Declaration defined the precautionary principle as: "Nations shall use the precautionary approach to protect the environment where there are threats of serious or irreversible damage. Scientific uncertainty shall not be used to postpone cost-effective measures to prevent environmental degradation" (Rio Declaration, 1992). According to Goldstein, the precautionary principle is one of those positive statements with which, in principle, everyone can agree. It is similar to the idea of sustainable development—something that is

[1]The views expressed here do not necessarily reflect the views of the Institute of Medicine, the Roundtable, or its sponsors. This chapter was prepared by staff from the transcript of the meeting. The discussions were edited and organized around major themes to provide a more readable summary and to eliminate duplication of topics

loosely defined. However, he noted that the use of the precautionary principle in a legal framework suggests the need for further scrutiny.

The basics of risk assessment comprise hazard identification, dose-response evaluation, human exposure evaluation, and risk characterization. Currently, there is some debate as to whether the precautionary principle is already incorporated into risk assessment, should be incorporated into risk assessment, or if the precautionary principle and risk assessment are completely antithetical. Individuals such as Joel Tickner and Lee Ketelsen (2001) and Mary O'Brian (O'Brian, 2000) question current approaches to risk assessment and lay out the argument for the use of the precautionary principle. O'Brian noted that risk assessment obscures and removes the fundamental right to say "no" to unnecessary poisoning of one's body and environment. Goldstein noted that these statements suggest that risk assessment has failed and we need a new approach.

However, Goldstein questioned the use of the precautionary principle used by Europeans. Although the EU has stated its support of the principle, it has carefully avoided defining it. Some individuals, he noted, question whether the precautionary principle is intentionally nebulous so the EU can use it to form trade barriers. For example, the European Union used the precautionary principle to develop the most stringent aflatoxin standard in the world (European Commission, 1997). It excluded $700 million of sub-Saharan produce to the advantage of European growers. The difference in risk is less than one cancer incident per year in Europe (Majone, 2002). In another example, based on the precautionary principle, the European Union banned imports of all beef from hormone-treated cattle, even though the European Union's own scientific committees did not find risk. The European Union lost this World Trade Organization case primarily due to the lack of risk assessment, as well as an inconsistent application of the precautionary principle seemingly to form a trade barrier. Goldstein further noted that these types of cases are going to continue with genetically modified foods and with other health and safety issues for which the EU uses the precautionary principle to form trade barriers. These cases are generalizations, but illustrate the different approaches to risk taken by the United States and by Europe. One obvious difference is that Europe does a better job of coupling environmental and trade policies. Further, one of the driving forces in the development of the precautionary principle in Europe has been a growing distrust of government and science as a result of mad cow disease, the French hemophilia scandal, and others.

> The definition of the precautionary principle used by Europeans is not fully defined for legal purposes. Some individuals question if the precautionary principle is something nebulous to erect trade barriers.
>
> *—Bernard Goldstein*

In a paper with Russellyn Carruth, Goldstein looked at whether the precautionary principle and whether it achieves its stated goals (Goldstein and Carruth, 2003). They asserted that the hazardous air pollutant components listed in the 1990 Clean Air Act is a form of the precautionary principle in practice (Table 3-1). Prior to 1990, the Environmental Protection Agency (EPA) had to determine which chemicals were "bad actors." Only after the EPA listed a chemical and went through a regulatory action could they begin to regulate it. In 1990, the Congress shifted the burden of proof by listing 185 chemicals to regulate and allowing the lengthy EPA rulemaking process only as a way to remove one of those chemicals from the list. The 1990 hazardous air pollutant amendments also specified that the best emissions standards need to be achieved regardless of the location of the source. This meant that a plant in the Mohave Desert had to achieve the same emission standards as those in the middle of Washington, DC. This regulation shifted the approach from a risk-based approach to a precautionary approach. Unfortunately, the result of the use of the precautionary approach is that EPA's expenditures for research and development in the area of hazardous air pollutants has gone down. This may be due to the notion that it isn't of regulatory interest to obtain the information.

Invoking the precautionary principle requires some degree of scientific uncertainty about the worst case. If there was scientific certainty, there would be no need to invoke the precautionary principle. Further, the precautionary action needs to have significant economic or social costs—if the costs were trivial the action would be taken without the need to invoke the precautionary principle. In essence, the precautionary principle is used for situations in which resources are to be invested despite there being no surety that adverse consequences will occur. Thus, the more precautionary a country is, the more often that it is going to spend money, resources, and social capital for the wrong reason. Goldstein argued that one needs to build in an evaluation to determine if the precautionary approach is warranted.

TABLE 3-1 Control of Hazardous Air Pollutants in the United States

	Before 1990	After 1990
Burden of proof	To list chemical, EPA must demonstrate that ambient levels of pollutant produce risk	To remove chemical from list, industry must demonstrate that chemical does not produce risk
Regulatory control for listed pollutant	Risk-based application of control technology	Maximum available control technology
Role of risk assessment	Primary	Secondary

SOURCE: Goldstein and Carruth, 2003.

Goldstein concluded that the precautionary principle, if done well, is primary prevention, and risk assessment is secondary prevention. (Secondary prevention would state the risk of breathing a chemical in a room, while primary prevention would never have the chemical in the room for people to breathe). However, he noted that one should not use the precautionary principle as a place to hide behind, a way to avoid understanding science, or a shortcut to avoid a trade-off decision.

GLOBAL CORPORATE POLICIES ON HEALTH, SAFETY, AND THE ENVIRONMENT

Voluntary corporate policies can provide improved protection of human health and the environment, particularly in poor countries, noted Barry Castleman, Environmental Consultant. The vacuum of regulation and liability in many countries has allowed global corporations to operate without applying safeguards required of them in Europe and the United States.

The tragedy in Bhopal, India, in 1984 brought the issue of corporate "double standards" to the world's attention. Numerous safeguards in effect in the United States such as plant design, safety systems, and maintenance had been neglected at the company's plant in India, noted Castleman. A corporate audit by Union Carbide Corporation 2.5 years prior to the Bhopal disaster had identified many of these problems (Ives, 1985).

> The more precautionary a country is, the more often that it is going to spend money, resources, and social capital for the wrong reason. The precautionary principle, if done well, is primary prevention, and risk assessment is secondary prevention.
>
> *—Bernard Goldstein*

After the tragedy in Bhopal, multinational corporations began to issue global corporate policy statements based on the premise that there was no justification for operating a chemical process under less strict conditions of pollution control and worker protection in one country than another. In order to be to be successful, these company standards have to be applied to all aspects of production and marketing, stated Castleman. Some corporations assert responsibility for not only their subsidiaries but also their suppliers by auditing the occupational and environmental conditions of these suppliers and requiring conformity with corporate standards. On the other hand, companies that transfer environmentally dangerous production to other ones, where they appear as the customer but not the manufacturer, can make no claim to corporate social responsibility.

Further, the same care needs to be applied in marketing of the products. "Double standards" issues arise in labeling, worker training, and product stewardship. For example, pesticides withdrawn from use in the United States should be removed from use worldwide, asserted Castleman. Another example is hazardous

waste disposal in countries that do not have the proper regulation or facilities set up by the government. In such countries, a responsible company should practice same policies of hazardous waste disposal as required in the United States.

In addition, there needs to be public disclosure of toxic releases worldwide, stressed Castleman. Corporations in the United States often have policies to not sell chemicals to companies that do not use them in a reasonably sound manner. This practice needs to be corporate policy in other areas of the world, regardless of liability considerations, asserted Castleman.

How to Prevent Double Standards Around the World?

Castleman proposed a comparative survey of global policies and practices of leading firms. The practices of the leasing corporations can be used as guidance to ensure that industries and products taking root in industrializing countries are not hazardous and polluting cast-offs from other countries. Leading corporations can demonstrate their sincerity about "no double standards" by participating in a comparative survey by questionnaire and interview. The survey could provide a composite-best model, with enormous benefits to health and the environment worldwide.

Another approach for sharing knowledge and experience would be to hold a conference at which corporate health, safety, and environment officials present their proudest achievements in transferring "green" technology and assuring conformity with high standards of performance worldwide, he said.

Corporate social responsibility needs to be more than vague platitudes, flexible work hours, and well-publicized charitable gifts. We need for corporations to apply their highest standards to protect human health and the environment worldwide, concluded Castleman. By understanding how leading firms try to avoid double standards, we can best encourage other companies to improve their performance and provide ideas to people in developing countries dealing with foreign investors.

THE REACH INITIATIVE

The European Union has the same issues as the United States but in a much more crowded situation, noted Robert Donkers of the delegation of the European Commission to the United States. The European Union has more than 450 million people in an area half the size of the United States. REACH (Registration, Evaluation, and Authorization of Chemicals) is a response to the opinion in the EU that the burden of proof of what chemicals are not safe is no longer on the authorities. Rather, it is on industry to prove that its chemicals can be used safely. Currently, the burden lies with the government, which needs to spend enormous resources to ensure that the chemicals can be used safely, noted Donkers. The European Union

is looking at REACH as an opportunity to ensure that industry is doing what they promised for years—responsible care and product stewardship.

Donkers noted that there is vast lack of information on the properties of chemicals. The current system is not working as it is impossible for authorities to get all the information on properties, uses and risks, which is needed to support risk management measures. Presently, there are more than 70,000 chemicals out there about which there is scant information. It takes time to collect information required for current regulations, and then it takes time to react to the information. At the same time, the European Union does not want to hamper companies from doing business, noted Donkers. The dilemma is that people need to be able to use the chemicals while the harmful impacts of such use are minimized. However, when we don't know all the impacts we can't make all the linkages necessary.

> The European Union is looking at REACH as an opportunity to ensure that industry is doing what they promised—responsible care in public use.
>
> *—Robert Donkers*

To begin to address the issue, the European Union is attempting to centralize the system so that the EU can avoid 25 different legal systems for a chemical, which would result from a country-by-country approach, if there will not be soon a functioning and harmonized instrument for all 25 EU member states. Donkers asserted that the European Union sees a need for REACH because the current system for chemical management is inefficient:

- It is difficult to identify risks.
- There is a lack of information about most substances on the market.
- The burden of proof lies with public authorities.
- There is no efficient instrumentation to address problematic substances.
- There is a lack of incentives for innovation.

The solution, the European Union believes, is a new chemical policy. This policy, according to Donkers, has substitution and precaution as the underpin of the system. It is based on principles of sustainable development and protection of human health and the environment, also taking into account the economic and social importance of the EU chemical sector and downstream user industry. It is to maintain and enhance competitiveness, but also increases transparency and will be in conformity with the EU obligations under the World Trade Organization's rules. In addition, it provides opportunities to integrate with international efforts. The REACH initiative, according to Donkers, will be based on information and science to be provided by industry and checked by authorities to determine if we need to take management action. The precautionary principle will be

invoked when industry will not play its role and does not deliver the information necessary; and, on the basis of information available, it would be irresponsible to wait to take action. Measures enacted on the basis of the Precautionary Principle are not permanent, are on a case-to-case basis, and are very regularly reviewed as more scientific information comes available.

As in the United States, current legislation created an artificial divide between old and new chemicals (those chemicals introduced into the market place after September 1981). REACH will do away with this divide. Registration will be required for all new or existing substances above 1 metric tonne (1,000 kg) per year per manufacturer/importer, which will be around 30,000 substances. The registration process will start with the High Production Volume (HPV) chemicals. The higher the volume produced and marketed, the more information will be required (Figure 3-1). The phase in period of existing chemicals is an 11-year plan and registration of the chemicals below the 1,000-tonne limit will be required at the end of the period around 2018. An important element of REACH will be data sharing, observed Donkers—there is a need to avoid duplication of tests where animals are involved. Not all chemicals will go through the evaluation process, which would only be for chemicals where industry proposes animal testing to complete the information or when a specific chemical is singled out for in-depth examination. For the large majority of chemicals, the information on the registration is all that will be required.

A specific group of about 1,500 chemicals will be subject to the authorization process. To get an authorization, the applicant has to show that for each use the risks can be adequately controlled. The chemicals in case are either carcinogenic, mutagenic, reproductive toxicants or persistent, bioaccumulative and toxic. If users could not demonstrate that they can manage 100 percent of the risk, a temporary authorization can be given if there is a clear higher societal benefit, which is greater than the cost, asserted Donkers. The selection of the chemicals for authorization is hazard based, but the decision (authorization) will be risk based.

> Downstream use is a part of the registration process. The manufacturer or importer needs to cover all uses identified by downstream users.
>
> *—Robert Donkers*

Identification of downstream use is a part of the process. The manufacturer/ importer needs to cover all uses identified by downstream users, noted Donkers. The downstream users and their providers must implement the supplier's risk reduction measures for identified uses. If they choose not to share their use information with suppliers, downstream users have to perform chemical safety assessments for "unidentified uses," and inform the agency accordingly. Finally, Donkers noted that downstream users need to enter into dialogue with their supplies and consider taking part in consortia of providers and cost-sharing practices.

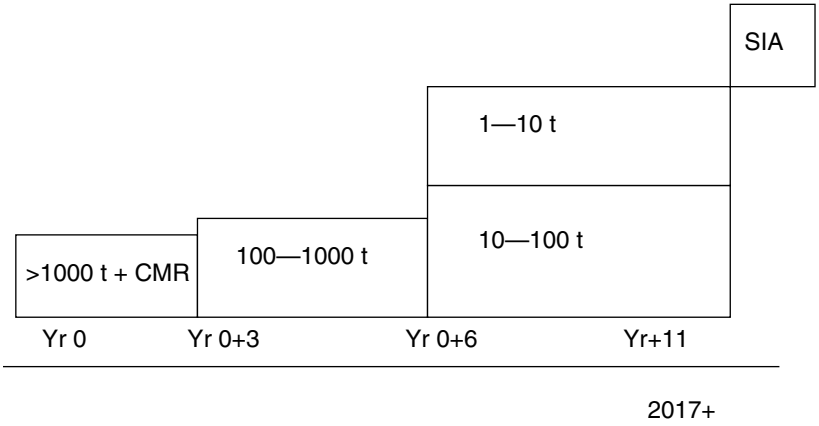

FIGURE 3-1 Schematic of the European Union's registration of substances. Not all chemicals will require registration. SOURCE: European Commission, 2003.

The cost of the program is currently estimated to be close to €6 billion, according to Donkers. The benefit of the program is still being studied, but initial figures from the World Health Organization estimate the avoided costs in terms of fatal cancer cases among the workers population alone are around €50 billion over a 30-year period. The environmental and health benefits will be evident, but will be hard to monetize as there isn't a good science base. Donkers concluded that the goal is to have an agreed legislation between the European Parliament and the Council of Ministers by 2006. Implementation will be monitored to ensure that it is consistent across the industrial sectors and provides transparency to make informed decisions about the use of chemicals by all stakeholders.

WORKING WITH REACH: PRACTICAL OBSERVATIONS

James Bus of Dow Chemical Company suggested that industry should not be viewed as pushing back on the REACH initiative in the context that it should not move forward. Rather, he noted that the initiative is a complex new piece of regulation that affects the marketing of chemicals in the European environment. It is reasonable to have a robust dialogue between the government agencies, affected parties, industry groups, and other stakeholders to ensure that, ultimately, there is a legislative outcome that achieves the purpose that was originally intended.

Bus suggested that the need for reform is real, both in Europe and the United States—where there is a distinction between new and existing chemicals. Dow does have an extensive database that has information on where their chemicals

are being utilized. However, it is not a perfect system. There is an opportunity for improvement. Any system that gives a greater degree of confidence of the full breadth of uses of a chemical can help to elucidate the potential risks, acknowledged Bus.

It is reasonable to have a robust dialogue between the government agencies, affected parties, industry groups, and other stakeholders to ensure that, ultimately, there is a legislative outcome that achieves the purpose that was originally intended.

—*James Bus*

The decentralized process of looking at chemical evaluations across the scattered governments has resulted in some inefficiency. Bus concurred that certainly high on everyone's agenda is an environment that offers a credible, scientifically based policy, where we have a good understanding of whether we are adequately protecting human health and the environment with the current use of chemicals in commerce. Further, he noted that a clear objective of any new system should be a system that creates greater transparency to customers, workers, and the stakeholder community.

We live and interact in a global world. Thus any environment that is created in the European Union needs to achieve appropriate international integration and harmonization and, at the same time, also needs to be consistent with the expectation of the World Trade Organization. Bus questioned whether the government can identify mechanisms to set priorities for those chemical selections. For the 30,000 chemicals, how do we drive a process that focuses as rapidly as possible on those chemicals that truly represent the highest risk to either health or the environment? Those chemicals that clearly have lower risks because of their properties, exposures, hazards, and so on, can be set aside for consideration at a later time during the evaluation process, noted Bus. Risk also should not focus just on production volume or drive the testing requirement for decision making, asserted Bus. The chemical industry recognizes that the risk equation does enter the REACH process; however, fundamentally the testing requirements are driven by production volume.

Certainly high on everyone's agenda is an environment that offers a credible, scientifically based policy, where we have a good understanding of whether we are adequately protecting human health and the environment with the current use of chemicals in commerce.

—*James Bus*

Bus suggested that the consideration of hazard alone should be more effectively and openly targeted with exposure and use information. This needs to occur not only in the registration and the licensing phases, but also during the authori-

zation phase. When it comes to maximizing use of all existing data, models are needed to help set priorities for the 30,000 chemicals through data sharing with the industry and with regulators.

Coupling information with a better understanding of exposure can allow for better decisions to be made. Bus suggested that one could use a tier-based risk screening process to set priorities for chemicals that undergo registration and authorization. In the tier-based process, one could fundamentally make conservative assumptions based on an exposure, hazard properties, or use scenarios of a chemical. From these assumptions, a number of questions about the level of risk could be asked. If the chemical doesn't pass the initial screen, the additional testing would be warranted, noted Bus. This tiered evaluation allows for reframing the assumptions and considering risk management decisions. The European Centre for Ecotoxicology and Toxicology of Chemicals is an organization in Europe, which is partly funded by the chemical industry, that has been exploring how this type of tiered-approached system might work. It is a stepwise process that will help everyone understand how we might approach risk characterization when considerations of exposure and use are factored in.

Coupling information with a better understanding of exposure can allow for better decisions to be made.

—James Bus

In practice, the tier-based process will assume a set of conservative assumptions with respect to exposure, hazard properties, and use scenarios. From these assumptions, questions are formulated to ask if the chemical represents a high level of risk even under those conservative levels of assumptions, noted Bus. If the chemical doesn't pass the initial screen, the value of a screening approach is that it allows further evaluation in the tiered process. This means that the assumptions could be refined with additional data, such as hazard date or other activities that could be undertaken. This additional screening might not require further testing, because one could decide that one could comply with those conservative risk evaluations simply by taking risk management decisions, concluded Bus.

Another issue of importance is substances that might be applicable for exemptions. For example, polymers are substances with large molecular weights that could be potentially excluded from meeting the health and environment requirements. The understanding is that, as the molecular weight increases, the biological activity of the polymers decreases, noted Bus. There was a debate earlier on in the process about what should be the molecular weight of the polymer in order to be considered for exemption. The current REACH proposal has decided to exempt most polymers. This, according to Bus, is valuable to help set the priorities again on the chemicals of most interest. Bus further suggested that research and development substances should be exempted because they are

contained in the environments in which they are used. Finally, he suggested that substances found in waste streams and other types of materials present a very complex scenario. These materials may be adequately covered by other regulatory initiatives that are in place in the European framework.

Isolated intermediates are another area that needs priorities set. The chemical industry uses a number of intermediate chemicals to make their final products. These intermediates are separated out of the process and are either stored or transported. The REACH proposal does have a series of considerations of when these intermediates should be tested. The question that the chemical industry has raised is not necessarily related to the process, but rather what are the implications for international trade, reamarked Bus. Potentially, it can create a different environment for those intermediates that come into a country via the importer.

Creating a smooth, efficient process is a fundamental concern of industry, noted Bus. The REACH process today has many lengthy, complex processes. In particular, observed Bus, the registration process is proposed to be done by a central agency, while the evaluation process is to be done by the member states. That division of activities can result in a cumbersome process, and there will need to be consistency across the member states on their decisions. Having a centralized process is one consideration that the industry would like to see as REACH moves forward, asserted Bus.

In the European Union, approximately 75 percent of chemicals are not produced in high volumes, observed Bus. These low-volume chemicals are produced by a limited number of companies; thus forming consortia to share experiences in terms of challenges and opportunities is not necessarily feasible. This will result in a particular burden of cost on the small to medium-sized enterprises that constitute approximately 90 percent of the European Union industrial sector. These companies will have to bear the research costs alone. In addition to the cost factor, there are some implications of sharing proprietary data, and there needs to be additional dialogue around these issues.

In the European Union, approximately 75 percent of chemicals are not high volume productions, noted Bus. The low volume chemicals are produced by limited number of companies; thus forming consortia to share experiences in terms of challenges and opportunities is not necessarily feasible.

—James Bus

In conclusion, Bus suggested that, as the REACH program moves forward, there is a need to have a productive dialogue between industry and the European Union authorities. This continued dialogue can help to achieve REACH's objectives by putting in place a chemical management program that achieves improvements and refinements in understanding human health and risk.

THE CANADIAN ENVIRONMENTAL PROTECTION ACT: TIERED APPROACH TOWARD REGULATION

The Canadian Environmental Protection Act (CEPA) is the primary federal legislation in Canada focusing on environmental protection and on the protection of human health from environmental risks. Broadly defined, environmental substances of concern under CEPA include both organic and inorganic matter, effectively spanning almost anything in the environment that could be harmful to human health. CEPA is not intended to compete with other statutes, such as the Food and Drug Act, the Hazardous Products Act, and the Pest Control Products Act, but rather comes into force where gaps exist in these or other statutes, noted Daniel Krewski, McLaughlin Center for Population Risk Assessment, University of Ottawa. In this regard, CEPA effectively provides a safety net for protecting both human health and the environment. For example, Krewski suggested that pharmaceuticals in Canada are regulated under their Food and Drug Act; however, should the disposal of pharmaceuticals in the environment pose a potential threat to human health or the environment, then CEPA would apply.

CEPA is not intended to compete with other statutes, such as the Food and Drug Act, the Hazardous Products Act, and the Pest Control Products Act, but rather is an umbrella safety net piece of legislation where gaps exist in the statutes.

—Daniel Krewski

CEPA was introduced in 1988 and is required to be reviewed periodically by law. CEPA is focused on national environmental issues, which are addressed in cooperation with the provinces. Provincial governments are responsible for the provision of health services and have considerable authority in environmental and health protection, but transboundary issues, including air quality, fall within the scope of CEPA. The provinces and the federal government work jointly to implement the intent of CEPA through federal/provincial/territorial committees (e.g., the Committee on Environmental Health, the Committee on Drinking Water). The act contains a number of key features, including jurisdiction and management. There is a shared jurisdiction of implementing CEPA between the federal departments of health and environment with Health Canada overseeing the health assessments, and Environmental Canada handling environmental assessments. However, decisions on control measures are determined jointly by the two ministers of these departments following consultation with a broad range of stakeholders, according to Krewski.

Environmental substances of concern under CEPA include existing substances—those in use in Canada in the period 1984 to 1986, and are listed on the domestic substances list (DSL), noted Krewski. The approximately 23,000 chemicals that fall under this classification require some form of efficient retrospective assessment of risk and subsequent risk management as appropriate

(Figure 3-2). He further noted that newer chemical substances are also of concern. Currently between 800 and 1,000 chemicals are introduced each year. Since 1994, the Canadian government has addressed these newly marketed chemicals through new substances regulations. Currently, no new substances can be introduced into the Canadian marketplace until prescribed information has been provided to the government and assessed within specified periods for potential and health impacts under CEPA.

When CEPA was first promulgated in 1988, first priority substances list (PSL I) containing 44 different substances was put forward, representing environmental agents of particular concern, as identified by an external multidisciplinary advisory committee. A complete, detailed assessment of the chemicals on this list was required to be finished within five years, which included a full review of the scientific literature on toxicity of the agent, leading to an assessment of the health risks associated with the substance. For substances determined to be "toxic," as defined in the Act (definition provided below), an appropriate risk management strategy must be developed within two years of completion of the risk assessment.

CEPA Toxic

A substance is toxic under CEPA if it is entering or may enter the environment in a quantity or concentration that is hazardous to either human health or the environment. Thus, according to Krewski, exposure is part of the definition of toxicity. If the exposure is sufficiently low that one would not expect an adverse health or environmental impact, then a substance would not be defined as legally toxic under CEPA—even though it may well be a toxic substance in traditional toxicological terms.

Once a substance is defined as toxic, it is placed on Schedule 1—the list of toxic substances. If it is determined to be highly toxic, it is scheduled for virtual elimination by reducing levels in the environment down to essentially zero. To do so, the government utilizes a cost-effective strategy over a period of years to virtually eliminate the substance from the environment.

> The risk management strategies that are developed for DSL substances are done using a multistakeholder issues table.
>
> *—Daniel Krewski*

The risk management strategies that are developed for existing toxic substances are done using a multistakeholder issues table. After a risk assessment is completed and the results have been summarized in a CEPA assessment report, a group of individuals representing the public, nongovernment organizations, government, industry, and other relevant stakeholders is convened to discuss possible strategies for reducing risk. This may include financial incentives or disincentives, regulatory sanctions, communications strategies, community-based approaches,

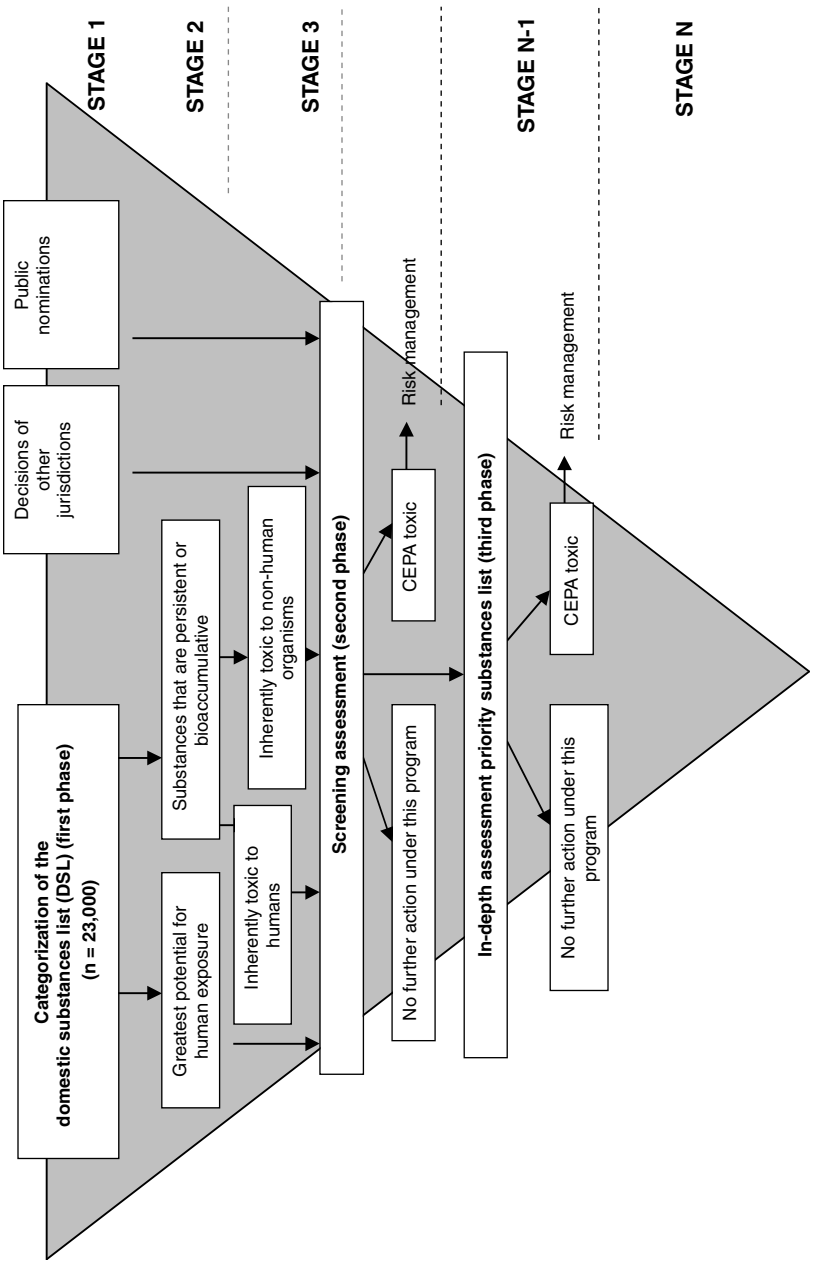

FIGURE 3-2 Flow chart that illustrates Canada's three-tiered approach for chemical management. SOURCE: Health Canada, 2004.

or any other innovative strategy that may be useful in addressing the specific risk management issue. The recommendations, formulated by the multistakeholder issues table are submitted jointly to the ministers of health and the environment for their consideration. These recommendations may be accepted, declined or accepted with modifications to become the risk management strategy for addressing the substances that are identified as toxic under the statute, noted Krewski.

Challenges of the Canadian Environmental Protection Act

One of the challenges in implementing the Canadian Environmental Protection Act is to coordinate the activities of Health Canada and Environment Canada. There is a need to ensure that numerous and sometimes complex human health risk assessments and environmental assessments of CEPA-toxic are coordinated and integrated in tandem. There was also the challenge of categorizing approximately 23,000 substances on the DSL, a task which has recently been completed according to innovative processes developed by Health Canada and Environment Canada. Finally, there are the operational challenges involved in administering such a broad-based statute, which covers emissions and effluents, new commercial chemicals, and existing substances on the DSL. CEPA also provides the legislative basis for the establishment of national objectives, guidelines and codes of practice, for example, for air and water quality in Canada.

> Media-specific approaches are not very conducive to looking at a chemical from cradle to grave, which can consider the entire life cycle of the chemical or a process. Media approaches can push a chemical from one medium to another, but never quite address the life cycle and what the alternatives might be.
>
> *—Lynn Goldman*

CEPA differs from the U.S. Toxic Substance Control Act (TSCA). Krewski suggested that one of the main differences is that, under CEPA, there is a broader scope for looking at nonregulatory options for risk management. For example, the use of multistakeholder issue tables, which provide for participation of industry, the public, and other stakeholders, can generate a wide range of proposed risk management actions.

U.S. APPROACH TO REGULATION: THE TOXIC SUBSTANCE CONTROL ACT AND PUBLIC HEALTH

It is important to note that, when discussing chemicals management, some of the management is outside of chemical statutes, and their management occurs in media-specific statutes, noted Lynn Goldman, Bloomberg School of Public Health, Johns Hopkins University. One example would be certain air pollutants

covered by the Clean Air Act. These chemicals are interpreted through specific approaches that are often based on an engineering approach and are not usually a risk-based approach. Media-specific approaches are not very conducive to looking at a chemical from cradle to grave, which considers the entire life cycle of the chemical or a process. Media approaches can push a chemical from one medium to another, but never quite address the life cycle and what the alternatives might be, noted Goldman.

As discussed earlier, the life cycle of a chemical starts with research and development, through production, and then use by workers. The use of the chemical can often be just as important as the production. For example, there may be minimal exposure in the production of certain paints, but the workers in the auto body shop who use that paint have a greater exposure. Often regulators do not have full information about a chemical because they lack information about its use. Goldman further noted that it is hard to assess a chemical's risk if you don't know about its use and exposure.

The central tenet to any law is the standard that the government is trying to achieve through its efforts, whether the tools are regulatory or voluntary. For example, the 1996 Food Quality Protection Act for food sets the standard to be a "reasonable certainty of no harm"; however, for nonfood uses, the standard is to avoid "unreasonable risk to health or the environment," observed Goldman. For the TSCA for all chemicals, the standard is the unreasonable risk standard. In addition to the factor of risk, it also includes whether the risk is reasonable in proportion to the costs that are required to control it. Thus the standard in TSCA is more than a common denominator—it doesn't differentiate between the types of exposure, the quantities of exposures, or the scenarios for exposures. The Food Quality Protection Act and several other statutes have specific provisions requiring that sensitive populations be protected. However, there isn't similar protection under TSCA. According to Goldman, clear direction has not been given to the EPA that sensitive population must be protected, whether those are children, the elderly, or those with genetic susceptibilities.

Thus, the standard in TSCA is more than a common denominator—it doesn't differentiate between the types of exposure, the quantities of exposures, or the scenarios for exposures.

—Lynn Goldman

The statutes also differ on cost and benefits. Costs and benefits for pesticides are a consideration for nonfood use, but not for food uses. For food uses, it is a public health decision. With TSCA, it is the same standard regardless of the exposure scenario. Further, noted Goldman, there is a significant burden on the government to prove that a standard has been met, which has rendered much of TSCA ineffective. One of the challenges under TSCA is for new chemical approvals. There is not a level playing field between new chemical and existing

chemicals; they are treated differently by the regulators. It is easier to continue to use existing ones, because they will hardly ever be evaluated. Thus there is a bias in the law against bringing new chemicals into the market. For pesticides (under the Pesticides Act), a company cannot bring a new chemical on the market without testing, without approval; but the EPA can establish categories of exemptions. For TSCA, there isn't a testing requirement prior to submitting them to EPA.

Enforceable consent agreements are agreements that are made between the EPA and the companies that have become the tool under which the agency can require further testing of new chemicals. These agreements are predicated on the fact that a hazard closely resembles something that is already on the market, which has been well studied, thus triggering a concern based on quantitative structure-activity relationship (QSAR). The problem with this approach is that some compounds do not have an extensive database, according to Goldman. Thus the process isn't going to inform regulators about completely novel risks as the chemicals come to market, such as risks of nanomaterials. It is easy to conclude, said Goldman, that a more robust data set such as the screening inventory data set (SIDS) used by the EU would be preferable. The government could also learn from the pesticide experience in the United States by having categories of exemptions to certain categories.

A second challenge under TSCA is existing chemicals. At the time that TSCA went into effect, approximately 70,000 chemicals were grandfathered into use and placed on the inventory. This is not a true list as some of the chemicals are mixtures, some chemicals have overlapping structures, and many are not in commerce. However, there is a large number of chemicals in commerce; for practical purposes EPA has primarily put the focus on high-production chemicals, those produced in the amount of at least one million pounds per year. This again is a limitation of TSCA as it has not been very productive in providing new data. Every year, only a few chemicals undergo testing through the use of test rules and agreements. Under TSCA, the government needs to make a finding of unreasonable risk or exposure in order to have the chemical tested. In the absence of direct information about hazard and exposure data, the government has used production volume as a surrogate for potential exposure. Although this allows for data to be collected, it is not exposure information.

> All the risk management for chemicals occurs under statutes like the Clean Air Act and not under the regulations directly covering these chemicals. The result is that the government focuses on end-of-the-pipe solutions rather than pollution prevention-related solutions.
>
> *—Lynn Goldman*

While tiering of testing and priority setting is one way to begin to address concerns, TSCA provides no clear direction about which priority should be addressed first. The EPA has begun to address the persistent bioaccumulative

chemicals, endocrine activity, mutagenicity, as well as the presences in some locations (e.g., home or school environments).

There is very little rulemaking and risk management coming out of the EPA as a result of TSCA. This means that virtually all the risk management for chemicals occurs under statutes like the Clean Air Act and not under the regulations directly covering these chemicals. The result is that the government too often focuses on end-of-the-pipe solutions rather than pollution prevention-related solutions. It further creates problems with shifting pollutants between media as discussed earlier. TSCA does not reward efforts to develop safer processes of resource reduction, nor does it replace media-specific regulations for all media.

INTERNATIONAL COOPERATION ON REGULATORY ISSUES: STRATEGIC APPROACH TO INTERNATIONAL CHEMICAL MANAGEMENT

The public needs to recognize that almost all man-made products involve the use of intentionally produced chemicals. Every year tens of thousands of chemicals are produced and used in commercial activities, noted John Buccini of the United Nations Environmental Program. Each year, the numbers will vary, but some estimate up to approximately 1,000 new chemicals enter into production each year, while older ones are rotated out. Thus there are a constantly changing number of products, articles, and chemicals. This is one of the primary problems with the management of chemicals: how does one hit a moving target, where the nature of the target is evolving as one is trying to take sight of it?

Many of the discussions in the workshop have focused on specific sectors or countries; however, there is a need for a more generalized approach to the global pursuit of sound management of chemicals. These are the man-made laws, but once a chemical is released, the laws of nature govern the chemical.

—John Buccini

Many of the discussions in the workshop have focused on specific sectors or countries; however, there is a need for a more generalized approach to the global pursuit of sound management of chemicals, observed Buccini. There are the manmade laws, but once a chemical is released, the laws of nature govern the chemical. This is an important point, noted Buccini, because once the chemical is released, it can't be returned. Following release, it will be subject to either short- or long-range transport and undergo degradation or transformation processes that will result in either a safer or more problematic chemical. Depending on the chemical and the nature of release, the chemical may result in local, regional, or global contamination. This can result in exposure of humans and wildlife with potential acute or chronic health or other adverse effects, noted Buccini.

In addition, it is important to note that all industry sectors release chemicals into the environment—whether intentional or not. While considering the management of chemicals, it is important to note that this is a cross-sectoral issue, including food and feed production, transportation, telecommunications, high tech, and so on. However, Buccini noted that many of the discussions have used a narrow interpretation of *corporate*. He suggested that it needs to be broadened to include the defense and military establishments within a country. He further noted that the idea of government as a polluter is something that hasn't really been addressed. Chemicals are released by all sectors, including the private *and* public sectors. He asserted that all sectors need to be held accountable.

Chemicals have emerged as a separate issue in recent years; however, it is also being recognized that chemicals constitute an element in issues such as biodiversity, climate change, international waters, land degradation, and ozone depletion, observed Buccini. Although some chemical issues are straightforward (e.g., persistent organic pollutants), it becomes complex when one sees the such linkages as those that exist between poverty and toxins. The dilemma, according to Buccini, is that chemicals can serve a wide variety of roles that establish or preserve an elevated standard of living in countries at all stages of development. They can contribute to resolving many modern issues. Both directly and indirectly, the public has come to view them as essential components of our modern life.

Despite the progress that has been made over many years, concerns exist that population-level effects may be occurring in present and future generations of wildlife and/or humans as a result of the widespread presence in the environment of complex mixtures of pesticides, industrial chemicals, and unintentionally produced substances. In the future, attention will be focused on those substances that are persistent, bioaccumulative, and toxic. Policies for the sound management of chemicals are recognized as essential components of overall public policy in countries at all stages of development, and they should be reflected in national sustainable development plans. There is a trend in industry to shift the production of high-volume chemicals from developed to developing countries. Thus one of the key global chemical issues is whether society can balance the benefits associated with the uses of chemicals with the immediate and long-term hazards posed by chemicals in the environment.

In the future, additional needs will focus on those substances that are persistent, bioaccumulative, and toxic. Policies for the sound management of chemicals are recognized as essential components of overall public policy in countries at all stages of development, and they should be reflected in national sustainable development plans.

—John Buccini

In 1992, as preparations were underway for the UN Conference on Environment and Development (UNCED), there was a heightened interest and activity in addressing toxic chemical issues. There were six program areas articulated as the items of urgent interest:

1. Strengthen international risk assessment.
2. Harmonize classification and labelling systems.
3. Increase the exchange of information.
4. Eliminate unacceptable/unreasonable risks posed by toxic chemicals.
5. Strengthen national capabilities and capacities for managing chemicals.
6. Prevent illegal international traffic in toxic and dangerous products.

There have been some international mechanisms established to coordinate the efforts of intergovernmental organizations and other international stakeholders in addressing the UNCED's goals and many international agreements have been developed. Currently, there are at least 52 global and regional agreements that address the use of chemicals. There were seven agreements developed in the 1970s, 13 in the 1980s, and 30 since 1990. These agreements cover air pollution, water pollution, biodiversity, specific toxic chemicals, chemical weapons, industrial accidents, storage and transportation, trade in chemicals, and transboundary waste. One problem facing the international arena is how to work with the plethora of agreements. At the World Summit on Sustainable Development in Johannesburg in 2002, the world leaders agreed on a goal of "aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment" (United Nations World Summit on Sustainable Development, 2002). It was noted in the specific recommendations that both technical and financial assistance will be needed for developing countries and economies in transition to build up their capacity. Whether it is to implement sound toxics policies or conventions, these countries need to have access to clean technologies, trained human resources, policies and legislation, and enforcement capacity. To help address the growing needs, the strategic approach to international chemicals management (SAICM) is beginning to consider strategic approaches to help with the sound management of chemicals. SAICM will include a high-level political declaration and an overarching policy

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strategy that is going to lay out the needs, the objectives, and the strategies for meeting the objectives, and a global plan of action to identify what would be done, when, and by whom. The expectation is that the development of SAICM will raise the visibility of the issue and will clarify the needs of countries. It will likely lead to increased control and/or regulation of chemicals in all countries, but it is hoped in a more coordinated and consistent fashion across the globe.

Legacy Chemicals and Encouraging the Drive to Sustainability

During the discussion, one participant noted the real need to encourage sustainable chemicals by embedding economic advantages to the next generation of chemical innovation—more than simply chemical management. Goldman noted that any new chemical is going to receive more scrutiny than something currently on the market. Although this creates a disincentive to bring forward something new, the expectation is that more stringent regulation does drive people toward improvement. This reasoning will drive industry toward green chemistry and alternatives. Goldman noted that the opposite could also occur. When REACH is enacted in the European Union, the United States, with a weaker chemical law, may become a dumping ground for chemicals that are no longer acceptable for use in Europe. Buccini noted that this has happened in the past. When the OECD decided to exclude the production of brominated flame retardants, the production was shifted to the developing world where the manufacturing processes were poor and finished goods were imported into OECD countries. Buccini concluded that if one wants to race toward sustainability in a country, one has to look at the global implications. The approach needs to reflect developments at a global level; otherwise, one may be merely redistributing risk to other countries.

4

Improving Community Health Globally[1]

The lack of institutional capacity and sound governance contributes to many of our global community health concerns. As soon as we begin to examine community health on a global scale, we encounter the issue of poverty, noted Garrick Louis, associate professor of systems and information engineering at the University of Virginia. Poor countries often lack basic services such as water, sanitation, transportation systems, and energy. For example, currently two billion people in the world do not have access to commercial energy. Without these services, it is difficult, if not impossible, to provide access to basic public health systems. A developing country's energy capacity is one important step to enhance a community's access to economic, social, and health resources, said Brian Flannery of ExxonMobil. Capacity building is therefore a necessary step toward improving community health.

Energy companies such as ExxonMobil Corporation have the potential to develop local capacity and, consequently, alleviate poverty as a mainstream activity in doing business. Issues of global community health can be examined from a number of perspectives including environmental management systems (EMSs), policy implementation, and corporate social responsibility. The principles of community health management can be illustrated by the ExxonMobil Chad-Cameroon oil pipeline project. This project involved the construction of an oil pipeline from ExxonMobil's oil production facility in Chad through neighboring Cameroon to the African coast. This large-scale project had to address numerous environmental, health, and economic impacts. The strategies for managing these impacts were sometimes cited as examples of successful implementation. How-

[1]The views expressed here do not necessarily reflect the views of the Institute of Medicine, the Roundtable, or its sponsors. This chapter was prepared by Erin McCarville from the transcript of the meeting. The discussions were edited and organized around major themes to provide a more readable summary and to eliminate duplication of topics.

ever, outside analysis identified weaknesses and suggested methods for filling in the health gaps left by ExxonMobil's pipeline project.

> As soon as we begin to examine community health on a global scale, we encounter the issue of poverty.
>
> —*Garrick Louis*

Addressing issues of capacity building and poverty is a difficult challenge for global corporations. Appropriate plans or management systems are necessary to ensure that an organization's public interest goals are identified, managed, and incorporated into the organizational culture. ExxonMobil Corporation offers one such example of a management system that was established to ensure that their safety, health, and environmental goals policies and goals are effectively implemented.

EXXONMOBIL: ENVIRONMENTAL HEALTH PERFORMANCE DRIVEN BY MANAGEMENT SYSTEMS

The key goal of ExxonMobil Corporation is to provide reliable sources of quality energy products at a reasonable cost to meet an individual's needs in both developed and developing countries, said Flannery. But at the same time, ExxonMobil must be aware of, and able to manage, the substantial environmental and health risks that are inherent in the business of oil production. ExxonMobil must therefore demonstrate the organization's commitment to the environment, health, and social responsibility while also staying attuned to changing societal expectations.

In an effort to address emerging safety, health, and environmental questions such as these, ExxonMobil established a safety, health, and environment (SHE) management system. The SHE management system incorporates ExxonMobil's goals by offering a structured management plan to protect safety, health, and the environment. The model for this management system includes five steps:

1. Identify the scope and objective.
2. Set procedures.
3. Identify the resources necessary for implementation.
4. Establish a verification and measurement process.
5. Create a system to receive and respond to feedback.

For the SHE management system to be effective, ExxonMobil needed to establish a widespread organizational commitment to the implementation of this management system model. Without management, leadership, commitment, and accountability, Flannery said, one does not have a management system. An organization must therefore integrate its management plan by incorporating its

goals into the business culture and identity. One method of internal integration involves aligning the SHE management system with ExxonMobil's other management plans. By coordinating the goals, procedures, and expectations of all of ExxonMobil's management plans, the company's entire management system portfolio has the potential to work in harmony. The SHE management system, for example, is designed to work closely with other systems such as ExxonMobil's Global Management System and Environmental Business Planning to ensure that goals and procedures among the management plans are uniform. This maintains operational and procedural consistency within the organization, said Flannery.

In addition to internal integration, ExxonMobil's management plans are also externally integrated through extensive global partnerships. ExxonMobil, for example, has recently led an effort to establish the International Petroleum Industry Environmental Conservation Association. This organization works to create effective global environmental operational standards for the petroleum industry.

Additionally, ExxonMobil has made many significant safety, health, and environmental strides. The global energy management system and its predecessors, for example, have resulted in approximately 35 percent energy efficiency improvements since the 1970s and 10 percent in the 1990s (ExxonMobil Perspectives, 2002). In addition, ExxonMobil leads the industry in many safety indicators, and their safety performance continues to improve at a rate of 22 percent annually (ExxonMobil, 2002). Many of these improvements can be attributed to effective management plans such as the SHE management system. Research, technology, and their deployment will provide the answers, not just public policy mandates, concluded Flannery. At the end of the day, things have to change either people's behavior or the systems by which we manufacture and use goods, services, and products. Multinational companies with strategic emphasis on research and development play an essential role in the development and global deployment of advanced technologies to address the sustainability challenge. Energy is critical to development. Without appropriate enabling infrastructure, capacity, and governance, we will not be able to address the needs and aspirations of two billion people without access to energy today.

HEALTH AND ENVIRONMENT IN PRACTICE: BUILDING OF EXXONMOBIL'S CHAD-CAMEROON PROJECT

Chad is located in the heart of central Africa and is one of the poorest countries in the world (Figure 4-1). According to a 1998 World Bank report, the per-capita gross national product in Chad was $180 compared to $490 in other sub-Saharan countries (World Bank PovertyNet, 2004). In addition, a 1995 survey found that 64 percent of Chad's population fell below the national poverty line (World Bank Group, 2004). In the 1990s, ExxonMobil began to develop a program to extract one billion barrels of oil per day from southern Chad and to build

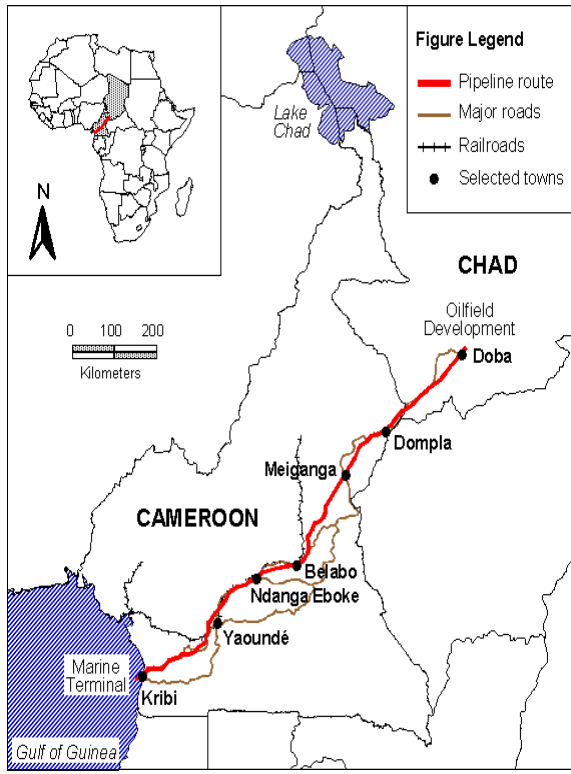

FIGURE 4-1 Map of ExxonMobil's oil pipeline route. This pipeline stretched over 1000 kilometers from ExxonMobil's oil field development in Doba Chad, through Cameroon, ending at Kribi, a port city on the west coast of Africa. SOURCE: Utzinger et al., 2005.

an oil pipeline through both Chad and Cameroon to transport oil to the African coast. Before construction could begin, ExxonMobil had to develop a strategy to address the social, economic, community, and structural challenges that such a large-scale project would pose, said Andre Madec of ExxonMobil.

The first challenge was the countries' governance structure and history of political instability. Not only did ExxonMobil work within the governments of Chad and Cameroon, they also facilitated close cooperation between the two politically disconnected countries. Secondly, ExxonMobil needed to address the countries' lack of capacity and basic infrastructure. Thirdly, they needed to respond to concerns from international nongovernmental organizations (NGOs) as well as local community members in Chad and Cameroon who wanted to ensure that the health and well-being of local residents were not negatively affected.

Finally, they needed to address significant local health concerns regarding diseases such as human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) and malaria. After identifying these challenges, ExxonMobil developed and implemented individualized strategies for mitigation.

The Role of Local Government in the Implementation of the Safety, Health, and Environment Management System

It is necessary for a company such as ExxonMobil to work with and empower the local administration, community groups, and aid organizations. It is this empowerment that builds the country's ultimate capacity to succeed, said Madec. To ensure that revenues from oil production in Chad were dedicated to local development and not dissipated through corrupt programs and individuals, ExxonMobil worked with the Chad government and the World Bank to develop a binding agreement called the revenue management plan. This plan outlined specific strategies for the use of oil production revenues. Seventy-two percent of all oil revenues were dedicated to identify priority areas including health, education, infrastructure, agriculture, the environment, and water resources. Five percent was devoted to community development and 10 percent was set aside in a savings program for future generations. Only 13 percent of the total oil revenues were allocated to the general government budget. Through this agreement, ExxonMobil hoped to ensure that oil production would continue to benefit the communities in Chad and Cameroon for years to come. This revenue management plan relied greatly on the involvement of local community groups, governments, and NGOs.

Lack of Capacity and Basic Infrastructure

To transport production equipment and materials necessary for the construction of the Chad-Cameroon oil pipeline, over 500 kilometers of roads needed to be built. However, with this new development came new issues of induced access and environmental degradation, noted Madec. Although the newly constructed roads provided villagers access to other towns, opening opportunities for trade and access to medical care, at the same time, they provided poachers and loggers easy access into formerly protected, inaccessible land, potentially threatening the environmental resources of Chad and Cameroon. ExxonMobil, therefore, had to work closely with governments and community groups to ensure that both the environment and community welfare were protected. In some situations, ExxonMobil determined that the removal of constructed roads was necessary to limit access to valuable natural habitats. But ExxonMobil also identified and maintained roads or bridges that acted as important transportation routes between towns, providing potential for trade and increased connectivity.

Individual and Community Compensation

The primary concern among community members within the oil pipeline path was displacement or loss of income during pipeline construction. ExxonMobil, therefore, established a compensation system to reimburse the impacted villages for temporary displacement and lost farming time. Unfortunately, official land compensation rates in Cameroon had not been updated in over 25 years. ExxonMobil, therefore, had to create its own compensation plan that took into account lost farming productivity during periods of pipeline construction. The compensation plan per farmer for three months of lost farming time was approximately $1,000; this sum is significantly higher than the average annual farming income of $180. ExxonMobil also offered systems to distribute this money effectively. In areas where purchasing goods was difficult, ExxonMobil created an in-kind compensation plan. Farmers received catalogues with products such as roofing materials, farming equipment, and bicycles that could be purchased with the compensation money. In addition, where possible, ExxonMobil set up savings accounts in local banks to encourage farmers to save their compensation funds, noted Madec.

Establishing effective community compensation strategies required a lot of communication with individuals, community leaders, and government. In fact, the most important tool when working with community groups is the ability to communicate, emphasized Madec. An example of the importance of communication in developing compensation plans is the Pygmy community in Cameroon. After speaking with community members, it became clear that the most valued public health service among Pygmy villagers was not standard medical supplies, food, or doctors; it was government identification cards which would allow the Pygmies access to government medical services and support. This example illustrates that individual or group needs cannot be assessed by outside parties with little or no understanding of the community structure, social dynamic, or history. It is only through on-site communication and direct contact that individual or community needs can be assessed.

Local Employment and Business Opportunities

When beginning the Chad-Cameroon oil pipeline project, ExxonMobil had the initial goal of employing 50 percent of their total workforce with local workers. However, it was apparent that the company needed to implement programs early on to train local workers in the necessary skills such as masonry, carpentry, and electrical engineering. The program was successful and by the end of the project more than 85 percent of the total workforce—80 percent in Chad and 90 percent in Cameroon—were local people.

In addition to providing work opportunities, ExxonMobil made a decision to contract with local suppliers for raw materials. Eight hundred million dollars of the $4 billion project costs were contracted to local suppliers of goods and ser-

vices. This investment in local economies required a conscious effort on the part of ExxonMobil Corporation. As individual contractors did not have the capacity to supply ExxonMobil's total production orders, the company had to break up tasks into more manageable pieces in order to give local business the opportunity to compete for contracts. The total number of contracted local businesses was more than 2,200 contracts, concluded Madec.

PUBLIC HEALTH LESSONS LEARNED FROM THE EXXONMOBIL CHAD-CAMEROON PIPELINE PROJECT

Community Health Outreach Program

In both Chad and Cameroon, ExxonMobil created health management plans to protect the health of pipeline workers and communities neighboring the pipeline. One of the major public health initiatives established by ExxonMobil during oil pipeline construction was the Community Health Outreach Program (CHOP), noted Burton Singer of Princeton University. The general objective of CHOP was to target selected health issues in communities potentially affected by the oil pipeline project while specifically focusing on locations in the vicinity of permanently staffed project field facilities. Strategies for the implementation of CHOP included (1) focusing on specific diseases and public health conditions most likely to affect the oil pipeline workforce or the larger community affected by the project; (2) initiating the program during construction and operation phases; (3) adapting support projects to varying sociocultural settings; and (4) targeting education and other preventive and curative project-related health issues.

ExxonMobil's CHOP program made great public health strides in Chad and Cameroon, noted Singer. By the end of 2002, local NGOs were working with 141 villages in Chad. These NGOs successfully ran 370 malaria education sessions and distributed 37,000 insecticide-treated bed nets, reaching over 122,000 people with their medical outreach programs (ExxonMobil's Chad Cameroon Development Project, 2004). The HIV/AIDS prevention and education campaign also reached over 140 villages by March 2003 (ExxonMobil's Chad Cameroon Development Project, 2004). Finally, the CHOP program recruited and trained 30 new nurses, increasing the total nursing population in Chad by approximately 20 percent, noted Singer (ExxonMobil's Chad Cameroon Development Project, 2004).

But although CHOP made great strides, ExxonMobil's program did have room for improvement, observed Singer. The lack of both environmental and health information in Chad and Cameroon and an incomplete assessment makes it difficult to address long-term issues of global community health, said Singer. One of the weaknesses of the CHOP program was that it was designed to focus on worker and community health within the narrowly defined pipeline project area, while the remaining region was, for the most part, ignored. The program did not establish any regional health plan to address the greater surrounding com-

munities' health. Additionally, it had no provision for infrastructure development such as the expansion of water and sanitation systems. Also, insufficient attention was devoted to tuberculosis prevention and treatment, and no cumulative impact assessments were performed, said Singer. He asserted that without a cumulative impact assessment, there is no way to determine the long-term impacts of a project.

CHOP's successful programs have application potential throughout Chad and Cameroon. By collecting health and environmental data on ExxonMobil's programs, regional health plans can be developed to incorporate CHOP's successful techniques. Extending this concept further, by collecting data, performing cumulative impact assessments, and referencing successful community health models, an effective national public health plan can be created, said Singer. A malaria prevention program, the Ifakara Center in Tanzania, and a demographic surveillance system (DSS) are three examples of how data collection and community health program models can be used in Chad to establish an effective long-term public health system.

Malaria Prevention Program

CHOP successfully implemented a malaria prevention program among ExxonMobil employees by distributing chemoprophylactic drugs to workers in high risk areas. The program helped reduce malaria rates among contractors and ExxonMobil employees from 2 percent at its peak to .03 percent at the end of the program, as shown in Figure 4-2 (Swiss Tropical Institute, unpublished). Similar programs could be used throughout high-risk malaria regions, noted Singer. Additionally, one of the techniques with potential malaria prevention applications is satellite imaging that provides data on soil moisture. It can be used to identify anopheles breeding sites and help governments identify high risk areas that can be targeted for malaria prophylactic programs, noted Singer.

Ifakara Center

A second possible model for Chad's public health system was the Ifakara Center in the Kilombero District of Tanzania. The Ifakara Center was first established in 1957 by the Swiss Tropical Institute. The purpose of this program was not only to conduct public health field studies, but also to begin a process of training local people—health workers, health practitioners, and researchers—in order to build Tanzania's health system capacity. Ultimately, the responsibility for funding and operating the center was transferred from the Swiss Tropical Institute to the Tanzanian government. This transfer of responsibility was successful and today, the center is run, staffed, and funded by the Tanzanian government and is integrated into the national public health system. This project has potential applications in Chad as a model for a successful community health center, noted Singer.

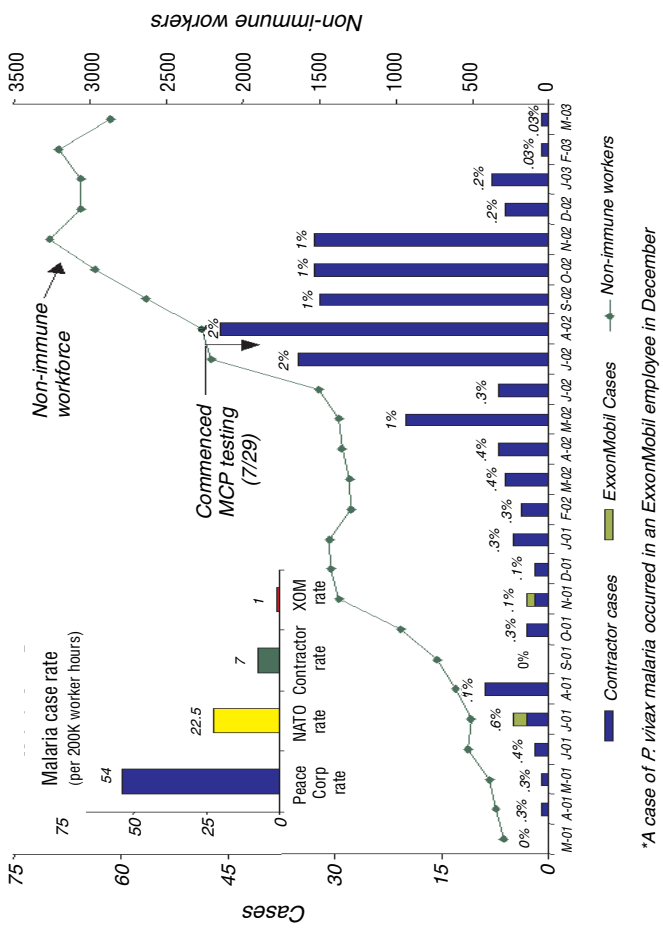

FIGURE 4-2 Graph of the confirmed non-immune falciparum malaria cases of ExxonMobil employees and contractors in Chad and Cameroon. After MCCP testing began on July 29, 2002, rates of malaria cases decreased from 2% in August 2002 to .03% in May 2003. This represents a case rate of 1 case per 200,000 worker hours for ExxonMobil employees and 7 cases per 200,000 worker hours for contractors. The ExxonMobil malaria case rate is less than the case rate for Peace Corps and NATO which record a rate of 54 and 22.5 cases per 200,000 worker hours respectively. SOURCE: Don deSavigny, Swiss Tropical Institute, unpublished.

Demographic Surveillance System

A final model proposed for Chad's public health system is the DSS. The DSS involves collecting data on births, deaths, causes of death, immigration, and emigration for a large dynamic cohort of individuals. Such extensive population data provides a powerful information platform for understanding health conditions, not only at a point in time, but also longitudinally, noted Singer. The DSS requires a significant investment of resources including software systems that maintain a record of demographic events, trained fieldworkers, transportation systems, data managers, and scientists, and has an estimated annual cost of approximately $130,000. But this investment is arguably worth the cost, argued Singer. With the information collected by the DSS, a government can assess the share of mortality burden for diseases such as HIV/AIDS, malaria, and tuberculosis. A government's public health budget can then be allocated according to the actual health threats of various diseases in order to ensure that monies are spent in the most effective manner possible. This system has been demonstrated to be effective in some African communities. The mortality rate for children under 5 years of age in areas where the DSS has been implemented is declining at roughly 14 percent per year in comparison to a mortality rate of 5 percent in conventional planning districts (Figure 4-3).

Methods of Managing Corporate Social Responsibility

Although ExxonMobil's community health program does have weaknesses that could be managed through program expansion, it is not necessarily ExxonMobil's responsibility to implement these programs, argued Singer. Rather, the question of corporate social responsibility is a complicated one that raises a number of difficult questions. In particular, what is the domain of responsibility for a company like ExxonMobil in looking after the health of communities that are proximal to where it does business? And who is responsible for project funding in the long run? ExxonMobil is in the oil business, not in the health business, but the question remains—what happens in not only the communities affected by the oil pipeline project but also communities throughout the entire country of Chad?

A potential method of managing questions of corporate social responsibility is to empower local governments to support and manage their own public health systems.

—Burton Singer

A potential method of managing questions of corporate social responsibility is to empower local governments to support and manage their own public health systems, said Singer. The revenue management plan created by ExxonMobil and the Chad government, and previously discussed in the chapter,

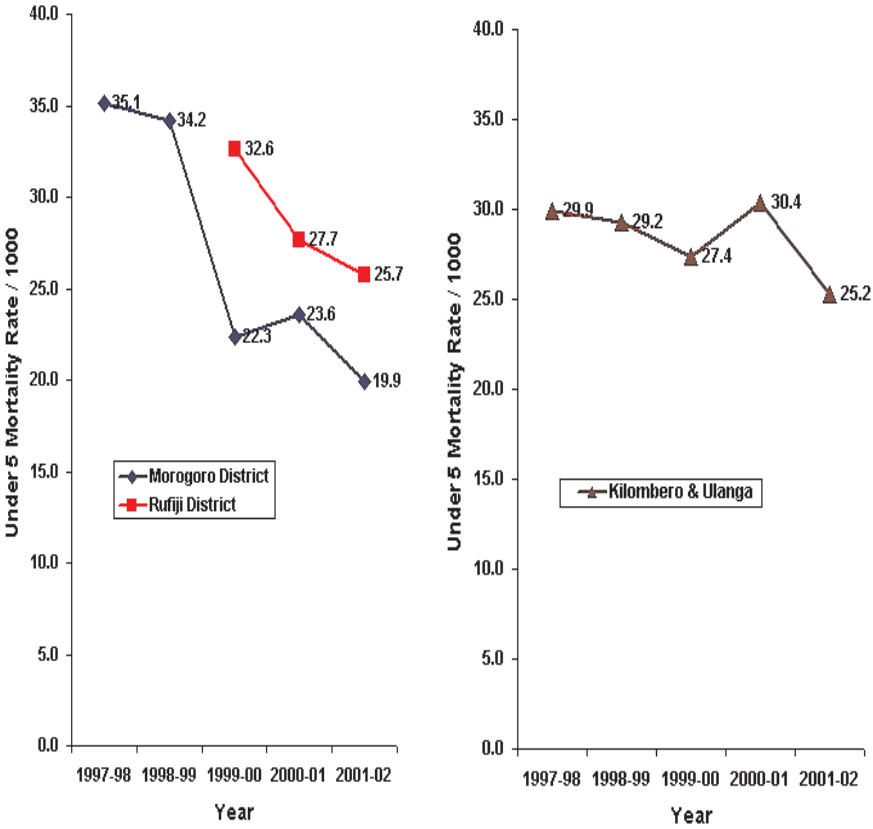

FIGURE 4-3 The two graphs show the under-five mortality rate per 1,000 individuals for two districts in Tanzania. The first graph depicts change in mortality rate for two districts, the Morogoro and Rufiji, that implemented evidence-based planning based on a demographic surveillance system, while the second graph depicts the change in mortality in conventional planning districts. The evidence-based planning district recorded a 14 percent decline in mortality rates while the conventional planning district recorded a 5 percent decline. SOURCE: Steven Phillips, ExxonMobil Corporation, unpublished.

offers an opportunity for Chad to manage their own system by providing guidance and direction for resource allocation. A revenue management plan that incorporates successful public health models will provide effective and reasonable solutions to Chad's public health problems. The revenue management plan really can play an important long-term role by creating a stable financial foundation on which a public health system can be developed, concluded Singer.

STRATEGIC MANAGEMENT OF ENVIRONMENTAL HEALTH MANAGEMENT SYSTEMS

We are living in a fragile, complex, and dangerous world, said Djordjija Petkoski of the World Bank Institute, the capacity-building arm of the World Bank Group. Imbalances in the world have direct impact on environment and health; thus, they are of great concern to the World Bank. There are two major imbalances in the world: a wealth gap and a generational gap. Much of the decision-making process in the world is limited to a small group of people, which increases the danger of having the concentration of resources with a very small portion of the population. About half of the world's population live in developing countries and are not party to of any such decision-making process. According to Petkoski, half of that population is younger than 25 years, one-third of global population is between 15–25 years old, and this trend is especially acute in the developing world; however, young people are rarely part of their government's decision-making process because they do not have the capacity and opportunities to do so. When the World Bank or other international development institutions provide loans, the governments are required to repay these loans over a period of 15–35 years. It is a commitment made today that the next generation will have to repay tomorrow. If young people are not part of the decision-making process they will not feel empowered and responsible to keep the commitments of those who made the decision on their behalf, noted Petkoski.

Turning to the critical issue of poverty reduction, Petkoski noted that the average person in sub-Saharan Africa earns less than $1 per day; about half of the globe lives on less than $2 per day (Chem and Ravallion, 2004). At the same time, the World Bank estimates that wealthy nations spend more than $300 billion on agricultural subsidies. Poverty has a substantial impact on the environment because the poor have less access to employment information and services; less formal or nonrelevant education is associated with risk behaviors, especially by youth. For example, economic need forces poor women and migrants into work environments that pose high risks, such as of contracting communicable diseases, including HIV/AIDS and severe acute respiratory syndrome (SARS). Furthermore, poor neighborhoods tend to have fewer doctors and pharmacies, inadequate transportation and recreation facilities, and lower availability of healthy food and clean water. According to Petkoski, more than 1 billion people in the world do not have access to clean water.

The environment is one of the major determinants of human health and well-being. It also impacts the economic welfare of the society. To improve our health through a better environment, the world needs a new framework for people from different sectors, including a corporate sector, to understand each other. The World Bank believes it is important to engage the corporate sector to be more actively involved in reducing the imbalances in the world. Issues such as air pollution, heavy metals, global climate change, and the built environment are greatly influenced by the private sector's decision making. The importance of investments

in public and environmental health is undeniable, and when we look at the flow of capital in developing world, it is evident that the flow of capital coming from institutions like the World Bank is minimal in comparison with the flow of capital coming from the private sector, said Petkoski. Therefore, the corporate sector needs to look beyond short-term profit making and develop a sustainable bottom line that addresses issues related to corporate social responsibility. One of the market-based solutions for the private sector is building broader social capacity, creating sustainable markets, and supporting environmental sustainability. The social legitimacy of sustainable markets, including capturing new market opportunities, depends on how efficiently social causes are addressed, said Petkoski. He further noted that there is a very limited role for the private sector in environmental health without sustainable markets. Developing a common language and shared understanding of the main challenges is probably the toughest problem, said Petkoski. The private sector is typically more flexible and responsive in making and implementing decisions; governments cannot possibly match their pace. Therefore, the private sector has the potential to help address governance gaps and compensate for its failures. Of course, communities also play a critical role in the decision-making process. They need to embrace a broader view of environmental health and be more engaged in the decision-making process, and that requires a lot of additional work in capacity building.

> Health challenges and their interdependence with economic, environmental, and social issues are becoming too complex. The resources and competence needed for addressing them are too dispersed for one sector to have all the solutions.
>
> *—Djordjija Petkoski*

Health challenges and their interdependence with economic, environmental, and social issues are becoming too complex, and the resources and competences necessary to address them are too dispersed for any one sector to have all the solutions, said Petkoski. Therefore, it is essential that organizations, such as the World Bank, foster effective multisectorial partnerships for capacity development. Such partnerships will allow for more meaningful dialogue and facilitate greater collaboration between social groups, governments, and the private sector, leading to greater impact on the ground, concluded Petkoski.

5

Corporate Social Responsibility[1]

Corporate social responsibility (CSR) has gained more interest in the past decade, however it is not a new idea; it dates back to the 1930s, said Eric Orts of the University of Pennsylvania. Just before World War II, German industrialist Walter Rathenau claimed that business corporations had become very large and that they had grown to be a significant part of the society. According to Rathenau, even though fundamentally a corporation's intent is the pursuit of private interests and profits for owners of the company, they are increasingly bearing the marks of an undertaking and, to an increasing degree, have been serving the public interest (Kessler, 1930). Further, philosophers John Dewey and James H. Tufts, in their book *Ethics* (1908), raised the concept that it is not sufficient to view companies as purely economic machines and that companies should be involved in public duty as well.

SUSTAINABILITY AND CORPORATE SOCIAL RESPONSIBILITY

CSR is not a static concept—it is a moving, evolving target, said Norine Kennedy of the U.S. Council on International Business. According to Kennedy, there is no solid definition of CSR; however, it is not a replacement for the governmental role and responsibility in meeting challenges of sustainable development.

Sustainable development within business promotion is expanding rapidly in several directions. Some interpret corporate responsibility to mean what companies should do above the call of law; others think it should be legally mandated at

[1]The views expressed here do not necessarily reflect the views of the Institute of Medicine, the Roundtable, or its sponsors. This chapter was prepared by Dalia Gilbert from the transcript of the meeting. The discussions were edited and organized around major themes to provide a more readable summary and to eliminate duplication of topics.

the national or international level; others, again, take the position that it is already here and we are already doing it, said Kennedy.

The scope of corporate responsibility varies country by country, region by region, interest group by interest group. At a minimum, it includes environmental issues but it also takes on social, ethical, governance, health, and other issues. Potentially, it is a very broad concept to cover, and it is a challenge for the business community.

Millennium Development Goals

As a follow-up from the world summit on sustainable development in Johannesburg in 2000, the United Nations developed Millennium Development Goals (MDGs) with the implications for corporate responsibility, environmental, and health issues. One hundred ninety-one UN member states endorsed the Millennium Declaration. There are 18 MDGs grouped around eight goals, most of them having 15–20 objectives.

The main notion of MDGs is that it is not just governments, but also other interest groups in society that are expected now to carry out the commitments. It is clear in the international arena that companies are increasingly expected and, in some cases, required to take on roles and responsibilities that are traditionally those of governments. Today's world and its markets are globalized, and the international impacts are unmistakable, said Kennedy. What happens internationally matters to companies in the United States. There's not a one-size-fits-all solution for corporate responsibility, which makes it quite a challenge as we are looking for an internationally-agreed-upon approach.

There are several references to health-related issues in MDGs, such as reduction of the mortality rate of children under 5 years by two-thirds, reduction of maternal mortality by three-quarters, and attempting to decrease the incidence of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), malaria, and other major diseases. Other health-related issues targeted in MDGs are safe drinking water and concern for slum dwellers' health. Finally, under the heading of a global partnership for development, there are two points: (1) access to medicines in cooperation with pharmaceutical companies and the private sector, and (2) make available benefits of new technologies, especially information and communications technology.

Another CSR incentive called the World Summit on Sustainable Development focuses on implementation and execution that is synchronous with the finance and trade negotiations of Monterey and Doha. According to the WTO, the November 2001 declaration of the Fourth Ministerial Conference in Doha, Qatar, provides the mandate for negotiations on a range of subjects, and other work including issues concerning the implementation of the present agreements (WTO, 2004). At the Summit on Financing for Development in Monterey, Mexico, delegates from participating nations pledged new resources for development

and to adopt the policies needed to ensure that these resources are well used. In Monterey, President Bush underscored the link between good governance, good policies, and human well-being when he put forward his concept of the millennium challenge account, noted Kennedy. This new type of assistance will go only to developing nations that are governed wisely and fairly, are strongly committed to investing in health and education, and that follow sound economic policies that encourage entrepreneurs and spur growth. Because of the World Summit on Sustainable Development, the UN becomes even more open to nongovernmental organizations (NGOs) and business. Therefore businesses now have the opportunity to be more engaged in UN discussions and bring forward business experts and practitioners who are involved in partnerships, noted Kennedy. It is also a challenge to businesses how to measure and report business performance in corporate responsibility and other areas where they have been active as members of the business community.

The World Summit on Sustainable Development work program refers to corporate responsibility in the following four places:

- Sustainable patterns of consumption and production that enhance corporate environmental and social responsibility and accountability through actions such as voluntary initiatives, standards, reporting, dialogue, financial institutions engagement, cleaner production initiatives
- Sustainable development in a globalizing world that actively promotes full development and effective implementation of intergovernmental agreements, initiatives, partnerships, regulations, and continuous improvement in corporate practices in all countries
- Health and sustainable development, a linkage between health and environmental protection, reduction of environmental health threats, access to health care services, safer technologies for drinking water and waste management, reduction of occupational injuries and illnesses, a link between public health promotion and reduction and elimination of HIV/AIDS, tuberculosis, and malaria, phasing-out of lead in gasoline and paint
- Strengthening of institutional frameworks that promote corporate responsibility and accountability and exchanging of best practices

The Role of International Organizations in Promoting Corporate Social Responsibility

International organizations play a major role in promoting better governance, and better economic processes in general, said Kathryn Gordon of the Organization for Economic Cooperation and Development (OECD). The OECD has a very distinctive way, a consensus-based way, of promoting better governments—governance among its member countries. A consensus development at the OECD is based on soft law instruments, meaning nonbinding statements of

values and principles. To make these soft law instruments meaningful, OECD engages in consensus-based peer reviews about how these values and principles are implemented in different national policy contexts. The instruments provide guidance for both government and corporate responsibilities in the investment area. On the government responsibility side, the instruments express the core investment values of transparency, nondiscrimination between foreign and domestic investors, and investment protection. On the corporate responsibility side, the OECD Guidelines for Multinational Enterprises provide guidance for international business. It is a comprehensive code of conduct that covers such areas as environmental management, human rights, anticorruption, and supply chain management. The OECD guidelines implementation procedures involve a distinctive and unique combination of voluntary and binding elements. Observance by business of the guidelines is voluntary, but the OECD governments assign a binding commitment to promote the principles of the guidelines among multinational enterprises operating in, or from, their territories.

> At a minimum, corporate social responsibility includes environmental issues, but it also takes on social, ethical, governance, health, and other issues.
>
> *—Norine Kennedy*

Challenges Ahead

Today's businesses face multiple challenges in terms of corporate responsibility. Businesses have to keep up with the new initiatives on a wide range of fronts such as voluntary, regulatory, stakeholders, partnerships, and others. Credible and meaningful indicators of how companies are contributing to the quality of life and how they are implementing corporate responsibility can be challenging, said Kennedy. These challenges are occurring at the same time the concept of corporate responsibility is evolving in several different directions. She noted that one single approach or definition is not going to meet the various needs; given the number of contexts in which businesses work, it is appropriate and healthy to have different approaches. Businesses need to watch very carefully the codes of conduct and guidelines of the MDGs and the World Summit for Sustainable Development, to come forward to talk about what has to be done and how it is going to be delivered, and to continue to argue for the enabling frameworks for corporate responsibility at the international level, noted Kennedy.

Some discussion participants noted that CSR functions effectively when there is committed leadership in corporations. They noted that corporate leaders need to transform into leaders who will move corporate responsibility efforts forward. Business schools, where those leaders are educated, are in a position to influence the transformation. Additionally, society, shareholders, and employees

need to become more vocal about what they are expecting from business leadership, thus becoming a determining factor about what corporations are focusing on and what their objectives are, noted some participants.

CORPORATE SOCIAL RESPONSIBILITY IN THE CONTEXT OF REGULATION

According to Orts, CSR is an orientation to business enterprise that claims a company has more than just an economic duty to shareholders and owners of the company; it is also a social entity that entails moral obligations and imperatives that go beyond legal requirements and compliance.

Many people in society at large, and especially the business community, do not believe that CSR is a good idea. For example, Orts noted that Milton Friedman is famous for saying that we should not have CSR because the constraints should be given by the government, so a company should maximize profits as much as it can, and the law should provide it with constraint (Friedman, 1970). The proponents of this view of CSR dispute that there is a tension between economic arguments about the need for businesses, especially public corporations, to focus on the bottom line, namely, shareholder value. On the other hand, there are ethical arguments, and every particular company needs to identify its ethical obligations that are either going to be constraining or a part of its definition as a business. Orts noted that the American Law Institute in its principles of corporate governance suggested that the primary objective of a company is to make profits for shareholders, but it still has to follow the law even if it is not cost effective (American Law Institute, 1994).

According to Orts, Stanford University professor David Baron clarified the ethical argument for social responsibility by distinguishing between what he called CSR and corporate social performance. True CSR involves an allocation of a firm's wealth toward some view of the public good motivated by normative, that is, ethical principles. Strategic CSR (or mere corporate social *performance*) involves actions that appear to be motivated by higher social purposes and are, in fact, motivated by profits, noted Orts. Extreme cases amount to simple deception or "greenwashing" (Baron, 2001). Therefore, when we talk about CSR in the context of environment and health, we are talking about true CSR, said Orts. Additionally, Orts quoted Paul Hawken's book *The Ecology of Commerce* in which the author says that business is a primary participant in destroying the world, and if businesses continue as they are going, there is not going to be a wildlife preserve, wilderness, or indigenous culture left (Hawken, 1993).

Many companies today realize that they are responsible for the future of the world, and they no longer accept the maxim that the business of business is business only, noted Orts. Their new premise is: Corporations are the dominant

institutions on the planet today; therefore they have to help address social environmental issues that affect humankind. This premise is increasingly becoming the ethically driven view of many large multinational companies. Globalization of the world implicates the idea of global corporate citizenship in globally constituted civil society and brings in the need for clarity about how to enforce different regulations; to whom should the multinational company owe their loyalties—whether they should be an American company or a global company—and what would be a global company's responsibilities in a broader civic sense. According to Orts, corporations are citizens of a global society and therefore owe a duty to participate in that general society.

> Corporations are the dominant institutions on the planet today. Therefore, they have to help address social environmental issues that affect humankind.
>
> *—Eric Orts*

Many governments in the world have basic capacity for addressing the complex societal challenges. Global problems such as global climate change, ozone layer depletion, biodiversity loss, depletion of fisheries and forests, hazardous waste, transportation disposal, migrating microbes, and invasive species, as well as local air and water pollution are global issues, and have a health component. Often it is not possible for individual governments to address them.

Legal Reform Strategies to Enhance Corporate Social Responsibility

We live in a very complex society in which the government is not going to be able to answer all the questions about what the standard rules are. Therefore, companies have to take a bigger role in this process and establish creative legal strategies, so called reflexive law, that go beyond the command-and-control approach, asserted Orts. Informational regulation in the form of mandatory disclosure of information similar to the toxic release inventory could also be used to enhance CSR. Environmental contracts are among other strategies that may help improve CSR. The idea of environmental contracts is that companies can have partnerships and work independently with NGOs or with other governments on specific issues. Laws could be passed to help promote this strategy. If a company made a contract about a specific issue, it might create more progressive and creative solutions to these problems than if it relied solely on the Environmental Protection Agency or the U.S. Congress, noted Orts.

Corporations may chose to be socially responsible and get involved in addressing certain social or health issues with precision and competence. However, these choices have to be made without losing sight of the fact that the primary interest for a company is an economic one, concluded Orts.

CORPORATE SOCIAL RESPONSIBILITY: ROLES OF GOVERNMENT, THE PRIVATE SECTOR, AND CIVIL SOCIETY

The Cause of Corporate Social Responsibility as a Phenomenon

The modern phenomenon of CSR is closely linked to that of globalization, stated Kernaghan Webb of Carleton University in Ottawa. Globalization increased movement of people, goods, ideas, and corporate activity across borders. In a globalized marketplace, the underlying premise is that organizations should behave with equal respect to people and the environment wherever they are. Advances in telecommunications (e.g., the introduction of the Internet), NGO activity, and media scrutiny mean that an organization's activities can be critically tracked and followed more easily than ever before, regardless of their location. Because governments do not have the ability to fully address environmental and social problems on their own (particularly in developing countries), the idea that corporations should take on some of this responsibility has gained currency. In effect, CSR is largely a response to state incapacity, stated Webb.

The result is growing expectation that firms should be economically, environmentally, and socially responsible wherever they operate, even if government regulations are inadequate or poorly enforced. These expectations apply to small, medium-size, and large firms, and all sectors: pharmaceutical, mining, refineries, chemicals, and so on.

Efforts by many organizations are underway to develop flexible, practical, standardized CSR approaches for a global economy. Intergovernmental-level initiatives include the Global Compact, the International Labour Organization declarations, OECD guidelines, the World Bank, and others. Individual governments such as the United Kingdom are taking lead roles, as well. Other initiatives include investment, standards, industry, and those that are NGO-driven or faith-based. Although the initiatives indicate considerable engagement on this issue of CSR, there is considerable variability from one to the other in terms of the actual content, scope, comprehensiveness, interoperability, and take-up, said Webb

As a result, even efforts made in good faith may suffer in the confusing abundance of initiatives. The lack of standardization can discourage business from good behavior and it can also discourage consumers, investors, and governments from rewarding good behavior. Competing initiatives can slow down the momentum of the CSR movement, cautioned Webb.

Corporate Social Responsibility Initiatives and Law

Even though laws and international conventions have limitations, they will remain the foundation for environmental and social protections in our society, said Webb. In part, as a response to these limitations, the private sector and NGOs have developed CSR-oriented voluntary codes and standards as supplements. For

optimal effectiveness, governments need to stimulate and structure these various initiatives.

There are strengths and limitations to laws. The strengths are that command-and-control regulatory approaches articulate societal positions on important issues and are the products of democratically elected legislatures in democratic countries. The laws are enforced by specialized government agencies and backed up by the courts. Command-and-control approaches have made considerable progress in improving the lives of people around the world. However, they have expensive, protracted development and enforcement processes, as well as jurisdictional constraints on subject matter, approach, and scope, noted Webb. Developing countries are particularly vulnerable to inconsistent and inadequate implementation and enforcement, in large part because of the inadequate budgets in place to fund such activities. Another downside to conventional command and control regulatory approaches is a tendency toward very inflexible and formal approaches that can lead to adversarial and legalistic behavior—a "going by the book" attitude toward compliance. This tendency can impede the development of optimal solutions to particular public policy problems, said Webb.

Further, with technologies moving so quickly, the law system is frequently put in a situation where it is one or two steps behind, no matter how hard governments try to stay on top of issues, said Webb. If limitations at the domestic level are challenging, they are considerably more problematic at the international level. Even though international laws have contributed to a lot of progress and provide the international regime of human rights, environmental protection, worker protection, and commercial activity, issues such as national sovereignty and the reluctance of states to agree to participate in, ratify, or implement international laws, slows down greatly the effectiveness of international laws to address social and environmental problems. Also, the divide between developing and developed countries is a particularly intransigent challenge for the international community because there is very little enforcement capacity at the international level and within developing countries, said Webb.

There are many possible ways to address the aforesaid issues and challenges. The International Organization for Standardization (ISO)—a nongovernmental body, although governments and private sector and others participate in it—generated the ISO 14000 series of standards, in particular, 14001, an environmental management standard. The ISO approach is intended to supplement legal regimes. It does not work as well when there is no effective legal regime because a management system works optimally in conjunction with a set of legislative or regulatory obligations, said Webb.

Environmental organizations have taken a lead role in developing a number of international voluntary certification regimes that apply to the CSR area. For example, the Forest Stewardship Council initiative started by the World Wide Fund for Nature was a response to the fact that the international intergovernmental community could not come up with an international forest protection

convention. This type of response is a paradigm change for NGOs because they moved from being rule takers, participating in someone else's processes, to taking the initiative themselves and realizing the power they have to do so. NGOs realized that they can have retailers as allies who can frequently act as surrogates for consumers, and they can require, on behalf of their customers, that their suppliers agree to the standard or will not get business from them. Businesses are seeking "social licenses," meaning individual companies are developing environmental, worker, and community-oriented codes for business reasons. At the same time, communities are entering into "good neighbor" agreements with companies. For example, in the United States, coal companies are the subject of good neighbor agreements where community members are allowed to go into the plants to do inspections and to check the company's records. Just like laws, the new developments have limitations. For example, in the United States the Responsible Care Program for chemical manufacturing sector seems like an effective industry-initiated voluntary initiative, yet 90 percent—not 100 percent—of the chemical industry and chemical producers in United States are involved in the program. In other words, because it is a voluntary program, there is no legal mechanism to require 100 percent industry participation. Primarily, the challenge with voluntary instruments lies in implementation and enforcement associated with conflicts of interest and transparency and accountability issues.

The new approaches should be applied as supplements to the laws, not as replacements for them, said Webb. In some cases, they may act as precursors, and sometimes industry asks that these voluntary initiatives become law.

As mentioned previously in this chapter, corporate social responsibility is not a new idea. It extends back to the late 1600s when Quakers were the first users of corporate social responsibility, said Webb. Even though they were interested in trust and ethical behavior, they found that there were strong business dividends for engaging in that behavior.

According to Webb, CSR can be described as attempts by businesses to balance and integrate their economic, social, and environmental responsibilities in a way that minimizes societal harm and optimizes societal benefit while providing wealth to business owners and shareholders. It includes, but is not limited to, philanthropy; it assumes compliance with law and is generally seen as a voluntary, non-mandated set of activities. The pressure for CSR is becoming stronger because businesses are realizing that failure to consider the interests of their workers, surrounding communities, civil society organizations, and customers can have negative consequences to their reputation, and it may have a negative legal and commercial effect. Businesses are realizing that working with stakeholders can have benefits, not only enhancing their legal license to operate in a community, but their social license to operate as well (in the sense of community acceptance).

Increasingly, in addition to governments using their legal pressures, customers, lenders, insurers, investors, and shareholders are providing additional pres-

sure for businesses to do the right thing. But it is very important to remember, cautioned Webb, that if businesses do not make money, they are not going to be able to engage in social responsibility; therefore, wealth creation does remain the main objective for business.

The Role of Governments in Corporate Social Responsibility

Today's societal problems necessitate concerted efforts of government, the private sector, and civil society. CSR represents the private-sector contribution to the efforts, but it is not a panacea; there are limitations on governments, intergovernmental legal instruments, to be able to address problems voluntarily. Governments can structure and encourage CSR as a supplement to conventional approaches, and organizations like the ISO can play an important role as a bridge between laws, intergovernmental instruments, community expectations for substantive obligations, and reporting standards. ISO is just one piece of the puzzle, said Webb.

Government encouragement of CSR stems from the understanding that CSR activities can assist governments in meeting societal needs. A country or an industry sector can be negatively or positively affected by individual firms' behavior. CSR can be a competitive advantage for a country. For example, the United Kingdom approach to CSR represents the most sophisticated model. It has realized the importance of CSR and has taken great effort to institute pension disclosure laws, support ethical trading initiatives, and encourage development of many other related initiatives, including those in the standards area. Among developing countries, Brazil is the CSR leader, using standards to encourage good business behavior.

The Role of the ISO Social Responsibility Standard

Webb suggested that ISO could play an important role in lessening industry confusion and increasing acceptance by developing a social responsibility standard. This would be a third-generation standard building on the management system standards that are already in place, and it would be a guidance document, not a specification document; that is, it would not be the subject of certification, but it still could build on existing approaches. Considering that there are more than 600,000 facilities around the world that have been certified to ISO 9001 or ISO 14001, ISO is well placed to develop a standard concerning operationalization of social responsibility ideas, said Webb. ISO seems to represent the most accepted international rule infrastructure. One hundred forty-five countries around the world—the majority of them are developing countries—participate in it. However, an ISO social responsibility standard would be only part of the solution, one piece of a puzzle, cautioned Webb. It would be one more additional element compatible with the existing initiatives and laws, concluded Webb.

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Panel Discussion[1]

The workshop over the course of two days highlighted a number of issues related to environmental health and the role of governmental regulation and corporate social responsibility (CSR). The final discussion was an opportunity to focus on the research needs, alternative approaches, and limitations of current tools.

HOW DOES ENVIRONMENTAL HEALTH LINK WITH CORPORATE SOCIAL RESPONSIBILITY?

The Roundtable uses a broader definition of environmental health by discussing the human health impacts of the natural, built, and social environments. In the past 8 years, the Roundtable has used this perspective to guide the workshop topics and discussions. Carol Henry from the American Chemistry Association reiterated this by noting that environmental health is more than individual chemicals; it includes infectious diseases, safe water, physical (built) factors, and most importantly, the socioeconomic factors. In fact, participants further suggested that issues such as air quality, water quality, obesity, and chronic disease all have environmental health components. These issues are complex. For example, the topic of air quality includes asthma rates in Europe and the United States, different air quality issues between urban and rural sectors, and even issues between developed and developing countries. Not all these problems can be solved by governmental entities—a message that numerous participants noted during the workshop.

[1]The views expressed here do not necessarily reflect the views of the Institute of Medicine, the Roundtable, or its sponsors. This chapter was prepared by Christine Coussens from the transcript of the meeting. The discussions were edited and organized around major themes to provide a more readable summary and to eliminate duplication of topics.

Addressing these issues requires implementing a public-private partnership by engaging multinational corporations to deliver capacity building, noted Peter Illig of International Society of Doctors for the Environment (now at Association Internationale pour l'Osteosynthese Dynamique). He noted that, for the developing country, the occupational setting is a healthier setting than the local community setting. The way to address many of the problems is to rebuild the linkages of health and the environment. The need to do this holds true for corporations as well as governments. There has been a defined separation between environment and health, and often environment officials and the health officials do not communicate with each other. There are significant cost benefits to be realized and improvements in efficiencies from recognizing those environmental sources of ill health that are often not only easy to identify but are cost-effective to address, noted Illig.

WHAT IS CORPORATE SOCIAL RESPONSIBILITY?

During the workshop, CSR was defined many ways, but in essence, according to Illig, the role of CSR is to balance and integrate the economic, social, and environmental responsibilities in order to minimize harm, optimize societal benefits, and provide or generate wealth. Webb suggested that CSR might be similar to a Trojan horse—it has been wheeled into the corporate and societal arena, and we are now trying to understand better what encompasses and what is inside it. He suggested that CSR is a concept about breaking down boundaries between governments, the private sector, and civil society organizations by recognizing there is a role for all three in addressing today's societal problems. CSR can break down traditional boundaries, including the barriers between health and the environment.

Governments need to examine ways that CSR can be used as a competitive advantage for companies, but also as a way of addressing the problems of the 21st century.

—Kernaghan Webb

Not all segments of industry are embracing CSR with equal vigor, noted Webb. However, currently, forestry, metal and mining sectors, and the chemistry industry have begun to deliver on CSR. Further, Webb suggested that governments, for the most part, have failed to recognize the importance of CSR for their region or its global implications. According to Webb, governments need to examine ways that CSR can be used as a competitive advantage for companies, but also as a way of addressing the problems of the 21st century.

The Need for Global Strategy

The United States relies on a framework of national regulatory structures and laws to address many of the environmental health challenges facing this nation. However, ,there is no comparable regulatory structures and laws on an international level, thus we rely on treaties and agreements. Some participants noted that these agreements do not have the ability to solve the complexity of the environmental health programs. In fact, this may be one reason that focus has shifted to international or multinational businesses and organizations to help in the effort, noted Carol Henry of the American Chemistry Council (ACC). There is a need for organizations such as the International Council of Chemical Associations (ICCA), which was formally organized in June 1989 to coordinate policy and programs for the global chemical industry and has representatives world-wide. The ICCA is able to represent the global chemical industry before international government organizations, with the result that the ICCA leadership challenged the membership to think strategically and develop a global research strategy about the potential impacts of chemicals on health and the environment. As with most international initiatives, Henry noted that many challenges exist including working with individuals with diverse backgrounds, perspectives, and languages. However, a strategy was completed and is in the process of being implemented. The panelists considered the strategies and challenges for involving industry in addressing environmental health solutions.

> The private sector needs stability; it needs prosperous societies to flourish.
>
> *—Richard Wells*

Corporate Social Responsibility Meets Market Competitiveness

The panelists discussed the idea that the private sector has a role in the world carrying capacity. Richard Wells of the Monterrey Institute of Technology and Advanced Studies stated that the private sector needs to be actively involved in improving society to remain profitable. He quoted Kofi Anan as saying that "The private sector cannot flourish if society fails." We (the public, industry, academia, and so on) need to think about the challenges in the developing world, particularly poverty, which is both a consequence and a cause of environmental degradation. The two cannot be separated. To engage with society, the private sector needs stability; it needs prosperous societies to flourish. This will be important as William Blackburn of William Blackburn Consulting noted, because the majority of the population growth will be in developing countries. Thus a company's future customers are going to be in these growing untapped markets. Wells noted that many multinational corporations recognize that by encouraging local small businesses, they can help to create markets for the future. Famously, Henry Ford said he paid his workers a living wage so they could purchase his products. Blackburn

pointed out that reputation is also important. For example, some companies in the medical industry are creating health programs in sub-Saharan Africa as an opportunity to enhance their reputation and to be viewed as reputable later when this market is developed. Charles Bennett of the Conference Board noted that this was underscored earlier in the workshop by the ExxonMobil example, which created an opportunity for local businesses to be a part of the supply chain during the building of the Chad-Cameroon pipeline. According to Bennett, programs such as this one help to develop a larger market for a variety of businesses.

Panelists also emphasized the need for corporations to understand the challenges in the area where they are doing business. Poverty is one issue that will need a multifaceted approach to address. According to Wells, the poor are disproportionately affected by environmental health hazards, but he noted that getting out of poverty does not necessarily reduce environmental impacts. The world's carrying capacity needs to be raised, and at the same time, we need radical improvements in technologies, innovation, and processes to improve the standard living. Wells noted that some companies, such as Cemex, send their executives to live in poor communities. Other multinational companies are reflecting the world in the workforce by hiring talented individuals from various countries and integrating them into the corporation, noted Henry. Webb noted that IBM's policy of ensuring a diverse workforce requires that IBM hire individuals from the area in which they do business. This is not completely altruistic, noted Webb, because corporations use these opportunities to learn; they can gain a better understanding of the culture, challenges, and needs of that locale. One final point was made that during the period of unrest in Bolivia in the early 2000s, some individuals observed that certain businesses were spared from the violence because they had established local CSR. One panelist summed up by suggesting that CSR makes good business sense.

Partnerships

It is unlikely that change is going to occur at the global level unless partnerships are formed that cut across private and public sectors, noted some panelists. Primarily because of the use of treaties among governments, there is a real need to involve stakeholders if gains are to be made in all areas of the world. One way, noted Henry, will be through innovative partnerships and voluntary initiatives. Partnerships provide increased value through opportunities for leverage from scientific, intellectual, and financial perspectives, as well as increased understanding of respective goals and needs. As partnerships and voluntary initiatives have been developed with government, academia, and industry in regional venues, similar approaches need to be considered and implemented on a global scale. There is a need for organizations such as the International Council of Chemical Associations, which was formally organized in June 1989 to coordinate policy and programs for the global industry. This group represents the global chemical

industry and has representatives from all parts of the world where the chemical industry exists. The leadership of the group challenged the membership to think strategically about priorities and the impacts of chemicals on health. Henry noted that they are working to develop a research plan to address the existence of man-made chemicals in the environment. As with most initiatives, she noted that many challenges exist, including working with individuals in numerous time zones; however, there is a real need for further collaborations in many sectors.

ENVIRONMENTAL MANAGEMENT SYSTEMS

Environmental management systems (EMSs) have been implemented in thousands of companies and provide an opportunity to look holistically at impacts. These systems are designed for continuous improvements and have procedures that address issues in a systematic manner. However, the EMSs do not create an environment to think about problems creatively and sometimes, we need disruptive innovation, while EMSs promote gradual, continual improvement, noted Wells. Societal issues such as the poverty/environment nexus are not going to be addressed with management systems and will need other strategies for the market growth. Addressing this problem will allow for further market growth, thus a new generation of management systems is needed.

> Societal issues such as poverty are not going to be addressed with management systems and will need other strategies for the market growth.
>
> *—Richard Wells*

EMS: Limitations

During the workshop and in the final panel discussion, the limitations and problems of EMSs were discussed. Blackburn noted that some companies that have management systems in place are performing well, while others with such systems are not. The reason may be in large measure embedded in why management systems are instituted. For example, he noted that some companies institute ISO systems simply because their customers require it, or they want some level of recognition. There isn't a commitment to institute the management systems to make fundamental improvements. In fact, during the meeting, various speakers and participants noted that commitment from top leadership was one of the major factors in determining the success of an EMS. Blackburn further noted that when a company implements a management system only because their customers require it, they may be inclined to pick a route with the least amount of effort. They may set objectives that will not really challenge themselves.

Accountability and Evaluation

Evaluation is another problem because the outside auditors spend the majority of the time on documentation and not enough time on whether the system is providing results. Various panel members suggested the need for transparency of the data and the need for accountability. Webb echoed these comments and suggested there is a role for nongovernmental organizations (NGOs) in assuring accountability. He suggested the value in a code of conduct on accountability that would be applied, making it easier for businesses and governments to work with known accountable organizations. He further noted that standards organizations need to be more transparent and open, and they need to engage in continual improvement.

How to Move from Management Systems to Health

Blackburn noted that during the workshop, speakers and participants discussed management systems and then spoke of health. However, there needs to be a discussion of how one goes from a management system to health—the connection needs to be made. He noted that management systems are there to help implement operational goals, whether one is discussing limits, standards, or some operational objective. One example might be ambient levels of pollutants that have been linked to certain exposures to individuals, which in turn may be affected by certain behaviors. From this, one can draw connections between management systems and disease or health effects. But, he noted, the connection has to be made, and that requires research. It has to be done in a context of other confounding issues like poverty, corruption, culture, and technology, he observed. In many cases, it has to be done on a global basis, because, after all, many problems are global, the exposures are often global, companies are global, and stakeholders are global. Finally, he concluded, it has to be done in the context of the governance mechanisms and structures that can help or hurt the health effects.

> We need a common language and a shared understanding around what the problem is in order to pursue the dialogue.
>
> *—Charles Bennett*

CHALLENGE AND OPPORTUNITIES

This workshop highlighted a number of diverse and complex issues that fall under environmental health, noted Bennett. While one can agree that these are important issues, the overall challenge is taking the information back down to a level that is important for businesses. There is a need to try to understand the importance of environmental health in the overall management equation to determine which systems at which points can be implemented to address the

issue, concluded Bennett. To do this, we need a common language and a shared understanding around what the problem is in order to pursue the dialogue.

The Need to Share Best Practices

According to many speakers, sharing best practices as they relate to CSR, both within and across industries and sectors, is another challenge. Henry noted that there are a number of sensitive issues, including cost and competitive advantage. Within their supply chain and stakeholders, corporations can use their best practices to help guide their operations. However, across industries, this was less likely to occur. Bennett noted that many business executives meet throughout the year to benchmark their practices. Often these practices include management or problem-solving approaches as opposed to the specific solutions, which are often proprietary and competitive. Thus he noted that to the extent that the approach is widely relevant, there is a lot of interest in it; however, when it reveals trade secrets, there are barriers to sharing. The panel noted that there is a need to create a dialogue on the issue of best practices, both within and outside of industry sectors. Blackburn suggested the use of accolades that acknowledge the individual accomplishments of corporations could encourage more discussion and sharing of best practices.

Research will clearly be important, but Wells cautioned about the potential problem of certifying best practices. He questioned whether there would be any incentive to improve beyond current practices. Management systems tend to ratify common practices rather than promote innovation. Jim Bus noted that when we talk about best practices, largely these are looking toward the future science and research that will frame the practices. Thus, programs such as the Long-Range Research Initiative provide opportunities for clusters of industry to gather with government, academia, and others to address a common research problem. He suggested that, although we recognize that we have a problem today, the emphasis should be on how science might frame a solution to the problem in the future. Thus there is an opportunity for the frameworks of best practices to research in this area that will make a difference for the future.

Research

During the course of the workshop, there were numerous calls for research on chemicals by various individuals, including the tools for hazard assessment testing for all the chemicals that are covered by the REACH program, the tools for risk assessment, and the tools to provide the metrics by which the various programs operate under CSR. Henry noted that government has to do part of it and industry has to do part of it. Bennett echoed many of these points by noting that today one sees more companies and NGOs involved in activities that were formerly undertaken by government. Research, he noted, was no exception.

Blackburn further noted that the research can occur in many places and does not have to be a large, centralized research program. He suggested creating incentives for research in small, medium-size, and large companies so that "we have a thousand flowers blooming here." One industry program that was mentioned was the Long Range Research Initiative (LRI) established by the ACC. The research priorities of the LRI are (1) to improve methods that help build a foundation to evaluate risks of chemical products to public health and environment, (2) to develop susceptibility factors to evaluate whether children or other vulnerable groups are adequately protected, and (3) determine where chemicals in the environment are to increase understanding of pathways from sources to humans and wildlife. Henry noted that it is important to think about these issues globally as chemicals do not recognize geographic boundaries. Thus the research programs need to reflect this and partnerships and collaborative approaches with government and academia are necessary to making progress in the field. One of the hallmarks of the program is the recognition that the perception of industry-sponsored research is not always favorable. To overcome this problem, the program established open and transparent practices, using third-party, independent investigators, who determine the experimental approaches and select the chemicals for use in the research. In addition, the researchers own their data and have control over when the results will be published without the right of prior review by the ACC. Transparency and credibility are important elements of the program and are necessary for its success. Research sponsored by the LRI is leveraged and coordinated internationally through the ICCA, thereby meeting the need of the global chemical industry to increase knowledge on the health, safety, and environmental impacts of chemicals.

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Appendix A

Workshop Agenda

GLOBAL ENVIRONMENTAL HEALTH IN THE 21ST CENTURY: FROM GOVERNMENTAL REGULATION TO CORPORATE SOCIAL RESPONSIBILITY

Sponsored by
The Roundtable on Environmental Health Sciences, Research, and Medicine
Auditorium, NAS Building
2101 Constitution Avenue, N.W., Washington, DC

OCTOBER 13, 2004

8:30 a.m. **Welcome and Opening Remarks**
The Honorable Paul G. Rogers
Chair, Roundtable on Environmental Health Sciences, Research, and Medicine
Partner, Hogan and Hartson

8:40 a.m. **Remarks and Charge to Participants**
Samuel Wilson
Member, Roundtable on Environmental Health Sciences, Research, and Medicine
Deputy Director, National Institute of Environmental Health Sciences, NIH

8:55 a.m. **Workshop Objectives**
Myron Harrison
Member, Roundtable on Environmental Health Sciences, Research, and Medicine
Senior Medical Advisor, ExxonMobil Corporation

SESSION I: WHAT ARE THE TOOLS FOR MONITORING ENVIRONMENTAL HEALTH IN COMPANIES?

Moderator: Ann Wolverton, U.S. Environmental Protection Agency, National Center for Environmental Economics

9:00 a.m. **Environment Management Systems: Overview and One Tool in the Toolbox**
Edwin Pinero
Director, Office of the Federal Environmental Executive

9:20 a.m. **Environmental Management Systems in Practice**
Deanna Matthews
Postdoctoral Researcher, Carnegie Mellon University

9:40 a.m. **Measuring What We Should Be Measuring: Limitation of Environmental Management Systems and Doing More Than Checking off Boxes**
Cary Coglianese
Associate Professor, Kennedy School of Business, Harvard University

10:00 a.m. **General Discussion**

10:30 a.m. **Break**

SESSION II: MOVING BEYOND COMPLIANCE: CAN INDUSTRY GET AHEAD OF THE CURVE?

Moderator: Charles Bennett, Senior Research Associate, Global Corporate Citizenship, The Conference Board

10:50 a.m. **Using Management Systems to Improve Performance in the Chemical Industry**
Terry F. Yosie
Vice President, The Responsible Care Initiative, American Chemistry Council

11:10 a.m. **The Implication of Technology for Environmental Health**
Braden Allenby
Professor of Civil and Environmental Engineering, and of Law, Arizona State University

11:30 a.m. **Cradle to the Grave: Impacts on Environmental Health**
Jack Azar
Member, Roundtable on Environmental Health Sciences, Research, and Medicine
Senior Vice-President, Environment, Health, and Safety, Xerox Corporation

11:50 p.m. **General Discussion**

12:10 p.m. **Lunch**

12:50 p.m. **Green Chemistry in the Pharmaceutical Industry: Alternative Synthetic Pathways**
Berkeley W. Cue, Jr.
Consultant, Pfizer, Inc.

1:10 p.m. **Product Stewardship: Responsible Care in Action**
Gregory Bond
Corporate Director of Product Responsibility, Dow Chemical Company

1:30 p.m. **Foxes and Henhouses: One NGO's Experiences with Voluntary Programs**
John Balbus
Director, Environmental Health Program, Environmental Defense

1:50 p.m. **General Discussion**

2:10 p.m. **Break**

SESSION III: GLOBAL IMPLICATION OF ENVIRONMENTAL STANDARDS

Moderator: Daryl Ditz, Coordinator, National Educational Campaign on U.S. Persistent Organic Pollutants Ratification, Center for International Environmental Law

2:30 p.m. **Balancing Risk, Assessment with the Realities of Uncertainties**
Bernard Goldstein
Member, Roundtable on Environmental Health Sciences, Research, and Medicine
Dean, School of Public Health, University of Pittsburgh

2:50 p.m. **Global Corporate Policies on Health, Safety, and Environment**
Barry Castleman
Consultant, School of Hygiene and Public Health
Johns Hopkins University

3:10 p.m. **The REACH Initiative: Promises for the European Union**
Robert Donkers
Counselor, Transportation, Energy, and Environment
Delegation of the European Commission to the United States

3:30 p.m. **The REACH Initiative: Can It Realistically Be Achieved?**
James Bus
Director of External Technology, Dow Chemical Company

3:50 p.m. **General Discussion**

4:10 p.m. **Canadian Environmental Protection Act: Protecting Human Health and the Environment**
Daniel Krewski
Professor of Medicine and of Epidemiology and Community Medicine, Institute of Population Health, University of Ottawa

4:30 p.m. **U.S. Approach to Regulation: TSCA and Public Health**
Lynn Goldman
Member, Roundtable on Environmental Health Sciences, Research, and Medicine
Professor, Bloomberg School of Public Health, Johns Hopkins University

4:50 p.m. **Working Across Borders on Chemical Issues: The Strategic Approach to International Chemicals Management (SAICM)**
John Buccini
Consultant, United Nations Environmental Program

5:10 p.m. **General Discussion**

5:30 p.m. **Adjourn**

OCTOBER 14, 2004

8:30 a.m. **Welcome Back**
The Honorable Paul G. Rogers
Chair, Roundtable on Environmental Health Sciences, Research, and Medicine
Partner, Hogan and Hartson

SESSION IV: IMPROVING COMMUNITY HEALTH GLOBALLY

Moderator: Garrick Louis, Associate Professor of Systems and Information Engineering, University of Virginia

8:40 a.m. **Opening Moderator Remarks**

8:50 a.m. **Environmental Health Performance Is Driven by Management Systems**
Brian Flannery
Manager, Science Strategy and Programs, Corporate Safety Health and Environment, ExxonMobil Corporation

9:15 a.m. **Health and Environment in Practice: Building of the Chad-Cameroon Project**
Andre Madec
Manager, Corporate Public Affairs, ExxonMobil Corporation

9:35 a.m. **Public Health Lessons Learned from the Chad-Cameroon Pipeline Project**
Burton Singer
Professor, Demography and Public Affairs, Princeton University

9:55 a.m. **Strategic Management of Environmental Health Management Systems**
Djordjija Petkoski
Lead Specialist, World Bank

10:15 a.m. **General Discussion**

10: 35 a.m. **Break**

SESSION V: CORPORATE SOCIAL RESPONSIBILITY

Moderator: Kathryn Gordon, Senior Economist, Organization for Economic Cooperation and Development (OECD)

10:55 a.m. **Sustainability and Corporate Social Responsibility**
Norine Kennedy
Vice-President for Environment, United States Council on International Business

11:15 a.m. **Corporate Social Responsibility in the Context of Regulation**
Eric W. Orts
Guardsmark Professor; Professor of Legal Studies and Management, Director, Environmental Management Program, Wharton School of Business

11:35 a.m. **Corporate Social Responsibility: Roles of Government, the Private Sector, and Civil Society**
Kernaghan Webb
Adjunct Research Professor, Law and Public Policy
Carleton University, Ottawa

11:55 a.m. **General Discussion**

12:30 p.m. **Lunch**

SESSION VI: CHALLENGES TO IMPROVING ENVIRONMENTAL HEALTH

Moderator: Peter Illig, Member, Roundtable on Environmental Health Sciences, Research, and Medicine, Executive Director, International Society for Physicians for the Environment

1:30 p.m. **Panel Discussion**
This panel will take a critical look at the challenges of environmental health to discuss some of these questions:

- How do we create dialogue with stakeholders and form partnerships?
- Are there research needs for innovation in environmental health in the industrial setting?
- Are we stifling innovation in environmental health by governmental practices?
- How can best practices be improved and shared by companies?

- How do we raise awareness of environmental health through accountability at all levels?

Carol Henry, Member, Roundtable on Environmental Health Sciences, Research, and Medicine, Vice-President for Research, American Chemistry Council
Richard Wells, International Adjunct Professor, Monterrey Institute of Technology and Advanced Studies
Charles Bennett, Senior Research Associate, Global Corporate Citizenship, The Conference Board
William Blackburn, Consultant, William Blackburn Consulting
Kernaghan Webb, Adjunct Research Professor, Law and Public Policy, Carleton University, Ottawa

2:30 p.m. **General Discussion**

3:30 p.m. **Summation**

3:40 p.m. **Adjournment**

Appendix B

Speakers and Panelists

Brandon Allenby, Professor of Civil and Environmental Engineering, School of Engineering, Arizona State University
Jack Azar, Senior Vice-President, Environment, Health, and Safety, Xerox Corporation
John Balbus, Director, Environmental Health Program, Environmental Defense
Charles Bennett, Senior Research Associate, Global, Corporate Citizenship, Townley Center for EH&S Management
William Blackburn, Consultant, William Blackburn Consulting, Ltd.
Gregory Bond, Corporate Director of Product, Responsibility, Dow Chemical Company
John Buccini, Consultant, United Nations Environmental Program
James Bus, Director of External Technology, Dow Chemical Company
Barry Castleman, Consultant, School of Hygiene and Public Health, Johns Hopkins University
Cary Coglianese, Associate Professor, Harvard University
Berkeley Cue, Consultant, Pfizer, Inc.
Daryl Ditz, Coordinator, National Educational Campaign on U.S. Persistent Organic Pollutants Ratification, Center for International Environmental Law
Robert Donkers, Environmental Counselor, Delegation of the European Commission to the United States
Brian Flannery, Manager of Science Strategy Programs, ExxonMobil Corporation
Lynn Goldman, Professor, Bloomberg School of Public Health, Johns Hopkins University
Bernard Goldstein, Dean, School of Public Health, University of Pittsburgh
Kathryn Gordon, Senior Economist, Organization for Economic, Cooperation and Development (OECD)
Myron Harrison, Senior Medical Advisor, ExxonMobil Corporation

Carol Henry, Vice-President for Research, American Chemistry Council
Peter Illig, Executive Director, International Society of Doctors for the Environment (ISDE)
Norine Kennedy, Vice-President for Environment Affairs, United States Council for International Business
Daniel Krewski, Professor of Medicine and Epidemiology and Community Medicine, Institute of Population Health, University of Ottawa
Garrick Louis, Associate Professor of Systems and Information Engineering, University of Virginia
Andre Madec, Manager of Corporate Public Affairs, ExxonMobil Corporation
Deanna Matthews, Postdoctoral Researcher, Carnegie Mellon University
Eric W. Orts, Guardsmark Professor; Professor of Legal Studies and Management, University of Pennsylvania
Djordjija Petkoski, Lead Specialist, World Bank Institute
Edwin Pinero, Director, Office of the Federal Environmental Executive
Paul Rogers, Partner, Hogan and Hartson
Burton Singer, Professor, Princeton University
Kernaghan Webb, Adjunct Research Professor of Law and Public Policy, Carleton University
Richard Wells, President, The Lexington Group
Samuel Wilson, Deputy Director, National Institute of Environmental Health Sciences, NIH
Ann Wolverton, Economist, U.S. Environmental Protection Agency
Terry F. Yosie, Vice-President, American Chemistry Council

Appendix C

Workshop Participants

Linda Allen, U.S. Department of State
Cindy Bethell, U.S. Senate
Amanda Blakeley, World Bank
Katherine Bliss, U.S. Department of State
William Boyd, U.S. Senate
Margaret Breida, American Industrial Hygiene Association
William Brock, Brock Scientific Consulting, LLC
Margaret Chu, U.S. Environmental Protection Agency
John J. Cohrssen, Public Health Policy Advisory Board
Eileen Collins, Rutgers University
Margaret Conomos, U.S. Environmental Protection Agency
Morris Cranmer, University of Arkansas
Joan Cranmer, University of Arkansas
Elizabeth David, Stratus Consulting
Dennis Devlin, ExxonMobil Corporation
Brian Doll, ExxonMobil Corporation
Bertha Dong, Government Accountability Office
Rob Donnelly, Shell Oil Company
Brenda Doroski, U.S. Environmental Protection Agency
J. W. Dunlap, JTxCo
Adele Egwu, National Institutes of Health
Jon Ehrenfeld, International Center for Technology Assessment
Stephanie Foe
Angeles Franco, Hospital Universitario, Gregoriio Marañón
Joseph Gainer
Mary Gant, National Institute of Environmental Health Sciences
Alan Hecht, U.S. Environmental Protection Agency
Steve Herrin
Cheryl Hogue, American Chemical Society

Sarah Hunt, National Academy of Sciences
Diana Jerkins, U.S. Department of Agriculture
Allen Jones, American Public Health Association
Michelle Khan, National Institutes of Health
Paul Koch, KEVRIC
Pat Koshel, National Academy of Sciences
Gary Krieger, NewFields, LLC
Robert Lee, U.S. Environmental Protection Agency
Neil Levy, U.S. Patent and Trademark Office
Richard Liroff, World Wildlife Fund
Whitney Long, ERG
Susan Lundquist, U.S. Environmental Protection Agency
Julie Manley, Abbott Laboratories
Jeffrey Marks, United Technologies Corporation
Mary Masulla
Mili Mavely, American Industrial Hygiene Association
Susan McDonald
Gerald McLaughlin, National Institute of Allergy and Infectious Diseases
John Meagher, Intercet Ltd.
Steven Phillips, ExxonMobil Corporation
Debora Rice, ExxonMobil Corporation
Joana Rosario, National Institute of Allergy and Infectious Diseases
Andrea Schultz, George Washington University
Karen Searfoss Ingram, Asyst
Daniel Shodell, Johns Hopkins University
Kevin Sikora, Eastern Research Group, Inc.
Jack Snyder, National Institutes of Health
Matt Stanberry, ICF Consulting
Jacob Steinberg, Albert Einstein College of Medicine
Madalene Stevens, U.S. Environmental Protection Agency
Kristina Svensson, ICF Consulting
Derek Swick, American Petroleum Institute
Lakew Temeselew, Howard University
Blandine Trouille, U.S. Department of Commerce
Stanley Tsai, Maryland Department of the Environment
Claudia Walters, U.S. Environmental Protection Agency
Edward Washburn, U.S. Environmental Protection Agency
Gary Waxmonsky, U.S. Environmental Protection Agency
Roberta Wedge, National Academy of Sciences
Charles A. Wells, National Institute of Environmental Health Sciences
Malcolm Woolf, U.S. Senate