ical and public health communities. The committee will ensure that there is an open and public implementation process for the new law by soliciting views from all stakeholders. Readers who are interested in attending Advisory Committee meetings in November or December in Washington, DC, or giving oral or written testimony may contact Margie Fehrenbach or Carol Peterson at EPA (tel. 703-305-7090) for further information.

As we proceed in developing the policies, guidelines, and rules required by the new food law, there will be ample opportunity for public participation at all stages. A number of approaches may be used, including public meetings; focus group discussions; talks at professional and other association meetings; and exchanging written, e-mail, and oral comments. I am looking forward to receiving many good ideas as we employ an open process for developing safer pesticides. We will also actively share decisions with the public as we make them.

The Food Quality Protection Act emphasizes the principles that already guide many of our activities at EPA. The Clinton Administration is committed to increasing our efforts to prevent pollution and disease; to protect infants, children, and other vulnerable groups; and to provide consumers with the information they need to make informed choices. We at EPA are seeking better ways to obtain input from all groups who share these goals and want to work with us to improve the public's health.

I want especially to call on the public health community to participate in this process—this is the first time any environmental law has required an agency to make a positive finding that children are protected. We need the public health community to help with questions such as "How do we make a finding of no prenatal or postnatal risks for children?" "How do we address multiple exposures to the same pesticides from different sources, to different pesticides that act via similar mechanisms, or to different pesticides that cause the same adverse effect, albeit by different mechanisms?" "How do we sensibly provide the public with the information it needs about pesticides in the home and on food so that people can protect themselves and their families?" These are questions that do not have easy answers—they need the public health perspective as well as the best available science.

Lynn R. Goldman, MD, is the Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency.

Address correspondence to Dr. Goldman, U.S. Environmental Protection Agency (7101), 401 M Street SW, Washington DC 20460; tel. 202-260-2902; fax 202-260-1847; e-mail <goldman.lynn@epamail.epa.gov>.

Gilbert S. Omenn, MD PhD

Putting Environmental Risks in a Public Health Context

Most environmental regulations are aimed at protecting the health of workers or the general public. Unfortunately, in the 1960s and 1970s, the role of public health agencies in environmental health receded as new agencies were formed, from the Environmental Protection Agency, Occupational Safety and Health Administration, and Consumer Protection Safety Commission at the national level to their counterparts in states and local jurisdictions. Our present regulatory system is dominated by actions directed at one chemical, one health risk, and one medium (air, water, food, soil) at a time, reflecting current statutes and the organization and orientation of environmental regulatory agencies. Wider use of public health concepts of total exposure and attributable risk and much greater engagement of public health agencies are needed.

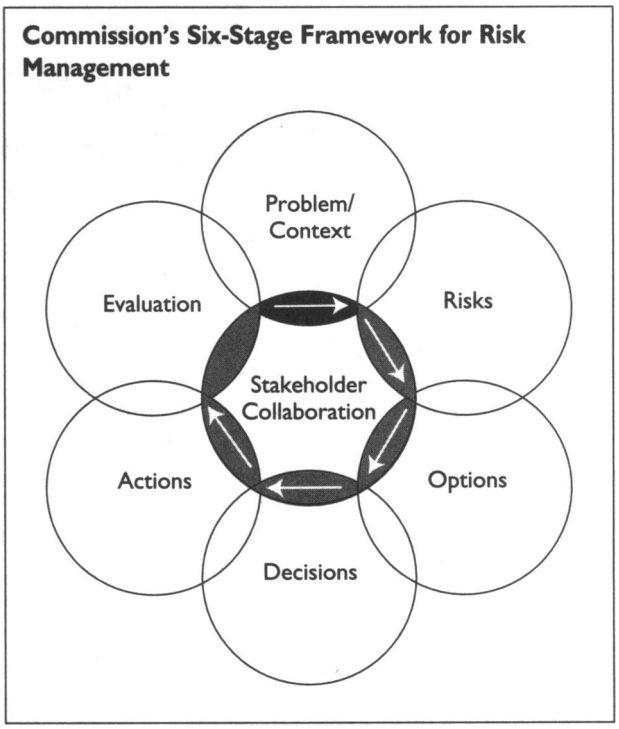
A new Framework for Risk Management has been proposed by the Commission on Risk Assessment and Risk Management. The Commission, mandated by Congress as part of the 1990 amendments to the Clean Air Act, has six members appointed by the Congress, three by the President, and one by the National Academy of Sciences. The Commission issued its *Report* for public comment in June 1996 after two years of meetings and public hearings around the country. The Commission's *Report* emphasizes risk management, with a six-stage process that begins by putting every environmental problem into a broad public health or ecosystem health context (see Figure). At the center are stakeholders, including local elected officials, public health officers, and people from communities and tribal nations affected or potentially affected by the environmental pollutants as well as regulatory agencies, the scientific community, labor and environmental groups, and regulated parties. The emphasis on community stakeholders reflects not only

a commitment to the right to know but also a recognition from testimony to the Commission that local people often have valuable information about sources of exposure, patterns of behavior, cultural practices, and local concerns that generic risk assessments and models would miss. Such information can provide guidance for the risk assessment step and for the development of cost-effective options for action.

The focus on a public health context challenges interested parties to identify all significant sources contributing to total exposure to an agent under regulatory scrutiny and all causes of particular health problems (endpoints) for which the chemical might be partly responsible. The framework emphasizes that we are exposed to mixtures—"chemical soups"—in the air we breathe, the water we drink, the food we eat, the things we touch. It encourages us to consider radiological and microbiological hazards and the frequent risk/risk tradeoffs we deal with in public health practice. It responds to logical questions many citizens ask: What dangers does my community face? How much does a particular industrial facility contribute to the total exposure of our community to a chemical or set of chemicals? How much reduction in the present rates of cancers or other diseases could result if a particular source of exposure were controlled or eliminated? What is the likely cost—and how long will it take—to reduce these risks? Are there other more significant risks that we are ignoring, some of which might be readily addressed? Is there some point of diminishing returns in reducing specific emissions or exposures, especially in light of the costs or hazards of doing so?

When the Commission began its work in 1994, the Congress was already actively considering legislation for "regulatory reform" that would give risk assessment and comparisons of risks greater prominence. In the 104th Congress, which took office in January 1995, regulatory reform was a key element of the Contract with America (HR 9, passed by the House of Representatives as HR 1022). Risk assessment was seen as a powerful tool for setting national priorities and cutting the costs of environmental protection. A prescriptive approach was proposed, requiring an increased investment in resources for risk assessment, extensive peer review, and judicial review. Over the subsequent months, these controversial proposals to overhaul key environmental laws and subject all decisions to a benefit/cost criterion, while reducing agency budgets, were derailed in the Senate. Public opinion polls showed that the American people want to maintain the well documented gains in air quality, water quality, waste disposal, pollution prevention, and product safety achieved since Earth Day 1970. We as a nation want to address both newer and ongoing threats to the environment. At the same time, however, there is strong sentiment to reduce perceived administrative and financial burdens and to assure that priorities are sensible. As in health care, there is tremendous ferment in the world of environmental regulation—offering the public health community a great opportunity for proactive roles.

A good example of the application of the Commission's Framework is the matter of residual risk in the Clean Air Act program for stationary sources (industry, commercial enterprises, utilities) of 189 specified chemicals considered hazardous air pollutants. The Environmental Protection Agency (EPA) has been mandated to issue MACT (Maximal Available Control Technolo-



The critical role of stakeholders in setting the context and guiding technical assessments is indicated by the black ellipse in stage one. The arrow is removed from stage six to discourage "paralysis by analysis."

gies) standards for 174 major source categories and thousands of subcategories. These emissions controls should markedly reduce emissions and, thereby, exposures and risks. Nevertheless, the Congress directed the Commission to assist EPA in determining how to estimate the risks that would remain after implementation of these controls and how to decide whether further risk reduction should be required. The Commission recommended that EPA and the stakeholders explicitly consider not just the risks attributable to a particular industrial source of one of these pollutants but all of the sources in the geographic area or airshed. If other facilities are emitting far more of the specified pollutant or if motor vehicles are contributing a large share of the emissions people actually breathe, further reductions of emissions at the regulated source may have little or no impact on exposures and risks for the population. This demonstrates why a multi-source, multimedia analysis is essential.

Then, as people commonly ask, what about mixtures of pollutant chemicals? The usual reductionist scientific approach requires examining purified chemicals one at a time, searching for detailed knowledge about the mechanisms of adverse effects. Such knowledge is valuable for regulatory purposes, basic understanding of chemical actions, and development of biomarkers of exposure, early effects, and individual variation in susceptibility that could be useful in public health surveillance and monitoring of specifically exposed populations. In addition, however, we could test environmentally important mixtures in the same cellular or animal assays we use for purified chemicals. Such work has been done with diesel exhausts, Los Angeles smog, organophosphorus pesticides, polycyclic aromatic hydrocarbons, and cigarette smoke. It would be ridiculous, of course, to test every permutation of dozens or thousands of chemicals under various conditions; it is practical to test representative samples under conditions of particular interest for regulatory purposes and for public health advisories about community-level exposures and risks.

It would also be useful to compare different kinds of risks—for cancer, birth defects, other health effects, and ecological impacts. Most states, many cities, and several tribal nations have conducted priority-setting exercises called comparative risk assessments. These are not comparisons of risks associated with specific chemicals and proposed risk reduction actions but comparisons of categories of risks. Such efforts are empowering for most participants, yet often end with frustration over the lack of any common metric for comparing different kinds of effects. The Commission suggests use of what EPA calls the "margin of exposure," the ratio of the exposure shown in people or deduced from animal studies to cause a particular kind of effect in, say, 10% of people compared with the present exposure level in various situations. Similar ratios can be estimated for the levels expected after more stringent regulation. These ratios could be a useful starting point for discussion comparing the risks of low-level exposures to chemicals with carcinogenic and other health effects.

All of us are stakeholders in the effort to make our system for reducing risks and improving public health as efficient and effective as possible.

The Commission addressed specific regulatory responsibilities across the many programs of the EPA, the Food and Drug Administration (the Delaney Clause, drug approvals, scientific evidence for claims of health benefits from dietary supplements), the Occupational Safety and Health Administration, the Department of Agriculture (meat inspection), and the Departments of Energy and Defense (hazardous wastes clean-up programs). Readers of *Public Health Reports* will find much of interest in this *Report* available at <www.riskworld.com>.

After all, all of us are stakeholders in the effort to make our system for reducing risks and improving public health as efficient and effective as possible.

Dr. Omenn is Dean of the School of Public Health and Community Medicine at the University of Washington, Seattle, and Chair of the Commission on Risk Assessment and Risk Management.

Address correspondence to Dr. Omenn, School of Public Health and Community Medicine, University of Washington, Box 357230, Seattle WA 98195; tel. 206-543-1144; fax 206-543-3813; e-mail <gomenn@u.washington.edu>.