Protecting Public Health & the Environment

Implementing the Precautionary Principle

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Introduction

TO FORESEE AND TO FORESTALL

When Rachel Carson completed her book, *Silent Spring,* she dedicated it to Albert Schweitzer who said, "Man has lost the capacity to foresee and forestall. . . . He will end up destroying the earth." To foresee and forestall is the basis of the Precautionary Principle. It is the central theme for environmental and public health rooted in the elemental concepts of "first do no harm" and "an ounce of prevention is worth a pound of cure." In its simplest formulation, the Precautionary Principle has a dual trigger: If there is a potential for harm from an activity and if there is uncertainty about the magnitude of impacts or causality, then anticipatory action should be taken to avoid harm. Scientific uncertainty about harm is the fulcrum for this principle. Modern-day problems that cover vast expanses of time and space are difficult to assess with existing scientific tools. Accordingly, we can never know with certainty whether a particular activity will cause harm. But we can rely on observation and good sense to foresee and forestall damage.

We have failed to heed Carson and Schweitzer's warning. Industrial development increased rapidly following World War II, with little regard for human health or the environment. Growth was considered akin to prosperity, and some small environmental damage was a small price to pay for the benefits of industrialization. Research and legislation developed during the

late 1960s and early 1970s acknowledged that there were substantial adverse impacts associated with unlimited growth. With increasing knowledge about the complexities of ecosystems, the human body, and the impacts of various stressors, we have realized that we actually understand much less than we thought we did about these systems.

During the 1970s and 1980s, tools such as risk assessment and cost-benefit analysis were developed to assist decision makers in making more rational decisions about industrial activities and their impacts. However, their incorporation into decision-making structures was based on the misguided belief that humans could fully understand the impacts of their activities on the environment and establish levels of insult at which the environment or humans could rebound from harm. Too much emphasis was placed on the role of science to model and predict harm in extremely complex ecological and human systems. Risk assessment, which was originally developed for mechanical problems such as bridge construction where the technical process and parameters are well defined and can be analyzed, took on the role of predictor of extremely uncertain and highly variable events. The risk-based approach, now central to environmental and public health decision making in the United States, has in part led to a regulatory structure based on pollution control and remediation, rather than fundamental prevention.

The quantitative, risk-based approach to environmental and public health regulation has taken on an importance in government agency operations. It allows agencies to justify and defend their decisions to the courts, businesses, and the public in the guise of objective, unbiased numbers, avoiding mention of the values implicit in decisions affecting public and environmental health. This approach is viewed as the "sound science" approach to decision making, where decisions are made on the basis of what we can quantify, without considering what we do not know or cannot measure. That is lumped under the category of "uncertainty," which can be addressed in a neutral way through additional information and modeling. The risk assessment process, however, is as much policy and politics as it is science. A typical risk assessment relies on at least 50 different assumptions about exposure, dose-response, and relationships between animals and humans. The modeling of uncertainty also depends on assumptions. Two risk assessments conducted on the same problem can vary widely in results.

Current environmental and public health decision-making processes, based primarily on the level of risk, suffer from several limitations, which constrain their ability to identify, anticipate, and prevent potential harm to human health and the environment. Decisions to take action to restrict potentially dangerous activities are often taken after science has established

a causal association between a substance or activity and a well-defined, singular adverse impact. Proving causality takes both extensive time and resources. During this research period, action to prevent potentially irreversible human and environmental harm is often delayed in the name of uncertainty and the harmful activity continues. For a variety of reasons, it may not even be possible to demonstrate a causal association in complex human/ecological systems.

For example, even basic knowledge about the impacts of the most widely used toxic chemicals is unavailable. Analysis of the impacts of human activities on health and the environment is wrought with uncertainty. This ignorance leads to an important question for decision makers, "How can science establish an 'assimilative capacity' (a predictable level of harm from which an ecosystem can recover) or a 'safe' level when the exact effect, its magnitude, and interconnectedness are unknown?"

Further, regulatory programs often demand the achievement of statistical significance in experimental and observational research. Even though an effect is not significant to a statistician, it still may be significant to the person or community. This "laboratory" model of science places an emphasis on minimizing Type I errors (incorrectly concluding that there is an effect when one does not exist) and thus unnecessary regulation at the expense of increasing the potential for Type II errors (incorrectly concluding that there is not an effect when there is one), placing humans and the environment in jeopardy. Achieving adequate statistical power (the predictive potential of an experiment) for a study to be considered acceptable is difficult if the number of subjects or effect is small.

Even low level exposure to stressors may cause adverse impacts. These impacts may be impossible to monitor or control. For example, there is growing evidence that some synthetic chemicals may disrupt the hormone system at very low levels of exposure and not at high doses (an inverted U-shaped dose response), with effects happening when exposure takes place during sensitive periods in the development of a fetus. It is virtually impossible to know what level of exposure will affect a fetus or what impacts that exposure will cause.

Science has not begun to address the wide range of physical and chemical stressors to which humans and ecosystems are exposed since it focuses on single chemicals/stressors in single media. If we are ignorant about the impacts of only single human activities on health and the environment, we are even more ignorant about the cumulative effects of many potentially harmful activities.

Finally, risk assessments and other analyses are very time consuming, con-

tentious, and costly. For example, a single risk assessment on a single chemical might take up to five years and cost upwards of $5 million. This excludes the cost of the harm that may be caused by the activity under study. Focusing on opportunities to prevent harm (e.g., using the Precautionary Principle) is a much more cost-effective use of limited resources.

There is a need for decision makers to bridge the gap between uncertain science (and the need for more information) and the political need to take action to prevent harm. As trustees of ecosystem and public health, government agencies have an obligation to prevent harm despite the existence of uncertain impacts. They must consider that there could be large political and economic consequences if they are wrong. The question of what society should do in the face of uncertainty regarding cause and effect relationships is a question of public policy, not science. A decision not to act in the face of uncertainty, to await further scientific evidence, is as much a policy decision as taking preventive action.

History of the Precautionary Principle

The term "Precautionary Principle" is relatively new to the national and international environmental policy arena, though the concept has its roots in hundreds of years of public health practice. Even early environmental legislation encompassed a precautionary approach to environmental protection. For example, in the legislative history to Sweden's first environment act, the Minister of Justice noted that environmental policy should lead to actions in the face of uncertainty and shift the burden of proof of safety to those who create risks.

The principle emerged as an explicit basis of policy during the early 1970s in West Germany as "Vorsorgeprinzip" or the "foresight" principle of German water protection law. At the core of early conceptions of this principle in Germany was the belief that society should seek to avoid environmental damage by careful "forward-looking" planning, blocking the flow of potentially harmful activities. The Vorsorgeprinzip has been invoked to justify the implementation of vigorous policies to tackle river contamination, acid rain, global warming, and North Sea pollution. Implementation of the foresight principle has given rise to a globally competitive industry in environmental technology and pollution prevention in Germany.

The Precautionary Principle was first introduced internationally in 1984 at the First International Convention on Protection of the North Sea, designed to protect the fragile North Sea ecosystem from further degradation due to the input of persistent toxic substances. At the Second North Sea Conference, ministers noted that "in order to protect the North Sea from possibly damaging effects of the most dangerous substances . . . a precaution-

ary approach is addressed which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence." Following this conference, the principle was integrated into numerous international conventions and agreements including the Maastricht Treaty, the Barcelona Convention, and the Global Climate Change Convention, among others.[1] The principle guides sustainable development in documents like the 1990 Bergen Ministerial Conference on Sustainable Development and the 1992 United Nations Conference on Environment and Development. It has become a central theme of environmental law and policy in the European Union and many of its member states.

The Precautionary Principle itself is a relatively new concept to environmental protection in the United States. However, as in many other countries, the general notion of precaution underlies much of the early U.S. environmental and public health legislation. For example, the former Delaney Clause of the Food, Drug, and Cosmetics Act prohibited the incorporation into processed food of any level of a substance that had been found carcinogenic in laboratory animals. The National Environmental Policy Act (NEPA) requires that any project receiving federal funding and that may pose serious harm to the environment undergo an environmental impact statement, demonstrating that there were no safer alternatives. The Clean Water Act (CWA) established strict goals in order to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." The Endangered Species Act requires the protection of threatened species beyond economic interests. The Occupational Safety and Health Act (OSHA) was designed to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions." The OSHA draft Carcinogen Standard (which was never put into practice) required precautionary actions any time a chemical used in the workplace was suspected of being a carcinogen in animals.

Early court decisions also gave substantial deference to the Environmental Protection Agency (EPA) to take action to prevent harm even before considerable evidence of cause and effect was gathered. For example, in the Reserve Mining Case, the court ruled that "the public's exposure to asbestos created a sufficient health risk to justify taking precautionary and preventive measures to protect the public health." In a case over EPA regulations requiring reductions in lead additives in gasoline, the court noted, "Where a statute is precautionary in nature, the evidence difficult to come by, uncertain or conflicting because it is on the frontiers of scientific knowledge, . . . we will not demand rigorous step-by-step proof of cause and effect."

Much of the early precautionary nature of U.S. environmental and occupational safety and health policy was lost during the 1980s, when the Rea-

gan administration disarmed these protections. In addition, a U.S. Supreme court case involving occupational health standards for benzene, and the rise in supremacy of quantitative risk assessment and cost-benefit analysis in environmental and occupational health, eroded the early precautionary nature of environmental and public health protections. The protection of health and environment has not fully recovered from these actions.

A strong public backlash to losses in environmental and health protections, coupled with the industrial disasters in Chernobyl and Bhopal, led to a rejuvenation of the grassroots activism in the United States and new calls for the public's right to know and expanded environmental protections. Creating a public right to know led to an understanding that companies were emitting enormous amounts of pollutants into the environment. This, coupled with a realization that pollution-control strategies were not eliminating but rather shifting pollution, led to the passage of the Pollution Prevention Act of 1990, which sets prevention as the highest priority in environmental programs.

Responding to the public's strong pro-environment sentiment, the U.S. government signed the Rio Declaration at the United Nations Conference on Environment and Development in 1992. Section 15 of the declaration calls for states to adopt the Precautionary Principle. The U.S. Environmental Protection Agency has admitted that it is bound by the Rio Declaration and must identify ways to implement the Precautionary Principle. In 1996, the U.S. President's Council on Sustainable Development, a multi-stakeholder presidential board, issued a statement of principles for sustainable development, among them is an implicit definition of the Precautionary Principle: "There are certain beliefs that we as Council members share that underlie all of our agreements. We believe: (number 12) even in the face of scientific uncertainty, society should take reasonable actions to avert risks where the potential harm to human health or the environment is thought to be serious or irreparable."

Perhaps the most noteworthy work on the Precautionary Principle in the United States has occurred in the Great Lakes Region and on the state level. In the Great Lakes, the International Joint Commission (IJC), a 100-year-old bi-national body established to protect waters along the Canadian–U.S. border, determined that attempts to manage persistent and bioaccumulative pollution in the Great Lakes had failed and these could not be managed safely. As a result, the commission issued a call to sunset all persistent toxic substances, noting that action is needed to protect health and environment "whether or not unassailable scientific proof of acute or chronic damage is universally accepted. Gordon Durnil, who was appointed by President Bush

to head the U.S. delegation to the commission, relates how the IJC reached its conclusions (see chapter 17). First he asked the various scientists serving on committees within the IJC to describe what they knew. He received a myriad provisos on lack of evidence and absence of significant proof linking chemicals to harm. Next he asked these scientists, what they believed. They believed that there was harm linked to these substances, even if they could not prove it.

On the state level, at least 25 states have established some type of pollution prevention legislation. California passed Proposition 65, which requires companies and other establishments to label any products that contain substances that could cause cancer or developmental harm. The Commonwealth of Massachusetts has passed several laws that are precautionary in nature. For example, its wetlands statute requires those building near wetland areas must demonstrate that no harm to wetland integrity will occur. The Commonwealth's Rivers Act requires that anyone building within a river buffer zone demonstrate that there is no other option for building. And the Toxics Use Reduction Act requires firms using certain toxic chemicals to identify alternatives to reduce or eliminate their use. Most recently, a bill was introduced in Massachusetts establishing the Precautionary Principle as a general duty for government agencies and businesses.

Business organizations have also begun to recognize the importance of implementing the precautionary approach as a corporate responsibility and its benefits business. Both the International Chamber of Commerce and the World Business Council for Sustainable Development have endorsed the Precautionary Principle as a management tool necessary to achieve sustainable development. There are numerous examples of individual companies and industries (e.g., British Petroleum with regards to global warming) taking precautionary action to avoid environmental and health harm. Author Stephen Schmidheiny explains that business leaders are "used to examining uncertain negative trends, making decisions, and then taking action, adjusting, and incurring costs to prevent damage." They support the Precautionary Principle not only because it can help them avoid liabilities, but also because of opportunities for innovation, improved corporate image, and product development.

History of the Wingspread Conference and This Volume

In 1993, the *New York Times* published a series of articles by Keith Schneider that stated that many environmental problems of modern times were exaggerated. This series of articles led to the publication of more articles,

books, and the establishment of so-called "sound-science" organizations. The attack on environmental and occupational health regulation during the 104th Congress incubated a need for the development of pro-active measures to fight this attack. Emerging issues, such as global climate change and endocrine disruption, reinforced the demand for new approaches to decision making in the face of uncertainty. Environmental groups, as well as the scientists and lawyers working with them, felt that the Precautionary Principle represented an important paradigm that addresses the limits of science while promoting action to prevent harm.

Environmentalists recognized that the Precautionary Principle had achieved some prominence in Europe and in international treaties but not in the United States among other countries. While they understood the underlying basis of the principle, it was unclear what precaution actually meant in practice. There was also no clear structure to integrate the principle into decision making in the way that risk assessment had been integrated over the past 15 years. To bring the Precautionary Principle to the forefront of environmental and public health decision making in the United States, advocates felt that a meeting was needed to develop a structure and methods for operationalizing the principle. From this need the Wingspread Conference on Implementing the Precautionary Principle was born.

During the weekend of January 23–25, 1998, the Science and Environmental Health Network convened 35 academic scientists, grassroots environmentalists, government researchers, and labor representatives from the United States, Canada, and Europe to discuss ways to formalize the Precautionary Principle. The workshop focused on understanding the history and scientific and political contexts under which the principle developed, its basis, and how it could be implemented in toxic chemicals policy, agriculture, and biodiversity. The Wingspread participants issued a consensus statement calling for and defining the Precautionary Principle. It states: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

The Wingspread Statement on the Precautionary Principle represents an important definition for the principle because it amplifies and clarifies both the Rio Declaration and the President's Council's statement. The Wingspread statement starts off with a call to action, because we have already reached our capacity for environmental insults. As defined at Wingspread, the Precautionary Principle has four components: (1) Preventive action should be taken in advance of scientific proof of causality; (2) the proponent of an activity, rather than the public, should bear the burden of proof of

safety; (3) a reasonable range of alternatives, including a no-action alternative (for new activities) should be considered when there may be evidence of harm caused by an activity; and (4) for decision making to be precautionary it must be open, informed, and democratic and must include potentially affected parties.

Since the Wingspread Conference, the Precautionary Principle has been invoked in places the convenors could not have predicted before January 1998. While toxics have traditionally been the domain for the Precautionary Principle internationally, in the United States it is gaining its greatest support among sustainable agriculture advocates. In Washington state, people protesting the use of hazardous waste in the manufacture of fertilizers called for decision making to be based on the principle. It has also been identified by advocates as the single most important issue in the enormous grassroots response to the U.S. Department of Agriculture's draft organic agriculture rule. Opponents of genetic engineering have also used the Wingspread Statement in international meetings.

In the United States it is likely that the principle will first be solidified at the local and state levels, given the more conservative nature of federal government policies and the entrenchment of risk assessment. Once successes are made at these levels, pressure can be brought on the federal government to institutionalize the principle. This differs from international experience with the principle, where it starts as a global concept and then works its way down to the local level. Nonetheless, several federal agencies are considering how to incorporate the principle into children's environmental health and other environmental concerns, and the Precautionary Principle was included in the "description" of endocrine disruption developed under the U.S. EPA's Endocrine Disruptor Screening and Testing Committee. In the summer of 1998, the Indiana Republican Committee adopted the Precautionary Principle as the basis for its environmental platform. The concept of precaution is beginning to take hold in the United States; however, it will be some years before it reaches the level of prominence held in Europe and other regions of the world. We hope that this volume will help to demystify and provide structure and credence to the notion of precaution.

Structure of This Book

This book is an outgrowth of the Wingspread Conference and the need to operationalize the precautionary approach in environmental and public health decision making. The majority of the chapters contained in this volume were written by Wingspread participants to guide discussions at the conference. Others were solicited after the conference to address other

important areas. This volume differs from previous discussions on the principle in that it struggles with the difficult questions of implementation and fundamental change required to support a more precautionary approach to environmental and public health hazards.

The book consists of four parts that provide a series of steps toward understanding and developing precautionary decision making. Taken together, the parts provide a compass to guide the reader toward a new way of thinking about ecosystem and public health protection, that is scientifically rigorous and grounded in ethics.

Part I, An Overview of the Precautionary Principle, provides an analysis of lessons learned from implementing the Precautionary Principle in Europe as a whole, and in Sweden, the country whose approach to regulating toxic substances has most clearly approximated precaution. These examples provide information on how precaution has been implemented to date.

Part II, Law and Theory, provides an overview of the factors that have led to the current way science and law are incorporated into decision making. The authors of these chapters argue that fundamental changes in law and science will be needed to support precautionary decision making. These include general legal duties for initiators of potentially harmful activities to act in a precautionary manner, shifting burdens of proof to initiators of activities, and expanding and modifying the science used in decision making so that it favors protection of health and the environment.

Part III, Integrating Precaution into Policy, describes practical approaches toward implementing precaution. These chapters provide examples of structures for integrating the principle in decision making, as well as the tools to implement precaution. These chapters describe a fundamentally new way of making decisions in the face of uncertainty—a way that is consistent with respect, common sense, and prudence. In addition, lessons learned from the U.S.–Canada International Joint Commission's approach to precaution are described.

Finally, Part IV, The Precautionary Principle in Action, provides examples of opportunities to take precaution as well as examples of occasions when it was not taken. These chapters provide an overview of the political, economic, and scientific barriers to Precautionary Principle implementation from the perspective of a farmer, policy analysts, a doctor, and a scientist.

When Rachel Carson used the words "to foresee and forestall" at the beginning of *Silent Spring,* she described humankind's hubris in thinking it could spread synthetic chemicals to serve human needs without disrupting fragile, interconnected ecosystems. While she was attacked by petrochemical interests and some in government for her observations, we now know

that she was right. Synthetic pesticides, such as DDT, have caused untold ecological and toxicological harm. In essence, the result of her systematic, careful observations was to foresee the potential harm caused by these synthetic chemicals. *Silent Spring* was a call to forestall this rapid development and deployment of pesticides and to return to an ethic of working with nature, not against it. That is the ultimate goal of precaution.

Note

1. The language contained in some of these international treaties discussed in this chapter is contained in Appendix B.