The Precautionary Principle and Environmental Policy

Science, Uncertainty, and Sustainability

Special Series Guest Editor

CARL SMITH

Introduction

In matters of personal health, prevention and precaution are widely recognized "best practices." Policymakers are eager to endorse suggestions that we exercise or eat more fiber, or avoid tobacco and alcohol.

Policies governing the release of toxic chemicals into the environment have not reflected similar common sense and foresight. However, there are some positive signs that this is changing.

In recent years, UNEP has hosted numerous rounds of intergovernmental negotiations, with the goal of establishing legally binding mechanisms to reduce the environmental burden of toxic chemicals. One treaty, on Prior Informed Consent (PIC), has been negotiated and will enter into force when (and if) ratified by 50 governments. Another, on Persistent Organic Pollutants (POPs) is in its final stages of negotiation.

The debate during these negotiations has underscored the challenges that governments face in making and implementing regulatory decisions. Many of these difficulties relate to the matter of risk assessment—in practical terms, the search for a scientific standard for harm that industry cannot override, and that will enable governments to justify the economic and political costs of regulation.

However, risk assessment is a science of uncertainty. Regulatory action can be postponed almost indefinitely by questioning the findings or methods of studies that show harm, or by insisting that more research is needed before final conclusions can be drawn. In the meantime, air, soil, and water continue to be contaminated and wildlife, workers, consumers, and communities continue to be exposed.

Even when solid evidence of hazard is at hand, a chemical can remain in production and use for a decade or more before a decision is made to ban or restrict it. In the interim, a persistent chemical may work its way up the food chain or be transported great distances via wind currents. By the time the regulatory debate has concluded, the chemical may be ubiquitous in the environment, from breast milk to Arctic ecosystems.

Some policymakers have worked to find ways to speed the regulatory process, while still acting responsibly. More than three decades ago, a principle known as "Vorsorgeprinzip," translated as the "foresight principle," or the "precautionary principle" was introduced in Germany as a yardstick for judging policy decisions. By the 1970s, it was reflected in West German environmental law.[1]

In the context of chemicals, the precautionary principle or approach responds to the complexity of environmental health problems, the paucity of information and subsequent uncertainty about cause–effect relations, and the slow pace of government testing and government decision making. At its core, the principle calls for preventive, anticipatory measures to be taken when an activity raises threats of harm to the environment, wildlife, or human health, even if some cause-and-effect relationships are not fully established.

The precautionary approach is a logical extension of commonsense concepts that guide daily life: "an ounce of prevention is worth a pound of cure"; "better safe than sorry"; the Hippocratic Oath's "first, do no harm." It challenges us to prevent harm before it occurs. It holds that when there is scientific evidence that an activity threatens wildlife, the environment, or human health, protective measures should be taken even in the absence of full scientific certainty.

The inclusion of this concept in the Rio Declaration on Environment and Development placed precaution on the global stage. Issued in 1992 by the United Nations Conference on Environment and Development (the "Earth Summit"), the Declaration enumerated Precaution as one of 27 principles to guide environmental and development policies:

> *Principle 15*
>
> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing

cost-effective measures to prevalent environmental degradation.

During the 1990s, the principle has taken root in international environment accords—both policies and binding legal agreements—that deal with a wide range of environment and development issues. These include the UN convention on climate change, the UN fisheries agreement for straddling stocks and highly migratory fish stocks, the London Convention (which deals with ocean dumping of industrial and radioactive wastes, and ocean incineration), and many other agreements.

During this same time frame, the arguments for a precautionary approach to chemical regulation have only become stronger. Findings regarding the endocrine-disrupting potential of certain chemicals raised the possibility that traditional risk assessment, with its focus on cancer, could be ignoring significant risk factors.[2] A review by the U.S. National Academy of Sciences noted that calculating pesticide risk on the basis of adult exposure ignored the realities of childhood exposures. The panel concluded that, "compared to late-in-life exposures, exposures to pesticides early in life can lead to a greater risk of . . . cancer, neurodevelopment impairment, and immune dysfunction."[3] These concerns have since spread to other environmental chemicals.

There are fundamental reasons to insist that precaution be at the forefront of policy discussions, though these realities are often given inadequate attention due to their simplicity, on the one hand, and their staggering implications, on the other. They remind us that the body of data that we *don't* know about chemicals dwarfs what we *do* know. Some examples:

- The blanketing of earth with man-made chemicals is an unprecedented event in human history. There is no "control group" free of exposures on which to base assurances of safety, and we cannot predict the long-range effects on the current test group of 6 billion individuals.
- The long-term health and environmental impacts of the great majority of individual chemicals have not been studied.
- Even in the case of the most dangerous and persistent chemicals, the worldwide volume of production and use cannot be accurately determined. Industry has retained the right to withhold production and trade figures as "confidential business information."
- For obvious reasons, pre-market testing of pesticides and industrial chemicals on human subjects is not acceptable.
- Very sparse data are collected on human exposures to toxic chemicals. A recent government investigation revealed this to be true even for compounds identified by the U.S. Environmental Protection Agency as hazards to human health.[4]
- Real-world variables, such as individual sensitivity and the synergies and interactions of multiple exposures, are limitless. It will never be possible to evaluate all possible cause–effect relationships.
- The data provided to support the introduction of chemicals into the marketplace (and the environment) are generated by chemical manufacturers. Government regulators do not conduct independent testing.

It is clearly not possible to achieve complete scientific certainty regarding the impact of a particular chemical, or class of chemicals, on the environment or human health, even at a community or state level. An estimate of global impact could be understood only as a mathematical exercise, deductive rather than inductive—at best, a pretty good guess.

The only certainty is that complete data will never be available. Precaution is the only reasonable response. This is particularly true in the case of persistent toxic chemicals, which are passed from ecosystem to ecosystem, from generation to generation.

The growing consensus to place precaution at the forefront of environmental policy is a hopeful sign. But this consensus must be reflected in strongly-worded and vigorously-enforced international policy. If it is, those who are responsible for protecting public health and the environment will have the authority to be proactive, not reactive, and to carry out their work in a hands-on, engaged manner—a development that is long overdue.

CARL SMITH
Vice President
Foundation for Advancements in Science and Education
Los Angeles, California

CLIFTON CURTIS
Director
Global Toxic Chemicals Initiative
WWF—World Wildlife Fund/ World Wide Fund for Nature
Washington, DC

Special Series Contributors

ANDREAS AHRENS, MSc
Okopol
Hamburg, Germany

CLIFTON CURTIS
Global Toxic Chemicals Initiative
WWF—World Wildlife Fund/
World Wide Fund for Nature
Washington, DC

GWYNNE LYONS
Toxics and Policy Advisor to
World Wide Fund for Nature
(WWF–UK)
Norwich, England

SUSAN MAYER, PhD
GeneWatch UK
Tideswell, Buxton, Derbyshire
United Kingdom

NANCY MYERS, MA
Science and Environmental Health Network
Windsor, North Dakota
ROMEO F. QUIJANO, MD
Department of Pharmacology
College of Medicine
University of the Philippines
Manila, Philippines

CAROLYN RAFFENSPERGER, JD
Science and Environmental Health Network
Windsor, North Dakota

CLAUDIA SALADIN, JD
Senior Attorney
Center for International Environmental Law
Washington, DC

ELIZABETH SALTER, MA
WWF European Policy Office
Brussels, Belgium

TED SCHETTLER, MD, MPH
Science Director
Science and Environmental Health Network
Physicians for Social Responsibility
Boston, Massachusetts

CARL SMITH
Foundation for Advancements in Science and Education
Los Angeles, California

ANDY STIRLING, MA, PHD
SPRU—Science and Technology Policy Research
University of Sussex
Brighton, East Sussex
United Kingdom

JOSEPH THORNTON, PHD
Center for Environmental Research and Conservation and
Department of Biological Sciences
Columbia University
New York, New York

JOEL TICKNER, PHD
Lowell Center for Sustainable Production
Department of Work Environment
University of Massachusetts Lowell
Lowell, Massachusetts

References

1. Gullet W. Environmental protection and the precautionary principle: a response to scientific uncertainty in environmental management. Environment and Planning Law J. 1997;14:52.
2. Colborn C, Dumanoski D, Meyers JP. Our Stolen Future. New York: Dutton, 1996.
3. National Research Council. Pesticides in the diets of infants and children. Washington, DC: National Academy Press, 1995.
4. U.S. General Accounting Office. Toxic chemicals: long-term coordinated strategy needed to measure exposure in humans. GAO/HEHS-00-80, May 2000.

Precaution: Belief, Regulatory System, and Overarching Principle

CAROLYN RAFFENSPERGER, JD, TED SCHETTLER, MD, MPH, NANCY MYERS, MA

The precautionary principle has been incorporated as a belief statement in international agreements for more than a decade. The 1998 Wingspread definition of the principle was the first to bring together four components that, in the past two years, have formed the elements of a broader, overarching approach to precaution that is a robust basis for its specific implementation: prompt action even in the face of scientific uncertainty, burden of proof and persuasion on proponents of potentially hazardous technologies, assessment of alternatives, and transparency. This broad approach to precaution is in direct conflict with the simplistic, easily manipulated principles and methods of risk-assessment–based risk management being exported by U.S. officialdom. In contrast to risk assessment, precaution, broadly defined, incorporates the full range of human intelligence in the task of protecting human health and the environment: flexibility, foresight, fairness, thoughtful consideration, and honesty. *Key terms*: precautionary principle; risk assessment; risk management; scientific uncertainty; environmental policy.

INT J OCCUP ENVIRON HEALTH 2000;6:266–269

We have lived for only 50 years with the knowledge that humans can destroy the world. That is a very short time for the kind of learning to take place that is required to make major changes in human behavior. It is no wonder, then, that so many of our efforts are directed toward changing fundamental ways of thinking about ourselves and how we act in the world—and that we have had so little success.

One reason for the explosive interest in the precautionary principle in the international community during the last several years is its power to engage the full resources of human intelligence in forming policies and practices that will protect the earth. The precautionary principle may be the intellectual result of our glimpse of the blue earth from space. In a second we understood the earth's beauty and fragility; the precautionary principle helps us understand some basic tenets of how to think and act on the basis of that understanding.

Received from the Science and Environmental Health Network, Windsor, North Dakota.

Address correspondence and reprint requests to: Carolyn Raffensperger, Science and Environmental Health Network, Rt. 1 Box 73, Windsor, ND 58424, U.S.A.; phone and fax: (701) 763-6286; e-mail: <craffensperger@ compuserve.com>.

But 50 years ago, World War II and the attendant technologic accomplishments also altered our understanding of ourselves, and those changes remain firmly imprinted. We learned that we could destroy the world in a single act—a fact that we found riveting in both its horror and its power. It took us longer to learn that we could destroy the world with cumulative acts that shatter the architecture of life. Before we fully understood the bargain we were striking in either case, we took the technologies of nuclear fission and chemical weapons, to name just two, and modified them in ways we thought fit civilian life: nuclear power and pesticides are obvious examples. World War II gave us glimpses of our destructive power but left us with the illusion that we could control it for "good."

That illusion is a result of narrowly rational thinking, the kind of thinking that led us, as we encountered unforeseen harmful side effects of the all-out technologic development that followed World War II, to cobble together a regulatory system out of rational elements. We measured harms, calculated risks, and weighed costs and benefits. Just as we thought we could turn destruction into good by rationally redirecting our efforts, we assumed that we could manage the harm that kept appearing in new forms.

We have been slow to learn just how much damage our technologies are capable of producing, and our regulatory systems have been even slower to deal with that damage. This late in the game we are learning that our regulatory systems are not equipped to prevent harm from novel or cumulative activities or from activities that have delayed or long-term consequences.

For at least 20 years it has been clear that current regulations are failing to forestall the vast changes and damage resulting from a human dominated planet.[1] The damage is not localized or short-term. The collapse of marine fisheries, the disappearance of amphibians worldwide, global climate change, the loss of biodiversity, habitat destruction, and the rise of environmentally related human health problems all signal failure.

The precautionary principle offers a different approach to regulation. However, it goes beyond that to provide a way of thinking, acting, planning, and making decisions about human activities that pose the threat—however uncertain—of serious, cumulative, or irreversible harm. It not only provides a framework for a more effective regulatory system, it is also a motivating belief and an overarching principle.

THE PRECAUTIONARY PRINCIPLE IN THE UNITED STATES SINCE 1998

U.S. officialdom and U.S. nongovernmental organizations alike are only now awakening to the challenge and potential of the precautionary principle. This awakening is due to the prominence the principle has taken in various international negotiations, treaties, and trade issues and to the coordinated work of nongovernmental organizations on the principle. The two phenomena are not unrelated but they are taking decidedly different directions.

Several U.S.-based organizations have been advocating for precaution for decades and were instrumental in inserting precautionary principle language in the 1990 London Dumping Convention, the 1992 Rio Declaration on the Environment and Development, and other international arenas. However, most of the work on the precautionary principle in the United States began in January 1998 when the Science and Environmental Health Network brought together, at a conference at Wingspread in Racine, Wisconsin, many of those who had been advocating for and writing about the principle internationally. The Wingspread participants defined the principle this way:

> 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. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the Precautionary Principle must be open, informed, and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.[2]

This statement brought together for the first time the four elements of precaution—each of which had been articulated in various formulations of the principle—that have come to be known as the overarching precautionary approach: prompt action even in the face of scientific uncertainty, burden of proof and persuasion on proponents, transparency, and assessment of alternatives.

Following the Wingspread conference, environmental activists began applying the principle in many areas. Massachusetts breast cancer activists adopted the precautionary principle as the basis for their work in preventing breast cancer rather than focusing on curing it. Anti-pesticide activists persuaded the Los Angeles Unified School District to adopt the principle in its approach to pesticide use. People working for sustainable agricultural systems used the principle in their analysis of genetically modified organisms.

This spreading enthusiasm and broader thinking about the principle brought new attention to the continuing international application of the precautionary principle. It soon became apparent that U.S. commercial and trade interests considered the principle a threat. On the one hand, the United States had signed on to the Rio Declaration, precautionary principle and all, and both President Bill Clinton and Vice President Al Gore continued to give lip service to the principle. But at the same time, U.S. trade and commerce representatives denounced the principle as a protectionist measure (the European Union invoked the principle in banning U.S. growth-hormone–fed beef) and ridiculed it as anti-science and a barrier to all technologic development.

Meanwhile, the United States has vigorously campaigned to make its version of risk assessment the comprehensive method for determining the probability of harm, and to make proven harm the sole basis for the international regulatory standards that govern trade—as it is, by and large, in the U.S. regulatory system. This increasingly successful campaign to export risk assessment and, in effect, the U.S. regulatory system has lent urgency to the growing international campaign for precaution.

THE PRECAUTIONARY PRINCIPLE VS RISK ASSESSMENT

Risk assessment and precaution are not opposites, although some advocates on both sides have made them out to be. Nevertheless, they represent vastly different approaches. The conflicts between risk assessment and precaution can be understood in two ways: 1) Risk assessment is misused. Risk assessment, properly used, might be a small part of a precautionary approach, but instead it creates a barrier to precaution. Precaution is written into large portions of the U.S. regulatory system but is often thwarted by the use of risk assessment. 2) Risk assessment is deliberately or easily manipulated to support economic interests at the expense of the environment and public health.

Consider these contrasts between a precautionary approach and one that enshrines quantitative risk assessment as the comprehensive guide to regulation:

- Risk assessment tries to determine how much harm we will tolerate. Precaution asks how much harm we can avoid.
- Risk assessment involves painstaking, often time-consuming evaluation of known hazards and the probability of harm. Meanwhile, if technologies continue to be used and rapidly developed during this process, harm may occur. Precaution places a "speed bump" in the way of technologic development to prevent harm from occurring.
- Precaution addresses uncertainty and the potential for major harm, even if it is not immediate. Risk assessment focuses on known, quantifiable hazards and often misses the big uncertainties.
- Precaution demands consideration of the need for potential harmful activities and safer alternatives to them. By doing this, the precautionary approach encourages us to set explicit goals and then consider

ways of achieving them. Risk assessment may be a useful tool in evaluating alternatives, but a risk-assessment–based regulatory system provides few opportunities for assessing the need for an activity in the first place.

- Risk assessment is used as a tool to help set certain standards in an uncertain world. Precaution does not pose absolutes. It requires that we explicitly acknowledge uncertainty. It is premised on the fact that we will never know everything but must act with as much care and foresight as possible.
- Risk assessment deals with chemicals, technologies, species, and activities one by one, case by case, test by test. Precaution uses all the resources of human intelligence to look at categories of suspect technologies, make informed guesses about harmful effects, and develop principles of behavior, judgment, and development. Precaution sets goals, tries to predict outcomes, and takes a proactive approach. Risk assessment can inform this intelligence but does not provide sufficient information. We cannot depend on it as if we were automatons.

RESPONSES TO CRITICISMS OF THE PRECAUTIONARY PRINCIPLE

Much of the current criticism of the precautionary principle comes from U.S. industry and trade interests.[3] The opening salvo of such critiques is often that the precautionary principle means whatever its proponents want it to mean in a given context, and that it is therefore useless as an overarching guide to policy decisions. They cite dozens of versions of the precautionary principle to support that view. Despite variations in the wording, however, all versions of the precautionary principle acknowledge the need for precautionary action when there is some evidence of the potential for serious, irreversible, widespread harm from some proposed activity, despite scientific uncertainty.

Other criticisms focus on how and where the precautionary principle is applied. Some critics argue that risk assessment makes the precautionary principle unnecessary. They say risk assessment is based on sound science and is inherently protective because it builds in conservative assumptions and safety factors. They insist that the precautionary principle, by contrast, is not science-based and that it raises unfounded fears based on tentative evidence. Some argue, on the other hand, that the precautionary principle applies only to major threats of harm involving large uncertainties and does not apply to small or known risks.

Some of these arguments stem from outright opposition to the precautionary principle or the wish to limit it to a very narrow range of applications. Official statements of the United States and the European Union alike have yet to acknowledge precaution as a broad, overarching approach. Often, attacks on the precautionary principle are actually attacks on precautionary action, or on actions critics assume will result from applying the principle. In fact, precaution as a principle allows for a broad range of action.

The precautionary principle requires explicit consideration of the kind and degree of potential harm, along with the degree of uncertainty about the likelihood of harm, before deciding how to act. For small risks, application of the precautionary principle would permit policies that are much less restrictive than if the potential for serious, irreversible harm were real but unquantifiable. The prescriptive aspect of the principle is that it requires consideration of potential harm and uncertainty. But it does not prescribe specific actions. Policy decisions must be made case by case.

Critics often assemble a list of adverse effects that might result if the principle were to be applied. They argue, for example, that it is impossible to prove that a proposed activity will be safe and, therefore, all innovation will be stifled. They argue that alternatives to a proposed activity may carry their own risks and that applying the precautionary principle is likely to cause us to worry more about possible risks than about known harmful activities.

These arguments are again based on narrow assumptions about what the principle requires us to do when making policy decisions. As a broad, overarching principle, precaution requires evaluating alternatives as stringently as any proposed activity. It requires monitoring initiated activities where the possibility of serious harm remains so that we can detect warning signs. The precautionary principle does not stifle science and innovation but actually supports more science rather than less. It requires larger analyses than narrowly conceived risk assessments. It requires us to ask whether a proposed activity is necessary, and, if so, whether other ways exist to meet the same goal.

Finally, critics argue that the precautionary principle, if widely adopted, will be used as a trade-protectionist measure, that is, as a cover for erecting barriers to free trade in order to protect jobs or markets at home. And yet, it is perfectly conceivable that a country might want to set higher standards for legitimate reasons. Some communities and cultures are more inclined to act in a precautionary way than others. To deny them this right is to impinge upon national sovereignty.[4] Although misuse of the principle is possible, it is important to recognize that there is no single right way to deal with threats of significant harm in the face of scientific uncertainty. National protective standards that are applied consistently internally and externally should prevail.

THE PRECAUTIONARY PRINCIPLE 2000 AND BEYOND

The precautionary principle originally had two narrowly circumscribed roles. First, it was a "belief" as expressed

by the U.S. President's Council on Sustainable Development.[5] This belief was carefully modulated so that it required few behavioral changes on the part of industry or government. Similarly, it was expressed as hortatory (belief) language in international treaties governing large ecosystems or transboundary problems. Until the Biosafety Protocol, completed in January 2000, the precautionary principle had not been included in the body of any international treaty.[4] As a preamble or annex to a treaty it was soft law and could not be enforced, nor did it bind nation states in a meaningful way.

Second, as conceived originally, even by the Wingspread participants, it was viewed as a regulatory device—a method for saying no to damaging technologies. Most of the work of nongovernmental organizataions in the United States has been to develop the precautionary principle in the regulatory and administrative arena.[6] As such, it was posed as an alternative to risk-assessment–based risk management.

The beauty of the precautionary principle is that it is a belief and a regulatory tool but it is much more as well. It is increasingly clear that it must be established as an overarching principle if it is to be a robust force for protecting human health and the environment.

As an overarching principle, precaution will do two things. First, it will help us make decisions far in advance of where they occur in the current regulatory system. By the time a technology gets to the point of current regulation, a company has often spent millions of dollars developing it. Government is squeamish about saying no when so much money is at stake. The precautionary principle offers us a chance to move precautionary decisions upstream and establish a precautionary, public interest research agenda. By setting goals for, say, the kind of agriculture we want, we can develop seeds and technologies that are responsive to public need and ecologic principles and are less likely to pose threats.

Not only will precaution as an overarching principle help set the research agenda; it will carry over into all aspects of society's interface with technology. From the research agenda and the conceptual phases of a technology through to judicial injunctions and court deference to scientific uncertainty, precaution must imbue our decision-making processes.

The second aspect of precaution as an overarching principle is more specific to the regulatory phase of technology development: The precautionary principle is not pitted as an alternative to risk assessment but will sit above risk assessment and all the other tools in the regulatory tool box. Accordingly, it will determine the tools used, including assessment of alternatives,[7] performance bonds, ongoing monitoring, and other precautionary techniques.

Those who wish to restrict the use of the precautionary principle demote it to the category of risk management based on risk assessment. When the principle is fully in play, all of its components—vigilance and prompt action based on full and fair consideration of need, alternatives, and the responsibility of proponents—are engaged. When the principle is overarching, it doesn't just dribble meager precautionary actions after business as usual.

We hope that it is not too late to change the way we make decisions about technology. There is too much at stake to risk the health and beauty of this world for the sake of a few dollars. Adopting the precautionary principle as a belief, a regulatory system, and most importantly as an overarching principle may be our saving grace.

Society must learn to be as intelligent as any ordinary mature human being if we are to survive and thrive. We can no longer operate on simplistic formulas, quickly outdated rules, and simple greed. Precaution is a way of getting beyond this destructive simplicity. It introduces flexibility, foresight, fairness, thoughtful consideration, and honesty into our development and use of technology and the earth environment. What we expect of any mature individual we must learn to practice as a society.

References

1. Lubchenco J. Entering the century of the environment: a new social contract for science. Science, 1998; January 23 491–7.
2. Raffensperger C, Tickner J (eds). Protecting Public Health and the Environment: Implementing the Precautionary Principle. Washington, DC: Island Press, 1999: 353–4.
3. Myers N. Debating the Precautionary Principle. Science and Environmental Health Network, 2000.
4. Raffensperger C. New biotech protocol modifies trade rules. The Environmental Forum. 2000;17:12.
5. President's Council on Sustainable Development. Sustainable America: A New Consensus. Washington, DC: U.S. Government Printing Office, 1996.
6. Tickner J. A map toward precautionary decision making. In: Raffensperger C, Tickner J. Protecting Public Health and the Environment: Implementing the Precautionary Principle. Washington, DC: Island Press, 1999: 162–86.
7. O'Brien M. Making Better Environmental Decisions. Cambridge, MA: MIT Press, 2000.

Precautionary Principle in International Law

CLAUDIA SALADIN, JD

The deregulatory nature of trade rules frequently brings them into conflict with the precautionary principle. These rules dominate debate over the content and legal status of the precautionary principle at the international level. The World Trade Organization (WTO), because of its power in settling disputes, is a key player. Many States are concerned to define the precautionary principle consistent with WTO rules, which generally means defining it as simply a component of risk analysis. At the same time, many States, especially environmental and public health policymakers, see the principle as the legal basis for preserving domestic and public health measures in the face of deregulatory pressures from the WTO. The precautionary principle has begun to acquire greater content and to move into the operative articles of legally binding international agreements. It is important to continue this trend. *Key words*: precautionary principle; international law; public policy; international trade; legislation.

INT J OCCUP ENVIRON HEALTH 2000;6:270–280

The precautionary principle is increasingly at the center of national and international debate over environmental and public health policy making. A broad range of individuals in the environmental and public health communities and in government are interested in the principle as a guiding principle of environmental and public health policy making that should inform all steps in the decision-making process.[1] The precautionary principle in the policy dialog is fairly clearly articulated; significant elements include:

- taking precautionary measures even if not all cause-and-effect relationships are fully understood;
- shifting the burden of proving safety onto the proponent of a potentially harmful activity;
- making environmental and public health decisions in an open, informed, and democratic way;
- examining the full range of alternatives to a particular activity; and
- relying on a weight-of-the-evidence approach, rather than waiting for absolute certainty.

The precautionary principle as articulated in international, legally binding instruments is not as fully articulated as it is in the policy dialog. At the international level there is debate as to both the content of the precautionary principle and its legal status. The more general articulation of the precautionary principle at the international level stems both from the nature of international law itself and from the "chilling effect" that the trade and environment debate has recently brought to bear at the international level on the further development of the precautionary principle. Because international law results from negotiations between States with different economic systems, legal systems, and stages of development, it is always a compromise. It is generally far less developed as a corpus of law than domestic law.

While the importance of the principle has increased, recently its further development and articulation as a principle of international law have been thwarted by the debate over the appropriate relationship between environmental and public health measures and international trade rules. The trade rules promote national laws that interfere with the free movement of goods and services as little as possible. Since the precautionary principle promotes measures that are the least harmful to public health and the environment, national measures based on the precautionary principle often come into conflict with the trade rules. Fears over coming into conflict with the trade rules and the lack of certainty over the relationship between international trade law and international environmental law threaten to "chill" the development of international environmental law and with it, the precautionary principle.

Consequently, the further development of international environmental law on the precautionary principle will be driven in large part by developments at the local and national levels. International law and national law have a symbiotic relationship. Especially in the environmental field, legal concepts and principles enter international law from domestic law. Once a legal norm is established in international law, that norm influences domestic law as countries implement their international legal obligations into national law. International recognition of the precautionary principle and international agreement on the key elements of its definition are important in promoting the principle's use locally and nationally and in furthering the development of international environmental law and sustainable development.

The precautionary principle originated in the domestic law of Germany.[2] The precautionary principle has been explicitly invoked in international legal instruments since the 1980s. The 1980s and early 1990s saw a process of international consensus building around the precau-

Ms. Saladin is Senior Attorney, Center for International Environmental Law, Washington, DC.

Address correspondence and reprint requests to: Claudia Saladin, JD, Center for International Environmental Law, 1367 Connecticut Avenue, NW, Suite 300, Washington, DC 20036, U.S.A.; telephone: (202) 785-8700; fax: (202) 785-8701; e-mail: <csaladin@ciel.org>.

tionary principle. With the United Nations Conference on Environment and Development (UNCED or the Earth Summit), the precautionary principle got broader international attention. All of the UNCED documents, with the exception of the forest principles, invoke the precautionary principle. In several post-UNCED agreements, including the recently concluded Biosafety Protocol, the precautionary principle has been more fully elaborated. The articulation of the precautionary principle at the international level, and particularly at the Rio Earth Summit, has now become influential in domestic law making and in judicial decisions at the local and national levels.

This article briefly discusses the sources of international law, provides some political context for the international debate over the precautionary principle, examines the development of the precautionary principle in international law, and concludes by giving a brief overview of how and why trade issues are shaping current debate over the precautionary principle.

SOURCES OF INTERNATIONAL LAW

The debate around the precautionary principle in international law relates to both its content and its legal status. The legal status of the precautionary principle is relevant in determining the relationship between the precautionary principle and other international legal norms, such as the WTO rules. In order to understand the nature of the debate over the precautionary principle's legal status, it is necessary to understand the basic sources of international law. International law traditionally derives its legitimacy from the consent of States. International law can be derived from several sources. The traditional sources of international law, defined in the statute of the International Court of Justice (ICJ) are:

- international conventions;
- international custom, as evidence of a general practice accepted as law;
- the general principles of law recognized by civilized nations; and
- judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.[3]

Treaties are negotiated between States and create specific legal obligations that bind the States that have become parties to a treaty. Treaties are the principal way of creating international law. Because they are written laws, it is relatively easy to determine the legal obligations created by treaties. Many of the articulations of the precautionary principle in international law discussed below are found in treaties. To the extent the precautionary principle is contained in a legally binding instrument, such as a treaty, it is binding on the parties to that instrument as it is written into that agreement.

Customary international law is the second principal way international legal obligations arise. To determine whether a norm is customary international law, two elements must exist: State practice—States act in a certain way, in this case they would apply the precautionary principle—and something called *opinio juris*. According to the jurisprudence of the ICJ, State practice must be extensive, be virtually uniform, and include those States most particularly affected by the norm (for example, the practice of land-locked States is not particularly relevant to the law of the sea). *Opinio juris* means that States must be engaging in their practice out of a sense of legal obligation, rather than from a sense of moral obligation or political expediency. Thus, for example, as States use the precautionary principle in domestic law, they are contributing to the development of international customary law. Some have argued that the precautionary principle has emerged as a principle of international law.[4] To make that determination would require a thorough examination of State practice that is beyond the scope of this article. As is discussed below, however, the precautionary principle is now finding greater articulation at the domestic level.

Once a norm is established as customary international law, it is binding on all States, regardless of whether they have contributed to the formation of the custom. If, however, a State has persistently objected to a customary norm during its creation, that State is what is called a "persistent objector." Persistent objectors are not bound by a customary norm to which they have consistently objected during its formation.

Frequently treaty law and customary law reinforce one another. For example, the Vienna Convention on the Law of Treaties is a treaty that governs the negotiation, conclusion, interpretation, amendment, and termination of treaties. In addition to being treaty norms, however, many norms contained in the Vienna Convention are widely regarded as customary international law that existed prior to creation of the Vienna Convention. In essence, the Vienna Convention codified already existing international law on treaties. Thus the Vienna Convention binds parties, and, to the extent it reflects customary law, also non-parties. In other instances, repeated reiteration of a norm in treaty instruments—as is the case with the precautionary principle—may also contribute to that norm's attaining the status of customary international law. Finally, as part of the body of international law, customary norms are relevant in interpreting treaties. If, for example, the precautionary principle were to be recognized as a norm of customary international law, then it would be relevant in interpreting other treaties, such as the trade agreements.

General principles of law common to all nations can also be international law. Widely accepted general principles include the principles of reciprocity, equality of States, and good faith.[5]

Finally, judicial opinions and the writings of "qualified

publicists" are subsidiary means of determining the rules of international law. In other words, they provide evidence of what the rules of international law are. Particularly in the case of customary law and general principles of law, the jurisprudence of international tribunals, such as the ICJ, can be important in identifying those norms and in crystallizing international consensus around them. The precautionary principle has been invoked before the ICJ in the *Case Concerning the Gabcikovo–Nagymoros Project* (Hungary–Slovakia), but the Court did not rule on the legal status of the principle.[6]

Another important aspect of international law, not referenced in the statute of the ICJ, that is relevant to the precautionary principle is the concept of "soft" law. Treaties and customary law are considered "hard" law—meaning they create binding legal obligations on States. Soft law refers to international instruments, such as declarations, UN General Assembly resolutions, and the resolutions of other international bodies, which are not legally binding. Perhaps one of the most famous soft law instruments in the environmental field is the 1992 Rio Declaration on Environment and Development. Soft law instruments, while not legally binding per se, are often extremely important in developing international consensus around specific issues or principles. Even though not technically legally binding, soft law instruments are often closely and carefully negotiated by countries. They, like ICJ opinions, may be evidence of emerging principles of international law.

POLITICAL CONTEXT OF THE INTERNATIONAL PRECAUTIONARY PRINCIPLE DEBATE

All of these different sources of international law have played roles in articulating the precautionary principle in international environmental law and in building international consensus around the precautionary principle. The political context of the precautionary principle is also important in understanding its evolution in international law and the debates around it. There is a basic conflict at the international level, primarily between the United States and the European Union, over both the content and the legal status of the precautionary principle. This conflict takes place within the larger context of what is essentially a trade dispute between the United States and the European Union.

Traditionally, trade rules promoted free trade by reducing and eliminating tariffs. As tariffs were progressively reduced, trade negotiators began to address non-tariff barriers to trade. A non-tariff barrier could be virtually any regulation that impedes the free movement of goods—for example, requirements that automobiles sold meet certain emission standards, rules that prohibit sale of goods produced by child labor, or rules requiring that products containing genetically modified organisms be labeled. In addressing the question of non-tariff barriers, the trade rules now define the permissible sphere of domestic regulation (for countries that are parties to the relevant trade agreements) in areas of law not traditionally considered to be trade law—including environmental and public health regulations, intellectual property law, and rules governing services. The trade rules tend to limit the scope of measures government can take, in order to prevent trade protectionism. As a result, the trade rules and other areas of law, including environmental and public health laws, are more frequently coming into conflict. This tension drives much of the trade and environment debate.

The precautionary principle is caught in this debate. The World Trade Organization (WTO) often applies a "least-trade-restrictive" standard for reviewing national laws and regulations that are alleged to be protectionist. In other words, they ask how a particular environmental (or public health) objective can be met in a way that restricts trade the least. The least-trade-restrictive standard drives the basically deregulatory nature of the international trade regime. In contrast, environmental and public health measures based on the precautionary principle ask what is the least environmentally harmful way to achieve a particular public policy objective—a "least-environmentally-harmful" standard, so to speak.[7] Thus, to achieve a particular public policy objective, the trade rules will presume (rebuttably) that a more trade-restrictive measure is probably protectionist. The precautionary principle, by contrast, creates a presumption in favor of those measures that cause the least harm to public health and the environment. Thus, the precautionary principle is often invoked when attempting to defend an environmental or public health measure that is being threatened by the trade rules as overly trade-restrictive and therefore protectionist.

The debate over whether the precautionary principle is a principle of international environmental law or simply an approach with no legal status takes place within this context. If the precautionary principle is a principle of international law, it would be relevant to disputes within the WTO over whether national public health or environmental measures are protectionist. If, however, it is merely an approach that has been incorporated into specific treaties, then precaution has no relevance beyond the treaties in which it appears and would not be relevant to WTO disputes, except to the extent it is explicitly incorporated into the legal texts of the WTO.

Recently, the European Union and the United States have been the main protagonists in this debate. The precautionary principle has a longer history in Europe than in the United States.[8] Article 174 of the Treaty of European Community, added in 1993, makes the precautionary principle one of the guiding principles of EU environmental law.[9] Moreover, the European Union has stated that they believe the precautionary principle to be a "full-fledged and general principle of international law."[10] By contrast, the United States has been unwilling

to acknowledge the precautionary *principle* as a binding *legal* principle, although they have agreed to a precautionary *approach* in specific agreements.

RIO PRINCIPLE 15: INTERNATIONAL CONSENSUS ON THE PRECAUTIONARY PRINCIPLE

One of the most widely accepted articulations of the precautionary principle by States is Principle 15 of the Rio Declaration:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[11]

Although there is consensus around the content of Rio Principle 15, there is no consensus around its legal status. The Rio Declaration is a soft law instrument and so does not create legally binding obligations. However, some Rio Principles are widely thought to be norms of international law.[12] The United States and the European Union in particular disagree over whether Principle 15 is an international legal principle, or simply a political statement.

Legal status aside, the content of Principle 15 is quite narrow. First, it says precautionary approach, rather than principle. It is applicable only where there is a threat of "serious or irreversible" harm. Moreover, it simply says that lack of scientific certainty shall not be a reason for postponing action. Rio Principle 15 does not, however, require action in the face of a threat of serious or irreversible harm. It provides only that lack of scientific certainty can not be used to justify inaction. Finally, measures are to be cost-effective.

EARLY EVOLUTION OF THE PRECAUTIONARY PRINCIPLE IN INTERNATIONAL LAW

Early evolution of the precautionary principle at the international level began in the 1980s. Much of the early development of the precautionary principle is in regional agreements within Europe. The precautionary principle was first explicitly introduced into international negotiations in the North Sea Ministerial Conferences. As early as 1980, the German Council of Experts in Environmental Matters found that the principle was a "requirement for a successful environmental policy for the North Sea ecosystem."[13] The principle was included in the Final Declaration of the Second International North Sea Conference in 1987[14] and at the third North Sea Conference in 1990.[15] These declarations, which are political statements rather than legally binding obligations, emphasize avoiding harm and understanding that action can be taken before all the cause-and-effect relationships are fully understood.

Eventually this process of invoking the precautionary principle in ministerial declarations led to the principle's inclusion in the 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic:

> The Contracting Parties shall apply the precautionary principle, by virtue of which preventive measures are to be taken when there are reasonable grounds for concern that substances or energy introduced, directly or indirectly, into the marine environment may bring about hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea, even when there is no conclusive evidence of a causal relationship between the inputs and the effects[.][16]

In this Convention, the precautionary principle appears in the general obligations article of the treaty. As part of a legally binding instrument, the precautionary principle in this case creates a binding obligation on the parties to the Convention. This formulation of the principle obliges parties to take "preventive measures" where there are "reasonable grounds for concern," even where the causal relationship between the input and the harm is not conclusively proven. This is a stronger formulation than, for example, that in Rio Principle 15. This formulation of the principle also speaks of reasonable grounds for concern that an activity will cause harm, rather than requiring a threat of serious or irreversible harm.

Other European regional agreements that have included the precautionary principle are the ECE Transboundary Watercourses Convention,[17] and several of the protocols to the Convention on Long-Range Transboundary Air Pollution.[18] In addition to these European Conventions, in 1991, over 50 African countries negotiated the Bamako Convention, which calls for the implementation of the precautionary principle, specifically referring to clean production as a means of implementing the principle.[19]

At a global level, the 1982 World Charter for Nature, which was approved as a UN General Assembly Resolution by 111 countries, endorsed a precautionary principle without explicitly invoking the term.[20] It emphasized preventing environmental damage, called for shifting the burden of proof to the proponent of potentially harmful activities, and argued for delaying activities where potential threats were not fully understood. It is not, however, a legally binding instrument.

The precautionary principle was also invoked in the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer. The Montreal Protocol is a global rather than a regional agreement, which illustrates the principle's acceptance by a wider group of States. Moreover, it is a legally binding treaty. The Montreal Protocol's preamble explicitly states that Parties to this protocol are "determined to protect the ozone layer by taking precautionary measures to control equitably total global emissions of substances that deplete it, with the ultimate objec-

tive of their elimination on the basis of developments in scientific knowledge, taking into account technical and economic considerations."[21] While the preamble to a treaty provides important context for interpreting the operative provisions of the treaty, it has less legal significance here than in the operative provisions of a treaty.

THE PRECAUTIONARY PRINCIPLE AT THE EARTH SUMMIT

The 1992 UN Conference on Environment and Development (UNCED) brought greater international attention to the precautionary principle and significantly furthered the consensus around the principle. In addition to Rio Principle 15, discussed above, UNCED delegates invoked the precautionary principle in both the Biodiversity Convention and the Climate Change Convention, as well as Agenda 21.

The Biodiversity Convention invokes the precautionary principle in the preamble, closely tracking the language of Rio Principle 15, without the reference to cost–effectiveness.[22] The UN Framework Convention on Climate Change makes explicit reference to the precautionary principle in Article 3(3):

> The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that such policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost. To achieve this, such policies and measures should take into account different socioeconomic contexts, be comprehensive, cover all relevant sources, sinks and reservoirs of greenhouse gases and adaptation, and comprise all economic sectors.[23]

This language closely tracks Principle 15, stating that scientific uncertainty should not be used as a reason to postpone action, but does not affirmatively endorse action. It does provide some clarification of what is meant by cost-effective measures. At least in the climate context, cost–effectiveness suggests the need to minimize the costs of achieving global environmental benefits and to reflect concerns about different socioeconomic development levels.

Agenda 21, which unlike the Biodiversity Convention and the Climate Change Convention is not a treaty, but a soft law instrument, also invokes the precautionary principle in several contexts. For example, in Chapter 35, which addresses "science for sustainable development," the introduction provides the following formulation of the principle:

> In the face of threats of irreversible environmental damage, lack of full scientific understanding should not be an excuse for postponing actions which are justified in their own right. The precautionary approach could provide a basis for policies relating to complex systems that are not yet fully understood and whose consequences of disturbances cannot yet be predicted.[24]

Again, this phrases the precautionary principle in the negative: scientific certainty is not a reason to postpone action in certain cases. The importance of the precautionary approach is reaffirmed subsequently in Chapter 35,[25] in which the parties agreed to achieve substantial improvements in:

> The interaction between the sciences and decision-making, using the precautionary approach, where appropriate, to change the existing patterns of production and consumption and to gain time for reducing uncertainty with respect to the selection of policy options.[26]

Thus, policy measures under the precautionary approach are viewed as a way of providing time during which scientific understanding of an issue may increase. Agenda 21 also encouraged use of the precautionary approach in a number of specific contexts, including protection of the marine environment[27] and water pollution.[28] In both cases, the signatories to Agenda 21 linked the precautionary principle explicitly to a variety of anticipatory and preventive policy measures.

POST–EARTH SUMMIT DEVELOPMENT OF THE PRECAUTIONARY PRINCIPLE

Post-UNCED developments of the precautionary principle are significant for several reasons. First, a number of efforts were undertaken to more fully define the precautionary principle in international law. Second, international agreements began to operationalize the precautionary principle by moving it from the preamble or general obligations provisions of agreements to their operative provisions. Finally, while beyond the scope of this article, there is evidence that increasingly the precautionary principle is being explicitly invoked in national law. Taken together, these developments represent a qualitative shift in the status of the precautionary principle in international law.

Following the Earth Summit, both the United Nations Environment Programme (UNEP) and the Commission on Sustainable Development (CSD) have convened expert groups to examine international law in relation to sustainable development. These efforts were aimed at elaborating some of the principles contained in the Rio documents, including the precautionary principle. Both of these efforts are significant because they are the work of groups of experts from different legal systems and from both developed and developing countries. Thus, while these are not legally binding instruments, they represent a significant contribution to international legal thinking around the precautionary principle. Under the

traditional sources of international law they could be considered the writings of "highly qualified publicists" and thus a subsidiary means of determining the rules of international law. They can also be considered a form of soft law.

In 1996, the UNEP-sponsored Expert Group's Workshop on International Environmental Law Aiming at Sustainable Development reviewed the principle, finding that: "[a] potential starting point for elaborating the precautionary principle is: Where there are threats of serious or irreversible harm, lack of full scientific certainty about the cause and effects of environmental harm shall not be used as a reason for postponing measures to prevent environmental degradation."[29] The expert group report included the following basic elements in the precautionary principle:

> (a) Affirming a preference for anticipating environmental harm and taking measures to avoid it or to choose the least environmentally harmful activity.
>
> (b) Recognizing that scientific certainty, to the extent it is obtainable, with regard to environment and development issues may come too late to take effective responses to environmental threats.
>
> (c) Recognizing that where there is an identifiable risk of serious or irreversible environmental harm, including for example extinction of species, widespread toxic pollution or major threats to essential ecological processes, it may be appropriate to place the burden of proof on the proposer of the activity potentially harmful to the environment.[30]

The CSD Expert Group Meeting on Identification of Principles of International Law for Sustainable Development reached similar conclusions:

> 70. The precautionary principle indicates that lack of scientific certainty is no reason to postpone action to avoid potentially serious or irreversible harm to the environment. The principle provides guidance for the development and application of international environmental law. Depending upon the formulation of the principle in international legal instruments, there may also be a requirement that measures taken in application of the principle should be cost-effective.
>
> 71. The core of the precautionary principle is reflected in Principle 15 of the Rio Declaration. . . . Central to the principle is the element of anticipation, reflecting a requirement that effective environmental measures need to be based upon actions which take a longer-term approach and which might anticipate changes in the basis of our scientific knowledge. At a general level the principle is understood to mean that States should act carefully and with foresight when taking decisions which concern activities that may have an adverse impact on the environment.
>
> 72. A more focused interpretation of the precautionary principle could require activities and substances which may be harmful to the environment to be regulated, and possibly prohibited, even if no conclusive or overwhelming evidence is available as to the harm or likely harm those activities may cause to the environment. An even more fundamental interpretation shifts the burden of proof in decision-making to require a person who wishes to carry out an activity to prove that it will not cause harm to the environment.[31]

These elaborations of the precautionary principle are more thorough than those in any of the earlier treaties, although of less normative value. Key elements in these interpretations of the precautionary principle are the shifting of the burden of proof onto the proponent of a potentially harmful activity, the emphasis on harm avoidance, and the notion that the precautionary principle means choosing the least environmentally harmful activity, in addition to the element of scientific uncertainty.

Since UNCED, the precautionary principle has continued to appear in international treaties, particularly the Straddling Stocks Agreement and the Biosafety Protocol. Its articulation in post-UNCED treaties is more developed than in the pre-UNCED treaties. Significantly, the principle emerges out of the preamble and into the operational articles of the treaties in this period. Since these are relatively recent agreements, they have yet to enter into force and so the practical effect placement of the precautionary principle in the operative articles of the treaties has on implementation of the treaties remains to be seen. The precautionary principle's placement in the POPs treaty is currently being negotiated.

Straddling Stocks Agreement

The Straddling Stocks Agreement addresses the problem of fish stocks that are highly migratory or straddle the jurisdictions of more than one State. Stocks of these fish, including for example tuna and swordfish, are currently heavily overfished by commercial fishing fleets using destructive gear or techniques. Because of their highly migratory nature, the populations and depletion rates of these fisheries are shrouded in uncertainty. It is also difficult to determine with scientific certainty when a stock is reaching a critical stage, until a fishery actually collapses. The Straddling Stocks Agreement aims at the long-term conservation of straddling fish stocks. Among other things, the Agreement establishes principles to guide States in implementing the Agreement, including the precautionary principle.[32] Article 6 of the Agreement then deals entirely with application of the precautionary approach:

> 1. States shall apply the precautionary approach widely to conservation, management and exploitation of straddling fish stocks and highly migratory fish stocks in order to protect the living marine resources and preserve the marine environment.
>
> 2. States shall be more cautious when information is uncertain, unreliable, or inadequate. The absence of

adequate scientific information shall not be used as a reason for postponing or failing to take conservation and management measures.[33]

Article 6 thus includes explicitly the affirmative requirement to be "more cautious" in the face of uncertainty. The rest of Article 6 adds detail on implementing the precautionary approach in the case of straddling fish stocks, including establishing reference points for specific stocks and the actions that should be taken when the reference points are approached. Measures include continued data collection and development of scientific knowledge contemporaneously with additional conservation measures. Annex II to the agreement contains further guidelines for application of precautionary reference points in the conservation and management of straddling stocks.

Biosafety Protocol

The precautionary principle is also embodied in the Cartagena Protocol on Biosafety, concluded this year.[34] The Biosafety Protocol creates an international framework for the transfer, handling, and use of living modified organisms (LMOs) resulting from biotechnology. Significant uncertainty exists around the environmental and health impacts of LMOs. The Biosafety Protocol establishes an "advance informed consent" procedure to ensure that importing countries can make informed decisions about whether and under what conditions to permit importation of certain genetically modified organisms. It provides that, when making a decision whether a transboundary movement may proceed, importing countries may rely on the precautionary principle. Specifically, it states in Article 10 that:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism . . . in order to minimize such potential adverse effects.[35]

The Protocol also includes a number of other references to the precautionary principle. It contains an almost identical statement of the principle in relation to the transboundary movement of genetically modified commodities that are intended for use as food, as feed, or for processing in Article 11 of the Protocol.[36] And it refers to the precautionary approach, as described in Principle 15 of the Rio Declaration, in both its preamble and its statement of objectives.[37] The presence of the precautionary principle in Articles 10 and 11 provides greater specificity with regard to the nature of the precautionary principle and its application in the context of LMOs. Because the Biosafety Protocol deals with trade in LMOs, it became a focal point of the trade and environment debate and focused international attention on the potential conflict between the trade rules and national measures taken based on the precautionary principle.

POPs Convention

The POPs Convention, which is currently in the process of being negotiated, will most likely contain the precautionary principle as well. Persistent organic pollutants (POPs) are a class of chemicals that persist in the environment, are capable of long-range transport, bioaccumulate in human and animal tissue, and have significant impacts on human health and the environment, even at low concentrations. The draft POPs Convention is designed to "reduce and/or eliminate" 12 of the worst POPs and to create a process for adding additional POPs to the Convention.[38] The current draft of the Convention contains provisions for eliminating or restricting production and use of intentionally-produced POPs, controlling releases of POPs by-products, and the process for adding to the treaty POPs chemicals beyond the initial 12. In addition to the preamble and objective of the Convention, a key place for elaboration of the precautionary principle in the draft POPs Convention is the provision on adding additional chemicals to the treaty.

The additional-chemicals provision of the draft Convention has proposed text on the precautionary principle, which is still being debated. This section of the treaty addresses what the criteria will be for adding new chemicals to the lists of chemicals that will be regulated under the Convention and the procedure for adding new chemicals to the Convention. To add a substance to the POPs Convention under the current draft, the substance must meet certain criteria related to persistence, bioaccumulation, potential for long-range transport, and adverse affect. If the substance meets those criteria, a risk profile is prepared. A decision is then made on the basis of the risk profile whether to proceed with a recommendation to add the substance to the Convention. In the text of this article of the draft Convention the precautionary principle appears in two places. The first is in determining whether the proposed substance meets the screening criteria: "The Committee shall examine the proposal and apply the screening criteria specified in Annex D in a [flexible,] [preventative,] transparent and integrative manner [, taking into account the precautionary principle]."[39] The other reference to the precautionary principle concerns whether a proposal should move forward, based on the risk profile. The specific text reads:

> [Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding a substance shall not prevent the procedure specified in this article from proceeding and shall not prevent the listing of substances on Annexes A, B and/or C.][40]

The effect of these placements of the precautionary principle in the article would be to apply precaution in determining whether a substance meets the specific criteria for POPs laid out in the treaty, and for allowing action on an additional POP to move forward based on the risk profile, even if some scientific uncertainty exists.

Another interesting post-Rio development is the extent to which the precautionary principle is increasingly finding its way explicitly into national legal systems. Although a thorough examination of State practice regarding the precautionary principle has not been done, there are some interesting examples. In Australia the precautionary principle has been incorporated in many recent federal environmental policies and strategies and incorporated into federal legislation.[41] Australia's judiciary has also recognized the principle in a number of environmental cases.[42] In 1996, the Indian Supreme Court adopted the precautionary principle in addressing pollution caused by tanneries in *Vellore Citizens Welfare Forum v. Union of India & ORS*.[43] In 1994 the Pakistani Supreme Court relied on the precautionary principle, and specifically Rio Principle 15, in rendering its decision in *Shehla Zia v. WAPDA*.[44] In 1993 the Treaty of European Union amended the Treaty Establishing the European Communities to make the precautionary principle the basis for EU environmental law.[45] The precautionary principle will thus increasingly find its way into EU law and the law of the EU Member States.

THE PRECAUTIONARY PRINCIPLE AND THE TRADE DEBATE

As discussed earlier, the precautionary principle has played an important role in the trade and environment debate. At the same time, the prominence of the trade debate has raised the international profile of the precautionary principle. The World Trade Organization (WTO) has profoundly influenced debate over the precautionary principle, for several reasons. First, the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), one of the WTO agreements, contains a precautionary-principle–like provision. To some extent the limits of that provision in the SPS Agreement have set the parameters of the debate around the precautionary principle more broadly.

The SPS Agreement establishes rules for national laws and regulations for the protection of human, animal, and plant life and health from the risks from disease, pests, disease-carrying or causing organisms, additives, contaminants, or toxins in foods, beverages, and feed stuffs. The SPS agreement requires that national SPS measures be based on risk assessment and scientific evidence.[46] Article 5.7 of the SPS Agreement allows WTO Members to maintain *provisional* SPS measures in the absence of sufficient scientific evidence. The relevant provision reads in full:

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.[47]

Because it deals with regulation in the face of scientific uncertainty, this provision is profoundly influencing debate on the precautionary principle. Unlike other articulations of the precautionary principle, this provision specifically defines measures adopted in the face of scientific uncertainty as "provisional" and requires that States continually seek additional information, in order to maintain the validity of their measures.

The existence of a risk-assessment requirement and a form of the precautionary principle in the SPS Agreement, has led to the precautionary principle's being defined within the WTO as simply a component of risk assessment. Such a view is at odds with the view of the precautionary principle as a guiding principle in environmental and public health decision making. In an effort to define the precautionary principle in a manner fully consistent with the trade rules, countries are showing constraint in defining the precautionary principle. For example, in February 2000 the European Commission issued a communication on the precautionary principle. The Communication is on the precautionary principle generally, but attempts to define the precautionary principle in a way that is fully consistent with the SPS Agreement. In particular, it defines the precautionary principle as a component of risk analysis.[48] Thus, the SPS Agreement threatens to set the terms of international debate over the precautionary principle

Second, several of the WTO Agreements, including the SPS Agreement, encourage WTO Member States to base their national measures, including environmental and public health measures, on international standards developed in specific international standardizing bodies, such as the Codex Alimentarius.[49] The SPS Agreement specifies that measures that conform to international standards are presumed consistent with both the SPS Agreement and the General Agreement on Tariffs and Trade (the overarching agreement of the WTO).[50] Measures not based on international standards must meet the risk assessment and other requirements imposed by the SPS Agreement. Prior to the SPS Agreement, Codex Alimentarius was a body that set voluntary international standards, which effectively set an international "floor" for food safety. Because the Codex standards are now the presumptive legal standards, they have essentially become a ceiling.[51] The now quasi-legal status of the Codex standards has significantly raised the stakes of

establishing standards within the Codex.[52] The debate over the precautionary principle has also moved into the Codex Alimentarius Commission on General Principles in the context of risk analysis. This again threatens to proscribe the precautionary principle as simply a component of risk analysis, rather than acknowledging the precautionary principle as a guiding principle in setting public health standards.

Third, the precautionary principle at the international level has developed primarily in the context of negotiations over international environmental agreements. Many feel that a concern to be consistent with the trade rules and a lack of clarity over the relationship between the trade rules and the rest of international law have chilled development of international environmental agreements generally, and the precautionary principle has been part of that.[53] The debate over trade in and labeling of genetically modified organisms has been a lightning rod for some of these conflicts. Negotiations of the Biosafety Protocol were stalled because of the trade implications of regulating trade in genetically modified organisms. In the ongoing POPs negotiations, the inclusion and placement of the precautionary principle (or precautionary approach) has again been a source of controversy. The European Union has been advocating the principle's inclusion in the agreement, while the United States has been more reluctant to see precaution included in the operative articles of the draft Convention. To the extent that negotiators avoid inserting the precautionary principle in international environmental treaties, international development of the precautionary principle may be hindered. Since including the precautionary principle in the operative articles of an agreement will impact the way the measure is implemented domestically, and how that domestic measure will be interpreted in a trade dispute, chilling the use of the precautionary principle in environmental agreements will also impact its development as a rule of law generally.

Finally, the WTO is much stronger both as an institution and as a set of detailed, legally binding rules than the international environmental regimes where the precautionary principle originates. To understand why the WTO has so profoundly influenced international debate over the precautionary principle, one must understand something of the institutional structure and strength of the WTO. The WTO is the primary political and legal institution regulating global trade. The WTO performs a variety of functions, primarily providing a forum for negotiations on trade liberalization, settling trade disputes, and administering and enforcing the WTO agreements.

The WTO has a powerful two-tiered system for settling disputes between WTO Members. The first tier is comprised of panels, made up of specially appointed trade experts who seek to resolve the disputes on the basis of the countries' obligations under the WTO agreements. The decisions of WTO panels may be appealed to the WTO Appellate Body if a Member State is not satisfied with the legal interpretation of the panel. The Appellate Body's decision is binding and final, unless all WTO Members, including the winning party, agree by consensus to reject it.[54] Such a strong dispute-settlement process is unique in international law. No non-trade international dispute-settlement process, including the International Court of Justice, has sanctions that can be imposed against a losing party without the losing party's consent. Thus far, the WTO has decided three cases relating to the SPS Agreement that elaborate on its risk-assessment requirement and on the relationship between the SPS Agreement and the precautionary principle.[55] By contrast, there are few international cases on environmental issues. One case before the ICJ has invoked the precautionary principle, but did not address the question of its status in international law or provide any greater detail as to its content in international law.[56]

CONCLUSION

Evolution of the precautionary principle at the international level has been slow, because international law making requires negotiation and agreement among over 100 countries. Since the Earth Summit, however, the precautionary principle has evolved from being a broad statement of principle, usually found in the preamble of an agreement, and has now begun to acquire greater content and to move into the operative articles of legally binding international agreements. From an environmental and public health perspective, it is important to continue this trend. These recent treaties have yet to enter into force (a process that can take years), so there has been little experience in implementing them or in judging what constitutes compliance with their provisions. Effective national implementation of the precautionary principle is important both for its own sake and for the development of the principle in international law. State practice on the precautionary principle will contribute both to the content of the principle internationally and also to the legal status of the principle. Thus, enacting the principle nationally and locally will contribute to the development of the precautionary principle as international law.

The development of the precautionary principle at the international level takes place within the context of a broader political and policy debate over the appropriate relationship between international trade rules and domestic environmental and public health measures. The deregulatory nature of the trade rules frequently brings them into conflict with the precautionary principle. The trade rules have come to dominate debate over the content and legal status of the precautionary principle at the international level for a variety of reasons. These include the relative institutional strength of the WTO in comparison with other international institutions and the inclusion of precautionary-principle–like language in the SPS Agreement. Faced with a conflict (or

potential conflict) between trade rules and the precautionary principle, given the strength and power of the WTO dispute-settlement process, and given the importance generally given to economic consideration, many States are concerned to define the precautionary principle in a way fully consistent with the WTO rules. Generally, this has meant attempting to define the precautionary principle as simply a component of risk analysis. At the same time, many States, and especially environmental and public health policymakers, see the precautionary principle as the legal basis for preserving domestic environmental and public health measures in the face of deregulatory pressure from the WTO.

The author thanks her colleagues David Hunter and Steve Porter for reviewing drafts of the article. Any mistakes are her own.

Notes

1. See, e.g., Mary O'Brien, Making Better Environmental Decisions: An Alternative to Risk Assessment (The MIT Press: Cambridge, MA, 2000); Protecting Public Health and the Environment: Implementing the Precautionary Principle (Carolyn Raffensperger & Joel Tickner, eds.) (Island Press: Washington, DC, 1999) [hereinafter, Implementing the Precautionary Principle]; Wingspread Statement on the Precautionary Principle (January 25, 1998), reprinted in Implementing the Precautionary Principle, supra, at 353; Joe Thornton, Pandora's Poison 343-49 (The MIT Press: Cambridge, MA, 2000).
2. See, e.g., Charles D. Siegal, Rule Formation in Non-Hierarchical Systems, 16 Temp. Envtl. L. & Tech. J. 173, 211 (1998); Sonja Boehmer-Christiansen, The Precautionary Principle in Germany—Enabling Government, in Interpreting the Precautionary Principle 31 (Timothy O'Riordan & James Cameron eds.) (BPC Books & Journals Ltd.: 1994) [hereinafter Interpreting the Precautionary Principle]; Konrad von Moltke, The Relationship Between Policy, Science, Technology, Economics and Law in the Implementation of the Precautionary Principle, in The Precautionary Principle and International Law: The Challenge of Implementation 97, 102 (David Freestone & Ellen Hey eds.) (Kluwer Law International: The Hague, 1996) [hereinafter The Challenge of Implementation].
3. Statute of the International Court of Justice, art 38(1), Oct. 24, 1945, available at URL: <http://www.icj-cij.org/icjwww/ibasicdocuments/ibasictext/ibasicstatute.htm>.
4. See, e.g., Harald Hohmann, Precautionary Legal Duties and Principles of Modern International Environmental Law, The Precautionary Principle: International Environmental Law Between Exploitation and Protection 344 (1994); James Cameron & Juli Abouchar, The Status of the Precautionary Principle in International Law, in The Challenge of Implementation, supra note 2, at 29 (arguing that the Rio Declaration was the culmination of the process of crystallizing the precautionary principle as customary international law); James Cameron & Juli Abouchar, The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment, 14 Boston College Int'l & Comp. L. Rev. 1 (1991).
5. Ian Brownlie, Principles of Public International Law 19 (4th ed.) (Clarendon Press: Oxford, 1990).
6. See Case Concerning the Gabcikovo-Nagymoros Project (Hungary-Slovakia), 1997 I.C.J. 25 (Sept. 25).
7. UNEP, Final Report of the Expert Group Workshop on International Environmental Law Aiming at Sustainable Development, ¶ 47(a), Doc. No. UNEP/IEL/WS/3/2 (4 Oct. 1996) [hereinafter UNEP Expert Group Report]; see also O'Brien, supra note 1.
8. Nicolas de Sadeleer, Two Approaches of Precaution: A Comparative Review of EU and US Theory and Practice of the Precautionary Principle (Centre d'étude du droit de l'environnement: Brussels, 2000).
9. Consolidated Version of the Treaty Establishing the European Community, art. 174(2), available at URL: <http://europa.eu.int/eur-lex/en/treaties/dat/ec_cons_treaty_en.pdf> [hereinafter EC Treaty]. The relevant portion of article 174(2) reads:

   > Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at the source and that the polluter should pay.

10. Commission of the European Communities, Communication from the Commission on the Precautionary Principle, COM(2000)1 at 11 (Feb. 2, 2000) [hereinafter EU Communication].
11. Rio Declaration on Environment and Development, Principle 15, June 14, 1992, U.N. Doc. A/Conf. 151/5/Rev. 1 (1992), reprinted in 31 I.L.M. 876 (1992).
12. For example, Principle 19: "States shall provide prior and timely notification and relevant information to potentially affected States on activities that may have a significant adverse transboundary environmental effect and shall consult with those States at an early stage and in good faith." Id.
13. Dr. Lothar Gündling, The Status in International Law of the Principle of Precautionary Action, 5 Int'l J. of Estuarine & Coastal L. 23, 24 (1990) (citing Der Rat der Sachverständigen für Umweltfragen, Umweltprobleme der Nordsee (1980)).
14. See id. at 25; Second International Conference on the Protection of the North Sea: Ministerial Declaration Calling for Reduction of Pollution, art. VII, Nov. 25, 1987, reprinted in 27 I.L.M. 835 (1988) ("Accepting that, in order to protect the North Sea from possibly damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence.").
15. Declaration of the Third International Conference on Protection of the North Sea, March 7-8, 1990, reprinted in 1 Yearbook of Int'l Envtl L. 658, 662-73 (1990) ("continue to apply the Precautionary Principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic, and liable to bioaccumulate even where there is no scientific evidence to prove a causal link between emissions and effects.").
16. See Convention for the Protection of the Marine Environment of the North-East Atlantic, art. 2(2)(a), Sept. 22, 1992, reprinted in 32 I.L.M. 1069 (1993) (entered into force March 25, 1998) (").
17. See Convention on the Protection and Use of Transboundary Watercourses and Lakes, Helsinki, art. 2(5)(a), March 17, 1992, reprinted in 31 I.L.M. 1312 (1992) (not yet in force) (stating that "the Parties shall be guided by. . . [t]he precautionary principle, by virtue of which action to avoid the potential transboundary impact of the release of hazardous substances shall not be postponed on the ground that scientific research has not fully proved a causal link between those substances, on the one hand, and the potential transboundary impact, on the other hand").
18. See, e.g., Protocol to the Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, preamble, June 25, 1998, UN Doc. EB.AIR/1998/2, reprinted in 37 I.L.M. 505 (1998) (not yet in force) ("[r]esolved to take measures to anticipate, prevent or minimize emissions of persistent organic pollutants, taking into account the application of the precautionary approach, as set forth in principle 15 of the Rio Declaration on Environment and Development."); Protocol to the Convention on Long-Range Transboundary Air Pollution on Heavy Metals, preamble, June 25, 1998, UN Doc. EB.AIR/1998/1 (not yet in force) ("[r]esolved to take measures to anticipate, prevent or minimize emissions of certain heavy metals and their related compounds, taking into account the application of the precautionary approach, as set forth in principle 15 of the Rio Declaration on Environment and Development"); Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Further Reduction of Sulphur Emissions, preamble, June 14, 1994, UN Doc. EB.AIR/R.84, reprinted in 33 I.L.M. 1542 (1994) (not yet in force) ("[r]esolved to take precautionary measures to anticipate, prevent or minimize emissions of air pollutants and mitigate their adverse effects").
19. Bamako Convention on the Ban of Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa, art. 4(3)(f), Jan. 29, 1991, reprinted in 30 I.L.M. 775 (1991) (not yet in force). The full text reads:

    > Each Party shall strive to adopt and implement the preventive, precautionary approach to pollution problems which entails, inter alia, preventing the release into the environment of substances

which may cause harm to humans or the environment without waiting for scientific proof regarding such harm. The Parties shall co-operate with each other in taking the appropriate measures to implement the precautionary principle to pollution prevention through the application of clean production methods, rather than the pursuit of a permissible emissions approach based on assimilative capacity assumptions.

20. World Charter for Nature, ¶ 11, Oct. 28, 1982, U.N.G.A. Res. 37/7, U.N. Doc. A/Res./37/7 (1982), reprinted in 22 I.L.M. 455 (1983) ("Activities which might have an impact on nature shall be controlled, and the best available technologies that minimize significant risks to nature or other adverse effects shall be used; in particular: (a) Activities which are likely to cause irreversible damage to nature shall be avoided; (b) Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed.").
21. Montreal Protocol on Substances that Deplete the Ozone Layer, preamble, Sept. 16, 1987, reprinted in 26 I.L.M. 1550 (1987).
22. Convention on Biological Diversity, preamble, June 5, 1992, reprinted in 31 I.L.M. 818 (1992) (entered into force Dec. 29, 1993) ("Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.").
23. United Nations Framework Convention on Climate Change, art. 3(3), May 29, 1992, reprinted in 31 I.L.M. 849 (1992) (entered into force March 21, 1994).
24. Agenda 21, ¶ 35(3), Adopted by the United Nations Conference on Environment and Development (UNCED) at Rio de Janiero, June 13, 1992, UN Doc.A/CONF.151/26 (vols. I-III).
25. Id. ¶ 35(5).
26. Id. ¶ 35(6)(c).
27. Id. ¶ 17(21) ("A precautionary and anticipatory rather than a reactive approach is necessary to prevent the degradation of the marine environment. This requires, inter alia, the adoption of precautionary measures, environmental impact assessments, clean production techniques, recycling, waste audits and minimization, construction and/or improvement of sewage treatment facilities, quality management criteria for the proper handling of hazardous substances, and a comprehensive approach to damaging impacts from air, land and water. Any management framework must include the improvement of coastal human settlements and the integrated management and development of coastal areas.").
28. Id. ¶ 18(40)(b)(iv) ("All States, according to their capacity and available resources, and through bilateral or multilateral cooperation . . . [could introduce] the precautionary approach in water quality management, where appropriate, with a focus on pollution minimization and prevention through use of new technologies, product and process change, pollution reduction at source, effluent reuse, recycling and recovery, treatment and environmentally safe disposal[.]").
29. See UNEP Expert Group Report, supra note, at ¶ 46.
30. Id. ¶ 47.
31. Report of the Expert Group Meeting on Identification of Principles of International Law for Sustainable Development, Geneva, Switzerland, 26-28 September 1995, Background Paper No. 3, Prepared by the Division for Sustainable Development for the Commission on Sustainable Development (18 April—3 May 1996 New York).
32. See UN Conference on Straddling Fish Stocks and Highly Migratory Fish Stocks, art. 5(c), Aug. 4, 1995, UN Doc A/CONF.164/38, reprinted in 34 I.L.M. 1542 (1995) (not yet in force).
33. Id. at arts. 6(1) & (2).
34. Cartagena Protocol on Biosafety, January 29, 2000, available at URL: <http://www.biodiv.org/biosafe/Protocol/Protocol.html> (not yet in force).
35. Id. at art. 10.6.
36. Id. at art. 11.8.
37. Id. at preamble and at art. 1.
38. International action to protect human health and the environment through measures which will reduce and/or eliminate emissions and discharges of persistent organic pollutants including the development of an international legally binding instrument, UNEP Governing Council Resolution 19/13C (Feb. 7, 1997).
39. Draft Text of an International Legally Binding Instrument for Implementing International Action on Certain Persistent Organic Pollutants, art. F(3),[hereinafter Draft POPs Convention] Report of the Intergovernmental Negotiating Committee for an International Legally Binding Instrument for Implementing International Action on Certain Persistent Organic Pollutants on the Work of Its Fourth Session, UN Doc. UNEP/POPS/INC.4/5, Annex II (25 March 2000). Brackets in the text of the draft Convention appear around those portions of the text to which the negotiators have not yet agreed.
40. Id. at art. F(7bis).
41. Charmian Barton, The Status of the Precautionary Principle in Australia: Its Emergence in Legislation and as a Common Law Doctrine, 22 Harv. Envtl. L Rev. 509, 523-35 (1998).
42. Id. at 535-42.
43. SCALE (PIL) 1981-87 (Kuldip Sing, J.) 703 (1996).
44. P L D 1994 Supreme Court 693 (Pakistan).
45. EC Treaty, supra note .
46. See Agreement on the Application of Sanitary and Phytosanitary Measures, April 15, 1994, arts. 2.2 & 5, available at URL: <http://www.wto.org/english/docs_e/legal_e/final_e.htm> [hereinafter SPS Agreement]. The WTO Appellate Body has interpreted the requirement that SPS measures be "based on" a risk assessment to mean that the country must demonstrate a "rational relationship" between the SPS measure and a risk assessment. See Report of the Appellate Body on EC Measures Concerning Meat and Meat Products (Hormones), AB-1997-4, ¶ 193, WT/DS26/AB/R, WT/DS48/AB/R (16 January 1998) [hereinafter Beef Hormones]; Report of the Appellate Body on Japan—Measures Affecting Agricultural Products, AB-1998-8, ¶ 84, WT/DS76/AB/R (22 February 1999) [hereinafter Japan-Varietals]. Both reports of the Appellate Body are available from the WTO document distribution facility at <http://www.wto.org>.
47. SPS Agreement, supra note , at art. 5.7.
48. EU Communication, supra note ; see de Sadeleer, supra note .
49. See SPS Agreement, supra note , art. 3.1, Annex A, para. 3. The Agreement on Technical Barriers to Trade (TBT Agreement) also encourages Members to base their measures on international standards and creates the presumption that measures based on international standards are consistent with the TBT Agreement. Agreement on Technical Barriers to Trade, April 15, 1994, art. 2.4, available at URL: <http://www.wto.org/english/docs_e/legal_e/final_e.htm>.
50. See SPS Agreement, supra note , at art. 3.2.
51. A Forced Evolution? The Codex Alimentarius Commission, Scientific Uncertainty and the Precautionary Principle 3 (International Institute for Sustainable Development Working Paper) (IISD: Winnipeg, forthcoming September, 2000).
52. Id.
53. See Center for International Environmental Law, Trade Measures and Multilateral Environmental Agreements: Resolving Uncertainty and Removing the WTO Chill Factor (A WWF International Discussion Paper) (WWF-International: Gland, Switzerland, 1999).
54. Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 17(14), reprinted in 33 I.L.M. 1226 (1994), available at URL: <http://www.wto.org/english/docs_e/legal_e/final_e.htm>.
55. Beef Hormones, supra note ; Japan-Varietals, supra note ; Report of the Appellate Body on Australia - Measures Affecting Importation of Salmon, AB-1998-5, WT/DS18/AB/R (20 Oct. 1998).
56. Case Concerning the Gabcikovo-Nagymoros Project, supra note 6.

Children's Environmental Health: A Case Study in Implementing the Precautionary Principle

JOEL A. TICKNER, SCD, POLLY HOPPIN, SCD

The plausible threat to children from environmental exposures and uncertainty as to the magnitude and nature of potentially harmful effects provide a rationale for taking precautionary measures to prevent such exposures. The authors present principles for applying precaution to children's environmental health, and policy tools for implementing them. A stronger focus on primary prevention and a better understanding of the risks are needed. *Key words*: precautionary principle; children; environmental health; public policy; prevention; comparative assessment.

INT J OCCUP ENVIRON HEALTH 2000;6:281–288

Protection of children from environmental health risks provides a compelling reason for implementing the precautionary principle. Children are not only more generally vulnerable to environmental exposures than adults, they also have little if any control over their environments. Children's unique susceptibility to toxic substances and other hazardous exposures begins in the womb and continues through infancy and puberty. While our understanding of these risks is still very limited, there is sufficient evidence to indicate that the development of some children is already being affected by environmental exposures. Taken together, these conditions—plausible threat of harm and uncertainty as to the magnitude and exact nature of harm—provide a rationale for taking precautionary actions to prevent potentially harmful exposures of fetuses, infants, and developing children. While vigorous government and private efforts in recent years represent a growing acknowledgement of the need to protect children from environmental health risks, a greater focus on primary prevention, in addition to a better understanding of these risks, is needed.

Following a discussion of why precautionary precaution should be applied to children's environmental health risks and the responses to date, we present principles for applying precaution to children's environmental health and selected policy tools for implementing this framework. We conclude that applying precaution to children's environmental health demands the adoption of public health policies that promote the fundamental redesign of production processes, products, and potentially hazardous activities. These actions must be supplemented with research efforts aimed at developing a greater understanding of children's exposures to hazardous substances and the root causes of environmentally-related diseases.

Received from the Lowell Center for Sustainable Production, University of Massachusetts Lowell (JAT); and the U.S. Department of Health and Human Services, New England Region, Boston, Massachusetts (PH).

Address correspondence and reprint requests to: Joel A. Tickner, PhD, Lowell Center for Sustainable Production, University of Massachusetts Lowell, One University Avenue, Lowell, MA 01854, U.S.A.; telephone: (978) 934-2981; fax: (978)452-5711; e-mail: <joel_tickner@uml.edu>.

WHY APPLY PRECAUTION TO CHILDREN'S ENVIRONMENTAL HEALTH RISKS?

The precautionary principle has been defined as "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."[1] Inherent in this and most definitions of the precautionary principle, dating back almost 15 years, is the notion of preventing the impacts of pollution on future generations. In this respect, the goal of precaution is to establish research and policies to protect those most vulnerable to environmental degradation (and those least able to protect themselves). Protecting those at greatest risk will generally provide health benefits for all in society.

While the susceptibility of children to environmental health risks has been recognized for decades, the publishing of the respected 1993 National Research Council (NRC) volume *Pesticides in the Diets of Infants and Children*[2] brought immediate and international attention to this vulnerability and to a large vacuum in research and policies that recognized this subpopulation. The NRC book marked the beginnings of the new field of "children's environmental health" and a large influx of research, policies, and government and nonprofit initiatives.

With respect to environmental health risks, it has been said on many occasions (including the NRC report) that "children are not little adults." Researchers note that the combination of disproportionately heavy exposure plus biologic vulnerability makes children very susceptible to injury caused by toxicants in the environment.[3] Some of the factors that make children more susceptible to environmental health risks include[2,4-9]:

1. *Rapid periods of growth and development creating windows of vulnerability.* The growth of human cells tissues, organs, and body systems occurs at different rates, with the most rapid periods of development occurring in utero, during infancy, and during puberty. During the first months and years of life, many organ systems, such as the reproductive organs and the immune system, undergo rapid growth and differentiation. Development of some systems, such as the nervous system, is not completed until age 18. During these periods of rapid growth and development, developmental processes are easily disrupted, creating windows of vulnerability where minute exposures can produce irreversible, lifelong effects.

2. *Age-related differences in absorption, metabolism, detoxification, and excretion of toxic substances.* Differences in size, immaturity of biochemical and physiologic functions in major body systems, and variations in body composition (water, fat, protein, and mineral content) can all influence differences in toxicity between children and adults. The metabolic pathways of children are immature when compared with adults, particularly in the first months of life. As such, the ability of a child to detoxify and excrete certain substances is often less than that of adults. Furthermore, children may absorb toxic substances from the gastrointestinal tract differently and to a greater degree than adults.

3. *Greater exposures to environmental hazards.* Kilogram per kilogram of body weight, children drink more water, eat more food, and breathe more air than adults. This means that they have substantially greater exposure to toxic materials present in water, food, and air. Children drink seven times more water per kilogram than does the average adult, eat three to four times more food per kilogram, and have a resting air intake twice that of an adult. Furthermore, children's diets (greater exposures to certain food groups) also increase susceptibility. For example, breast-fed infants are exposed to levels of dioxin that exceed adult exposures by as much as a factor of 50.[8] Behavioral characteristics of early childhood—hand-to-mouth behavior, hours spent close to the ground, and increased time spent outdoors and in small rooms indoors—magnify children's exposures to toxic substances and other hazards.

4. *A longer period of exposure to environmental hazards.* Children are exposed to toxic substances from the fetus and throughout life. Exposures to toxic substances early in life can lead to a greater risk of chronic effects that are expressed only after long latency periods.

There is well-documented evidence that children are being exposed to toxic substances through their food, water, air, and toys. Almost 2.6 billion pounds of chemicals were released into air, water, and land by industrial facilities in the United States in 1997.[8] A metabolite of the pesticide chlorpyrifos is present in the urine of over 90% of children from representative samples.[8] Many other pesticides and industrial chemicals have been identified in the urine, fat, blood, and breast milk of adults and children. One million children in the United States still exceed the currently accepted threshold for blood lead level exposure that affects development.[8] Children are exposed to phthalate esters from PVC toys[10] and medical devices, at levels near those that cause adverse reproductive-tract effects in laboratory animals.[43]

Many of the chemicals and other hazards (e.g., particulates) to which children are exposed have been shown to have adverse impacts in laboratory experiments. Schettler et al.[7,8] and others have identified a wide range of chemical substances that cause adverse reproductive, developmental, or neurotoxic effects. These include: metals (lead, mercury, manganese, arsenic, cadmium); organic solvents (methylene chloride, glycol ethers, trichloroethylene); pesticides (DDT; atrazine, chlorpyrifos, parathion, lindane); tobacco smoke and nicotine; dioxins, and PCBs. Several of these substances have been shown to be "endocrine disruptors," chemicals that mimic or block hormones or otherwise interfere with normal hormonal activity, often at extremely small doses.[7,12] Chemicals identified as endocrine disruptors include dioxins and PCBs, alkylphenols, bisphenol-a, phthalate esters, and various pesticides.

Uncertainty regarding the nature of exposures,[13] specific vulnerability and variability among children, and limited knowledge about the toxicities of chemicals and complex mixtures make it difficult to determine the extent of links between environmental exposures and adverse health effects in children. For example, the U.S. Environmental Protection Agency has estimated that less than 10% of the industrial chemicals produced in the highest volumes (over one million pounds per year) have a full complement of toxicologic screening data. More than 40% have no toxicologic data whatsoever.[14]

Requirements for testing pesticides are more rigorous than those for testing industrial chemicals. But even for pesticides, data relevant to entire categories of health effects—such as reproductive and developmental disorders—may be missing. This has led some analysts to note that "by default, we are conducting a massive toxicological experiment and our children are the experimental subjects."[3]

In general, little is known about the impacts of low-level exposures during windows of vulnerability or the impacts of cumulative and interactive exposures to multiple chemicals and other stressors such as poverty.[7,12] Given the number of chemicals in commerce—over 75,000—and the discovery of more and more ways in which chemicals can disrupt normal functioning, it is implausible that full data sets on toxicity would ever be available for all hazardous substances.

Additional testing and research can reduce much of the uncertainty involving risks to children's health from

environmental exposures, though resources necessary for comprehensive testing of all circumstances would be enormous.* Generating political will to study potential associations or ask questions not asked before can also reduce uncertainty. But some uncertainty results from inherent limitations in our scientific tools, as well as indeterminacy (we cannot control the many unpredictable human factors interacting with human, environmental, and technologic factors), and ignorance (we do not know what we do not know).[17]

In addition to children's unique susceptibility to environmental contamination, there is a growing body of evidence linking certain types childhood diseases and conditions at least partially to environmental exposures. Many people can remember the tragedy of Love Canal. Still, between three and four million children and adolescents in the United States live within one mile of a federally designated Superfund hazardous waste clean-up site.[3] Childhood lead poisoning represents perhaps the clearest example of the impacts that a lack of precaution can have on children's health. Poor and minority children are at increased risk of environmentally-related illnesses because of poor housing and their proximity to both industrial and agricultural production and disposal sites.[18] Evidence pointing to the impacts of environmental exposures on children's health include[6,8,9,19,20]:

- Epidemologic studies have identified associations between childhood exposures to PCBs, mercury, cadmium, lead and some pesticides and neurologic and developmental disorders.
- Rates of asthma in children under 5 years of age have increased 160% in the past 15 years. Substances in indoor and outdoor air are recognized to at least exacerbate and possibly trigger asthma.
- It is estimated that nearly 17% of children in the United States under age 18 suffer from one or more learning, developmental, or behavioral disabilities. Attention-deficit hyperactivity disorder (ADHD) affects approximately 3–6% of all schoolchildren. Research points to environmental exposures as a contributing factor.
- Approximately 8,000 children under the age of 15 are diagnosed as having cancer each year. The incidences of certain types of cancer, such as acute lymphocytic leukemia and brain tumors, have increased over the past 15 years. Some examples of environmental contaminants associated with cancer include: tobacco smoke, asbestos, some hazardous wastes, and some pesticides.

Several factors limit the capacity of epidemiology to discern links between environmental exposures and adverse health effects. These include: long latency periods for some diseases; difficulty in following children over long periods of time; the subtlety of certain health effects; the difficulty of tracking specific exposures (and confounding); and the rare nature of some childhood illnesses. The absence of statistically significant associations may in turn be misrepresented as conclusive evidence of no or minimal risk to children from environmental exposures.

THE U.S. FEDERAL RESPONSE TO CHILDREN'S ENVIRONMENTAL HEALTH RISKS

Since the landmark 1993 National Research Council report, discussed earlier, the U.S. government has undertaken a vigorous and far-reaching program to assess and reduce risks to children's health from environmental exposures. In 1996, U.S. EPA administrator Carol Browner announced a seven-step National Agenda to Protect Children's Health from Environmental Threats. The National Agenda instructs the agency to ensure that EPA standards are protective of children; develop a scientific research strategy to fill gaps in knowledge; develop policies to address cumulative exposures of children; and expand education and the right to know.[21] Browner established the Office of Children's Health Protection to coordinate these activities at EPA.

During that same year, Congress passed the Food Quality Protection Act, the first environmental law to require explicit consideration of risks to children in establishing standards for pesticide residues in food. The 1997 Presidential Executive Order 13045 on Children's Environmental Health calls for Federal agencies to "ensure that [their] policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks."[22] The Executive Order called for the establishment of a research agenda on children's environmental health and establishment of principles and priorities for protecting children's environmental health.

The federal Executive Order resulted in a large-scale mobilization of research and regulatory agencies, as well as academic institutions and nonprofits. The Order created the Cabinet-level task force† charged with recommending strategies for protecting children from environmental threats to health and safety. The task force identified four priority areas for immediate attention—childhood asthma, unintentional injuries, developmental disorders, and childhood cancer—and developed multiagency strategies to meet urgent research and programmatic needs in these areas.[23] The EPA and various agencies of the U.S. Department of Health and Human Services—the Centers for Disease Control and Preven-

*There is also uncertainty that is directly related not to science, but rather to political decisions to not study a hazard or deliberate efforts to conceal risks. The case of lead in gasoline and in paint provides a clear example of the latter.[15,16]

†Task Force on Environmental Health Risks and Safety Risks to Children.

tion, the Agency for Toxic Substances and Disease Registry, and the National Institute of Environmental Health Sciences—have taken the lead in expanding research, outreach, and education on children's environmental health issues. For example, they have established a network of eight academic research centers dedicated solely to the study of children's environmental health risks. This network undertakes wide-ranging research to analyze preventable causes of environmental disease and is charged with translating scientific findings into intervention and prevention strategies.[5] Other agencies have also stepped up their activities. With its Healthy Homes Program, the Department of Housing and Urban Development has expanded its work to reduce risks from lead in housing to include interventions to reduce triggers for asthma and physical hazards associated with childhood injuries.

Despite these promising activities, the vast majority of federal funds spent on health-related activities support screening for hazards and quantification of risks. In some cases, restrictions on emissions of pollutants or uses of industrial chemicals follow. But research and promotion of alternative, less hazardous, approaches to manufacturing, pest control, and other uses of chemicals is scarce and occurs largely in the private sector, disconnected from federal or state regulatory systems. Aggressive action by the government to reduce risks to children from an environmental exposure is very rare, particularly before the risks are fully understood and quantified. The removal of lead from gasoline, tied to subsequent dramatic reductions of levels of lead in the blood of children, is one of only a few examples of this kind of action.

Take, for example, the case of phthalate ester plasticizers in PVC children's toys. The Danish government determined that, taken together, knowledge of exposure, animal toxicity, children's susceptibility to chemical insults, and the availability of alternatives were sufficient to propose a ban on these toys.[24] Elimination of uncertainty was not a prerequisite for taking action. In the United States, the Consumer Product Safety Commission conducted a detailed quantitative risk assessment (estimating exposure through adult volunteers) and arrived at the conclusion that no apparent significant risk existed, but that due to lingering uncertainties industry should voluntarily remove phthalates from toys.[10] The CPSC report did not examine alternatives that would avoid the risks from phthalates.

PRINCIPLES FOR APPLYING PRECAUTION TO CHILDREN'S ENVIRONMENTAL HEALTH

Implementing the precautionary principle in order to better protect children from environmental risks demands a broad reorganization of both environmental science and policy so that it is more effective at anticipating those risks and promoting cost-effective alternatives to hazardous products and processes. The precautionary principle should be viewed as both an overarching principle for environmental health decision making and a guide to individual decisions in the face of uncertainty. This would ensure that "precautionary thinking" is infused throughout the entire decision making process: problem formulation, data collection, assessment of alternatives, weighing of evidence, decision-making, implementation of those decisions. It would lead to decisions that better consider the limits of science and of uncertainty and are more supportive of prevention and innovation. Below we present a set of principles to guide the application of precaution to children's environmental health:

1. Shifting the Questions Asked in Environmental Health Policy

One fundamental change the precautionary principle requires is that scientists and policymakers begin to ask a different set of questions about activities and potential hazards. Instead of asking, "What level of risk is acceptable?" or "How much contamination can a human safely assimilate (usually a healthy male adult)?" they must ask, "How much contamination can we avoid while still achieving our goals?" and "What are the alternatives or opportunities for prevention?" This requires tools to comprehensively analyze not only risks but also feasibility of alternative technologies and products.

The most important aspect of shifting the questions asked in environmental health policy is that it reorients the focus of environmental policy and regulations from analysis of problems to analysis of solutions. Rather than quantifying only the risks of an inherently hazardous activity (emitting a chemical from an industrial facility), assessment of alternatives focuses on what could be done to meet a similar need that would be inherently less hazardous.[25] Examining choices permits a broader range of questions and considerations about activities. It allows for an examination of a product or activity as a whole and whether its purpose can be served in a less harmful and possibly more effective way, rather than simply a narrow examination of one aspect of that activity (the amount of harm it might cause). It allows a more comprehensive range of experience and information (scientific, technologic, etc.) to be used in decision making than does traditional risk assessment. Nonetheless, assessing alternatives will not eliminate the need to assess risks, but this can be done incorporating broader vision for science (see below).

A focus on alternatives may also allow decision makers to partially bypass contentious debates over proof of harm and causality, instead dedicating scarce resources to solutions. It allows precaution to be used as a means of saying "yes" to innovative, cleaner technologies, countering critiques that the principle is used only to stop technologies. Some tools for instituting prevention and assessment of alternatives include: toxics use reduction, pollution prevention, and clean production planning;

environmental impact statements; pre-market testing; labeling; and strict exposure limits (see next section).

2. Shifting Presumptions

In addition to switching the questions decision makers ask about environmental risks, the precautionary principle shifts the presumptions used in decision-making. Rather than presuming that specific substances or activities are safe until proven dangerous, the precautionary principle establishes a presumption in favor of protecting the environment and public health. This switch of presumption places the responsibility for developing information, regular monitoring, demonstrating relative safety, analyzing alternatives, and preventing harm on those undertaking potentially harmful activities. It also empowers government agencies to act to prevent harm and allows them to create disincentives for undertaking potentially harmful activities. Accordingly, in the case of scientific uncertainty, protection of health and the environment are given more primacy than the economic benefit of a hazardous activity. Of course, these tradeoffs are not always black-and-white: a potentially hazardous activity may benefit public health, as in the case of pesticide spraying to reduce transmission of a mosquito-borne virus.

Examples of shifting presumptions exist in public health. Drugs are not allowed on the market until the manufacturer can demonstrate safety and efficacy. Further, pesticides are not judged innocent until proven guilty. However, what is missing in pesticide regulation is the latter steps in the process: assessment of alternatives, less reliance on chemicals, and promotion of non-chemical approaches.

3. A Redefinition of "Sound Science"—Reconfiguring the Science Used for Policy

A critical step in implementing the precautionary principle is to expand the array of scientific tools used to inform policy decisions. Because of the complexity and uncertainties in understanding children's environmental health risks, the science brought to the table needs not only to help reduce uncertainty to the extent possible but also to provide information relative to a preventive, precautionary approach. Science that can best inform precautionary decisions asks different questions and uses different methods than the science historically relied upon by risk managers. These changes in content and method include: broadening hypotheses to examine systems and cumulative and interactive effects of multiple stressors; a greater reliance on interdisciplinary approaches (as has been the case in climate change and endocrine disruption) and information from different constituencies; the integration of critical qualitative information into scientific results; and more explicit discussion about uncertainties (what is known, not known, can be known, and suspected).[26] Decision-making approaches need to go beyond examining risk and causality to considering the magnitude of potential harm, reversibility, temporal and spatial scales, vulnerable populations, and availability of alternatives.[11]

4. Improving democratic methods of participation

A more participative process for decision making under the precautionary principle would likely improve the ability of decision makers to anticipate and prevent harm to children's health. Fiorino[27] has identified several main arguments for more democratic environmental decision-making processes: Non-experts see problems, issues, and solutions that experts miss by thinking more broadly and not being bound by disciplinary constraints; lay judgments reflect a sensitivity to social and political values and commonsense that experts' models do not acknowledge; and the lay public may have a better capacity than experts alone for "institutionalizing regret," accommodating uncertainty, and correcting errors. Finally, broader public participation processes may increase the quality, legitimacy, and accountability of complex decisions.

Given the public nature of environmental decisions, more effective processes for involving those affected by degradation (in this case parents and advocates for children and future generations) are needed. Such processes must be both "fair" and "competent," meaning that they allow all those who want to participate access to the decision-making process from the beginning and that they provide financial and technical resources so that the lay citizen can participate on equal terms with experts.[28] These processes should increase the "decision authority" of affected publics so that their participation is more than token and contributes substantively to the ultimate outcome.

POLICIES FOR IMPLEMENTING A PRECAUTIONARY FRAMEWORK TO ADDRESS CHILDREN'S ENVIRONMENTAL HEALTH RISKS

Based on the previously described principles, a set of policies is needed for implementing a precautionary approach to children's environmental health. The basis of these tools is threefold: 1) reducing and eliminating children's exposures to potentially harmful substances, activities, and other conditions; 2) redesigning production processes, products, and human activities so as to minimize risks in the first place; and 3) establishing goals for restoring human and ecosystem health. Such policy tools need to be supplemented with a research agenda designed to provide "early warnings" to make possible rapid interventions to prevent damage to health. Some policy tools for implementing a precautionary approach to children's environmental health include:

Clean Production and Pollution Prevention

Clean production and pollution prevention involve

changes to production systems and products to reduce pollution at the source (in the production process or product-development stage). This includes reducing the raw material, energy, and natural resource inputs (dematerialization), as well as reducing the quantity and harmful characteristics of toxic substances used (detoxification) in production systems and products.[29,30] A central aspect of clean production is understanding the "service" that a production system or product provides and seeking out safer alternatives to provide that same service (e.g., chlorinated solvents provide degreasing). A majority of U.S. states and many foreign countries have some form of a pollution prevention or clean production program, which have demonstrated success in reducing industrial and product-related pollution, while reducing costs. Swedish hazardous substance law is based on the "substitution" principle, which states that those handling chemical products must take all precautions necessary to prevent or minimize harm to humans or the environment, including avoiding chemical products for which less hazardous substitutes are available.[31]

The Massachusetts Toxics Use Reduction Act represents one concrete, effective application of pollution prevention and precaution. The Act encourages firms to identify ways to reduce their reliance on toxic substances rather than calculate acceptable emissions levels. Firms are required to understand how they use chemicals and for what purposes. They must then develop plans to reduce their waste and use toxic substances and measure progress. In ten years of experience with the Act, toxic chemical emissions have been reduced more than 80%; toxic waste, 48%; and toxics use, 33%, indexed for changes in manufacturing activity. Massachusetts firms have saved more than $15 million in the process, excluding the unquantifiable benefits to health and the environment.[32]

There is an enormous need—and opportunity—to apply clean production and pollution prevention to the design of cities, living spaces, and building materials. The burgeoning "green building" movement provides basic principles for more healthy and environmentally-friendly design that minimizes hazardous and non-hazardous materials; is energy-efficient yet allows sufficient fresh-air ventilation; minimizes build-up of allergens; and sites houses so as to minimize environmental impacts and improve air quality (e.g., designing cities to minimize air pollution from transport and production facilities).

Goal Setting for Environmental Health

Goal setting involves the establishment of aggressive, preventive health goals (e.g., eradication of teen smoking) and development of policies and measures to achieve those goals, while minimizing social disruption (also known as "backcasting"). Goal setting focuses not on what futures are likely to happen but rather how desirable futures can be obtained.[33] Categories of goals include: 1) goals for reducing exposures to hazardous substances, including body burdens (e.g., a 50% reduction in children's body burdens of toxic substances); 2) goals for reductions in hazardous substances and activities (e.g., phase-outs of the most hazardous chemicals); and 3) goals for reductions in the incidences of environmentally related diseases. Goals can also be achieved through the establishment of "red flags," deterrent signals as to which substances and activities are undesirable—for example, lists of chemicals of concern. The northern European countries have been leaders in developing goal-setting processes for environmental health.

In Sweden, Parliament passed a set of Environmental Quality Objectives for the millennium. The overarching goal of these objectives it "to hand over to the next generation a society in which the main environmental problems have been solved." The goals that have been developed are issue-based (water quality, forests, etc). They include implementation steps and measures to track progress.[34]

To achieve the goal of a "nontoxic environment," the Swedish Chemicals Policy Committee developed a set of policies and goals, including: elimination of persistent and bioaccumulative substances from products by the year 2015; elimination of all reproductive toxicants, carcinogens, and mutagens from consumer products by the year 2007; and a progressive phase-out of mercury, cadmium, and lead in products.[35] Implementing this goal requires acknowledging that the chemical-by-chemical risk-assessment process is generally slow and ineffective as well as identifying and acting on characteristics in chemicals that are inconsistent with health and sustainability.[36]

The Danes have also developed a strategy for goalsetting in the area of toxic chemicals.[37] The Danish strategy is based on a goal of protection of the environment so that growth can take place while respecting health and the preservation of animal and plant life. The prevention of health hazards is to be achieved through cleaner technologies. In order to protect the marine environment, discharges of dangerous chemical substances are to be ceased entirely within one generation (25 years), with the ultimate goal of reducing concentrations of substances to near background levels for naturally-occurring substances and to near zero for synthetic substances.

In 1997, the Danish Minister of the Environment established the "Bichel" Committee to evaluate "the overall consequences of phasing out the consumption of pesticides within the agricultural industries."[38] While finding that a complete phase-out of pesticides would not be economically possible, the Committee recommended a strategy for pesticide reduction, including: mandatory use reductions; reduction in exposures; and a changeover to more organic farming methods.

In The Netherlands, goal setting occurs at a firm or sector level, where sectors establish five-year environmental plans (including goals and metrics), and enter into "covenants" with regulators that provide firms in that sector flexibility to achieve the plan's goals unless they

fail to do so, in which case regulations are imposed.[39]

Pesticide Use Reduction/Integrated Pest Management

The use of pesticides in agriculture and general pest control are among the most important environmental risks to children's health. Substitutions of less hazardous chemicals and processes have the potential to substantially reduce those risks. Policies to encourage agricultural production less reliant on pesticides would apply precaution to an important set of children's health risks (both exposures from food residues and exposures of low-income and minority children living near farms).

Policies to reduce reliance on pesticides in buildings would further reduce children's risks. Several local governments and states have enacted pesticide-use–reduction regulations for schools. The Los Angeles Unified School District (the largest in the United States) recently instituted an integrated pest-management (IPM) program that acknowledges the inherent risks that pesticides pose to children. The policy commits the district to select the least harmful method for controlling pests (non-chemical preferred).[40] The recently passed Massachusetts Children's and Families' Protection Act, prohibits the use of the most toxic pesticides at schools and day care centers and requires that these institutions develop IPM plans and notify parents before any spraying takes place. The Consumer's Union and the World Wildlife Fund have proposed a method for tracking progress in pesticide reduction that captures both reductions in toxicity and reductions in overall dependency on pesticides that are inherently hazardous.[41]

A Precautionary Children's Environmental Health Research Agenda

Landrigan[5] and others have argued persuasively for a new paradigm of environmental research that is centered on the needs and exposures of children. Under this paradigm, the child, not the chemical or hazard, is at the center of the analysis. Currently less than 3% of total federal research is devoted to children's health (including environmental), even though children represent 30% of the U.S. population.[42] Children represent the future of our society, yet environmental research is just beginning to consider their unique vulnerabilities. A precautionary children's research agenda would focus on rapid identification of environmental hazards to children's health, as well as potential exposures. It would broaden our understanding of the unique susceptibility of children to environmentally related illnesses. It would take a holistic look at categories of risks and examine root causes and broad-based measures for prevention. It would ask broader questions about risks, to include cumulative and interactive exposures and the effects of long-term low-level exposures and exposures during "windows of vulnerability." The underlying purpose of the research agenda would be to support preventive public health policies to protect children.

CONCLUSION

While children are exposed to a range of both natural and human-made hazards during their development, exposures to toxic substances and other environmental hazards deserve special scrutiny because they are largely preventable. Applying precaution to children's environmental health will require the development of innovative scientific and policy methods and tools that shift the focus of decision making towards primary prevention. It will also require both a willingness and a capacity on the part of government and private institutions to undertake these changes. Nonetheless, this does not mean that we should discard the many useful tools we currently use to assess and reduce environmental risks to children. It does mean that we need to continuously refine and improve upon them as our knowledge of exposures, hazards, and disease progresses.

Precaution should be espoused as much more than a risk-management principle. It needs to apply the content and methods of science used by policymakers to how products, production processes, and activities are designed; to how information is weighed in making a decision; and to who is involved in the decision process. Precaution is driven by respect for human and ecosystem health and for future generations. It depends on more holistic thinking, and acknowledges what we know and do not know. There is no "one size fits all" approach to applying the precautionary principle, as each decision has unique characteristics, affected publics, and levels of scientific evidence and understanding of alternatives.

The original German "spirit" of *Vorsorge* (or foresight), from which the precautionary principle is derived needs to be instilled in efforts to apply precaution to children's environmental health. The *Vorsorgeprinzip* principle takes the future into account and institutes an ethic of aggressive, careful forward planning for sustainability, stimulating both innovation in environmental technologies and job creation.[43] Most articulations of the principle to date, however, have focused on anticipatory action once harm is suspected rather than developing strategies for preventing it in the first place.

Foresight demands that we develop a vision for the type of world we want for our children and aggressively work towards achieving that vision. This vision might include: walking to school without having to cross busy streets; not seeing billboards urging unhealthy behaviors; not being at risk of violence in and out of school; not being born with a body burden of toxic substances; and being able to breathe healthy air, drink uncontaminated water, and eat safe, healthful foods. Current initiatives under way to address environmental risks to children's health provide a unique opportunity to implement the precautionary principle in environmental science and

policy, which can result in a cleaner, safer, and healthier future for all.

References

1. Raffensperger C, Tickner J (eds). Protecting Public Health and the Environment: Implementing the Precautionary Principle. Washington, DC: Island Press, 1999.
2. National Research Council. Pesticides in the Diets of Infants and Children. Washington, DC: National Academy Press, 1993.
3. Landrigan, P, Suk W, and Amler R. Chemical wastes, children's health, and the Superfund Basic Research Program. Environ Health Perspect. 1999;107:423–7.
4. Wargo,J. Our Children's Toxic Legacy: How Science and Law Fail to Protect Us from Pesticides. New Haven, CT: Yale University Press, 1998.
5. Landrigan P. Risk assessment for children and other sensitive populations. In: Bailar J (ed). Uncertainty in the risk assessment of environmental and occupational hazards. Ann NY AcadSci. 1999: 895.
6. Children's Environmental Health Network. Resource Guide on Children's Environmental Health. San Francisco, CA: CEHN, 1999.
7. Schettler T, Solomon G, Valenti M, and Huddle A. Generations at Risk: Reproductive Health and the Environment. Cambridge, MA: MIT Press, 1999.
8. Schettler T, Stein J, Reich F, Valenti M. In Harm's Way: Toxic Threats to Child Development. Boston, MA: Greater Boston Physicians for Social Responsibility, 2000.
9. May M. Disturbing behavior: neurotoxic effects on children. Environ Health Perspect. 2000;108:262–7.
10. United States Consumer Product Safety Commission. The Risk of Chronic Toxicity Associated with Exposure to Diisononyl Phthalate (DINP) in Children's Products. USCPSC, 1998.
11. Tickner J. A map toward precautionary decision-making. In: Raffensperger, C, Tickner j (eds). Protecting Public Health and the Environment: Implementing the Precautionary Principle. Washington, DC: Island Press, 1999: 162-186.
12. Colborn T., Dumanoski D, Myers JP. Our Stolen Future. New York: Dutton Books, 1996.
13. Hubal E, Sheldon L, BurkeJ et al. . Children's exposure assessment: a review of factors influencing children's exposure, and the data available to characterize and assess that exposure. Environ Health Perspect. 2000;108:475–86.
14. United States Environmental Protection Agency. Chemical Hazard Data Availability Study: What Do We Really Know about the Safety of High Production Volume Chemicals. Office of Pollution Prevention and Toxics, USEPA, 1997.
15. Kitman J. The secret history of lead. The Nation. 2000, March 20: 11–43.
16. Markowitz G, Rosner D. Cater to the children: the role of the lead industry in a public health tragedy, 1900–1955. Am J Public Health. 2000;90:36–46.
17. Wynne B. Uncertainty and environmental learning. In: Jackson T. Clean Production Strategies. Boca Raton: Lewis Publishers, 1993: 63–84.
18. Landrigan P, Claudio L, Markowitz S et al. Pesticides and inner-city children: exposures, risks, and prevention. Environ Health Perspect. 1999;107, suppl 3: 431–7.
19. United States Environmental Protection Agency. Asthma and upper respiratory illnesses. Office of Childrens Health Protection, USEPA, 2000. Available at <www.epa.gov/children/asthma.htm>.
20. United States Environmental Protection Agency. Childhood Cancer. Office of Childrens Health Protection, USEPA, 2000. Available at <www.epa.gov/children/cancer.htm>.
21. United States Environmental Protection Agency. Our History. Office of Children's Health Protection, USEPA, 2000. Available at <www.epa.gov/children/whowe/history.htm>.
22. The White House. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks, April 21, 1997.
23. United States Environmental Protection Agency. President's Taskforce on Environmental Health and Safety Risks to Children. Office of Childrens Health Protection, USEPA, 2000. Available at <www.epa.gov/children/whatwe/fedtask.htm>.
24. Seerdorff L. Head of Division, Danish Environmental Protection Agency. Personal interview, May 21, 1999.
25. O'Brien M. Making Better Environmental Decisions: An Alternative to Risk Assessment. Cambridge, MA: MIT Press, 2000.
26. Barrett K, Raffensperger C. Precautionary science. In: Raffensperger C, Tickner J (eds). Protecting Public Health and the Environment: Implementing the Precautionary Principle. Washington, DC: Island Press, 1999: 106–22.
27. Fiorino D. Citizen participation and environmental risk: a survey of institutional mechanisms. Issues in Science and Technology. 1990; 15:226–43.
28. Renn O, Webler T, Wiedermann P. Fairness and Competence in Citizen Participation. Dordrecht, The Netherlands: Klewer Academic, 1995.
29. Jackson T (ed). Clean Production Strategies. Boca Raton, FL: Lewis Publishers, 1993.
30. Geiser K. Cleaner production and the precautionary principle. In: Raffensperger C, Tickner J (eds). Protecting Public Health and the Environment: Implementing the Precautionary Principle. Washington, DC: Island Press, 1999: 323–36.
31. Wahlstrom B. . The precautionary approach to chemicals management: a Swedish perspective. In: Raffensperger C, Tickner J(eds). Protecting Public Health and the Environment: Implementing the Precautionary Principle. Washington, DC: Island Press, 1999: 51–70.
32. Toxics Use Reduction Institute. Massachusetts Is Cleaner and Safer. Lowell, MA: TURI. 1997
33. Dreborg K. Essence of backcasting. Futures. 1996; 28:813–28.
34. Swedish Parliament. Swedish Environmental Quality Objectives. Government Bill 1997/98:145, passed as 1998/99:MJU6, 1999.
35. Swedish Committee on New Guidelines on Chemicals Policy. Summary of the report of the Swedish Committee on New Guidelines on Chemical Policy. From, Non-Hazardous Products: Proposals for Implementation of New Guidelines on Chemicals Policy. Statens Offentliga Utredningar–SOU 2000:53.
36. Swedish Ministry of Environment, Swedish Environmental Protection Agency, Swedish National Chemicals Inspectorate. Chemicals with Certain Properties Should be Automatically Banned. Swedish Environment. 1998;2:1–2.
37. Danish Ministry of Environment and Energy. A Strategy for Intensified Efforts in the Field of Chemicals—in Demark, in the EU, and Globally. Copenhagen, Denmark, 1999.
38. Danish Ministry of Environment and Energy. The Consequences of Reducing the Use of Pesticides Have Now Been Dlucidated. Faktuelt 21. Copenhagen, Denmark, 1999.
39. van Dunne J (ed). Environmental Contracts and Covenants: New Instruments for a Realistic Environmental Policy? Rotterdam, The Netherlands: Vermanda Lelystad, 1993.
40. Montague P. Preferring the least harmful way. Rachel's Environment and Health Weekly. 2000, January 27: 684.
41. Benbrook C, Groth E, Halloran J, Hansen M, Marquardt S. Pest Management at the Crossroads. Yorkers, NY: Consumers Union, 1996.
42. Olden K, Guthrie J. Children's health: a mixed review. Environ Health Perspect. 2000;108:A250–A251.
43. Boehmer-Christiansen S. The precautionary principle in Germany—enabling government. In: O'Riordan T, Cameron J (eds). Interpreting the Precautionary Principle. London, U.K.: Earthscan, 1994: 31–61.

An Environmentalist's Vision of Operationalizing the Precautionary Principle in the Management of Chemicals

GWYNNE LYONS, BPHARM, ANDREAS AHRENS, MSC, ELIZABETH SALTER-GREEN, MA

In Europe and elsewhere, there is compelling evidence that humans, wildlife, and the environment are being damaged by man-made chemicals. Recognizing that regulatory initiatives are needed to try to prevent harm before it occurs in the future, the precautionary principle has become a focus of attention on both sides of the Atlantic. The authors suggest a way to implement the precautionary principle in the management of chemicals, outlining how this guiding principle can be given a practical relevance within regulatory initiatives to reduce the risks posed by chemicals currently traded in the European Union and elsewhere. *Key words*: precautionary principle; chemicals management; legislation; overarching principle; comparative assessment; substitution principle.

INT J OCCUP ENVIRON HEALTH 2000;6:289–295

There is compelling evidence that humans, wildlife, and the environment in Europe and elsewhere are being damaged by man-made chemicals. Recognizing that regulatory initiatives are needed to try to prevent harm before it occurs in the future, the precautionary principle has become a focus of attention on both sides of the Atlantic.

This article suggests a way to implement the precautionary principle in the management of chemicals. It outlines how this guiding principle can be given a practical relevance within regulatory initiatives to reduce the risks posed by chemicals currently traded in the European Union (EU) and elsewhere.

The rest of the article is organised as follows. First, the main legal texts that determine the application of precaution in the EU and some of the Commission of the European Communities' (The Commission's) thinking on the subject are outlined. It is argued that the Commission's Communication on the Precautionary Principle, of February 2000,[1] wrongly ascribes the application of the precautionary principle as being part of risk management, rather than as an overarching principle.

Received from the WWF-UK (World Wide Fund for Nature), Norwich, England (GL); Okopol, Institute for Ecological Assessment and Environmental Policy Ltd., Hamburg, Germany (AA); and WWF European Policy Office, Brussels, Belgium (ESG).

Address correspondence and reprint requests to: Gwynne Lyons, Toxics And Policy Advisor to World Wide Fund for Nature (WWF-UK), 17 The Avenues, Norwich NR2 3PH, England; telephone: -44-1603-507363; fax: -44-1603-507363; e-mail: <g.lyons@mcmail.com>.

The second section sets out an environmentalist's vision of the precautionary principle. The precautionary principle is seen an overarching mechanism to lower the risk that chemicals pose by:

1. ensuring that chemicals lacking hazard data are not marketed;
2. taking account of the needs and acceptance of risk expressed by society;
3. aiming to achieve a high level of protection (for example, hazardous substances originating from human activity should not be found in breast milk or in the open seas),
4. ensuring that the least risky option is chosen to deliver the goods or service, and giving preference to risk reduction through substitution rather than emission control;
5. basing the quantification of risk on worst-case assumptions; and
6. taking action without delay based on the best available knowledge at the time and giving preference to human health and the environment rather than the economic interests of companies.

It is therefore argued that the precautionary principle should embrace concepts such as societal need and the acceptability of risk. In order to ensure that the least risky options are chosen, comparative assessment and the implementation of the substitution principle are seen as the way forward.

The third section discusses the possibility that a robust application of the precautionary principle might lead to future trade wars. The fourth section challenges the World Trade Organization's (WTO's) and the Commission's vision that action taken in the name of precaution should *always* be potentially temporary, particularly with regard to bioaccumulative and/or persistent chemicals. With reference to the Commission's Communication on the Precautionary Principle,[1] and with reference to a case study, shortfalls in the current proposed application of this principle within the EU are identified.

The conclusion is that the precautionary principle can be implemented to deliver a high level of protection, and that it is possible to balance the dual societal expectations of a clean and healthy environment and access to technologic developments.

APPLICATION OF PRECAUTION IN THE EU

In the EU, there are two references to precaution that are particularly important in indicating the scope of the precautionary principle. These are the Amsterdam Treaty and a ruling (relating to BSE) from the Court of Justice.

The Amsterdam Treaty, which is the bedrock of the EU, amended Article 130r(2) of the Treaty of Rome, and incorporated provisions already introduced by the Maastricht Treaty of 1992. It states:

> Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community; It shall be based on the precautionary principle and on the principles that preventative action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. (Article 174)

The Treaty explicitly refers to the precautionary principle as applying to environmental policy, but it is generally accepted as also being applicable to health policies. This is indeed confirmed by a 1998 ruling from the Court of Justice, which also suggests that within the EU, preventive measures may be taken when there is uncertainty as to whether or not a risk exists, not just the extent of that risk:

> Where there is uncertainty as to the existence or extent of risks to human health, the Commission may take protective measures without having to wait until the reality and seriousness of those risks become apparent. (Court of Justice, Judgement of 5 May 1998, C180/96, Point 99)

The Commission's Communication on the Precautionary Principle[1] gives further preliminary guidance on how it sees the application of the precautionary principle in the EU. However, the Commission's Communication does not have legal standing, but is an initial position that will be an important starting block in the debate both within the EU and globally. Critically, the Commission sees the application of the precautionary principle as a risk management tool, rather than an overarching principle:

> . . . application of the precautionary principle is part of risk management, when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy. (5)

The Commission therefore appears to have confused the precautionary principle with precautionary action taken under the precautionary principle.

The Communication clearly shows that the Commission considers that before the precautionary principle is applied, there has to be an evaluation of available scientific information, and an evaluation of the potential adverse effects (5.1.2). This implies that the precautionary principle will not be allowed to be a central pivot of EU environmental policy, and will relegate it to being used only in special circumstances. The view of the authors is that this is wrong; the precautionary principle should always apply, and should be used as an overarching guiding principle.

With regard to the costs of taking precautionary action, the Commission's Communication stresses the need to compare the benefits and costs of taking action and of not taking action. However, the Communication underlines that "examination of the pros and cons [of taking action] cannot be reduced to an economic cost–benefit analysis." Thus, the Commission highlights that the efficacy and public acceptability of the various options are also important. In accordance with case law, the Commission affirms that requirements linked to the protection of public health "should undoubtedly be given greater weight than economic considerations" (6.3.4). This is very much welcomed.

The need for "proportionality" is also stressed by the Commission, which means that any measures based on the precautionary principle should not be disproportionate to the desired level of protection. The Communication stresses that banning a substance will not always be the correct response as the desired level of protection may be reached via other means, such as restricting its use to certain applications, or recommendations for populations at risk.

AN ENVIRONMENTALIST'S VISION OF HOW TO IMPLEMENT THE PRECAUTIONARY PRINCIPLE

The precautionary principle should be seen as an overarching principle rather than a risk management tool. Several components need to be embraced by this overarching principle and these are further outlined in the following points 1 to 5. First, for example, it is argued there is a need to ensure that extremely hazardous substances do not reach the market. Second, there is a need to ensure that hazardous chemicals are used only where necessary, and where they are needed, and that only those that provide the safest options should be used.

Mechanisms are undoubtedly needed to improve the present system of chemicals management in the EU, where most chemicals have not been adequately tested, and only a relatively small number are prioritized for risk assessment. Furthermore, the risk-assessment process is currently prescribed in such a way that risk-reduction measures are not required unless it can be shown that the chemical is likely to be found at levels that cause harm.

Some individuals are of the opinion that risk assessment is based on firm "sound" science, while the application of the precautionary principle has little to do with sound science. However, nothing could be further from

the truth, because it is "sound" science to acknowledge the limitations of our current knowledge and the uncertainties that prevail in risk assessment. It is crucial to avoid being misled by the formal framework of risk assessment into thinking that the quantification of risks is more accurate than it really is. Yet all too often the weight put upon the conclusion of a risk assessment is greater than the science would dictate, given the many assumptions and uncertainties therein. In conclusion, therefore, it is sound science to acknowledge that to more effectively prevent harm, a precautionary strategy that reduces exposures to the most hazardous substances is needed.

1. Ensure That No Chemical Lacking Hazard and Fate Data is Marketed

In order to put in place a more precautionary approach to chemicals management, it is imperative that all chemicals be adequately tested. In this way, only those that are deemed to be reasonably safe, or those that pose lesser risks, are allowed onto the market. Furthermore, to ensure that emerging concerns, such as endocrine disruption, are dealt with effectively, it needs to be recognized that more resources must be directed to developing new test methods and protocols. Older "existing" chemicals should also be tested to the best standards of the time, and the costs borne by the manufacturers. Since1981, EU-wide legislation has meant that no new chemical can be put on the market without prior testing. However, the 100,195* older chemicals, termed "existing" chemicals, which were traded in the EU prior to 1981 have not been evaluated to the same standards. For these substances, there is a frightening lack of hazard data available, even for the 2,500 chemicals traded in quantities of 1,000 tons per year or more. For example, a recent study in the EU has shown that only 14% of these chemicals have even the basic EU set of test data available.[2] Furthermore, only 3% have a full data set, including long term ecotoxicity results, degradation behavior in various environmental compartments, and a complete mammalian toxicity profile. This situation is similar the world over.

Within the review of chemicals legislation under way in the EU, as of mid-2000, the Commission is pushing for manufacturers of existing chemicals, particularly those produced in high volume, to provide hazard data similar to those required for new chemicals. However, at this time it is not clear that this will become a legal guillotine for those existing chemicals lacking such data. Such a measure is a vital component of any future legislative framework based on minimum precaution. Without such a firm foundation, the management of chemicals is currently based on a "suck-it-and-see" approach, rather than precaution. Furthermore, few chemicals will ever be "spat out" by such a system because even if epidemiologic studies do reveal increased incidences of certain diseases, it is almost impossible to obtain proof of cause-and-effect for any particular chemical. This is because of the widespread exposure to a vast array of chemicals, and the potential time delays between exposures and effects.

2. Take Account of the Needs and Acceptance of Risk Expressed by Society

Risk assessment of existing industrial chemicals in the EU is based on a comparison of the predicted exposure or predicted environmental concentration (PEC) with the predicted no-effect concentration (PNEC). If the PEC:PNEC ratio is less than 1, that is, the no effect concentration is not exceeded, then no risk reduction measure is required. This approach is an exercise in setting an acceptable level of exposure. This means that both man and the environment are considered to be able to tolerate, or assimilate, a certain degree of contamination.

This PEC–PNEC approach operates irrespective of the merits of the use of the substance. Yet arguably the level of protection that is acceptable will vary and will depend on the benefits that the product delivers to society. This introduces the concept of risk acceptability. For example, it can be assumed that the public would tolerate a higher level of risk from a substance used to make a false hip joint (which gave years of added mobility and where there was no suitable safer alternative) than they would from babies sucking on plastic soothers leaching phthalates (where safer alternatives exist). Thus, if societal "need" for a substance were low, then it could arguably be justified to impose a greater margin of safety.

This concept of risk acceptability also embraces the fact that higher risks are more acceptable if the risk is borne by the person who gains the benefit. The concept of protecting the innocent victim is particularly embodied in the desire to reduce the risks for babies and children. Public communication and public participation and cultural preferences are all important considerations in evaluating the acceptability of a risk.

The framework within which risk assessment currently operates takes no account of the values of the public, and furthermore, because it is such a technical exercise it excludes the public from participating in the decision-making process.

3. Aim to Achieve a High Level of Protection

The Commission should not be constrained to take precautionary action only when there is a known threat of almost cataclysmic proportions. Indeed, the Commission's Communication recognixes that the scope of the precautionary principle extends:

> . . . where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern

*It is estimated that somewhere between 20,000 and 70,000 "existing" chemicals are still on the market.

that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level or protection chosen by the EU.

This illustrates that the EU is at liberty to choose a high level of protection. Indeed, in certain circumstances, the EU can be seen to have already chosen a high level of protection. For example, in relation to the contamination of drinking water by pesticides, the permitted level was set at the limit of detection, as it was considered that pesticides should not be allowed to contaminate water sources, irrespective of their known toxicity. In the same way, high levels of protection, or "the goal of a clean environment" could be chosen with regard to man-made hazardous substances contaminating breast milk or the marine environment.

4. Ensure That the Least Risky Option is Chosen to Deliver the Goods or Service, and Give Preference to Risk Reduction through Substitution Rather than Emission Control

Comparative assessment. The framework within which risk assessment currently operates in the EU has led environmentalists to see it as a tool that leads to business as usual. The length of time it has taken to assess the risks of just a handful of chemicals is clearly unacceptable. Similarly, the high wall that has to be climbed to almost prove that a chemical is unsafe before significant control measures are imposed does not serve the public interest. For example, even for chemicals assigned high priority by the EU, it is not possible to be confident that current risk-assessment procedures, and hence regulatory actions based on a PEC:PNEC approach, will protect man and the environment. This is because there are many uncertainties about the long-term effects of exposures to chemicals and the interactive effects of exposures to cocktails of chemicals.

Underpinning the proposal that the precautionary principle should be an overarching guiding principle is the fact that risk assessment focuses more on evaluating a problem than on solving it. Comparative risk assessment should be part of this overarching principle as it provides a workable mechanism to facilitate a shift away from the use of the potentially most harmful chemicals, and reduce the risks to human health and the environment.

Take as an example the use of flame retardants in household goods. The need to reduce the risk of fire is clearly a societal need. However, the means by which this is achieved should be subjected to comparative assessment. The option of reducing the speed at which a fire takes hold by the use of flame-retardant chemicals should be weighed against the option of using less flammable construction materials, and the mandatory use of non-chemical alternatives such as sprinkler systems, fire escapes and smoke alarms.† If a chemical flame retardant were considered to be necessary, then comparative assessment would dictate that all the chemicals that could be used in that situation should have their benefits and risks assessed together and a comparison made, such that only the least risky options were used.

This system of comparative assessment would ensure that where there were less risky alternatives available, these would be used. The introduction of comparative assessment would therefore lead to positive lists of substances authorized or recommended for certain specified uses.

The principle of comparative assessment has recently been included in EU legislation on biocides.[3] It enables the prohibition of a biocide if there is another active substance on the market that is significantly less risky to health or to the environment. The Biocides Directive includes a number of conditions, for example, there has to be practical experience with the new alternative.

Within comparative assessment, the question is no longer "is this substance likely to cause harm to man or the environment," but is rephrased "given there is an accepted need—what is the best way (the least risky way) to serve this?"

Comparative assessment should, however, be used only to accelerate substitution for safer alternatives. The non-availability of alternatives should not delay implementing controls over a substance if the risk assessment of that substance concludes that predicted no-effect concentrations (PNECs) are likely to be exceeded.

Apart from having a place within the risk assessment of prioritized chemicals, comparative assessment, or the "substitution principle," should be included in general duties given to users or suppliers of chemicals. For example, in Swedish legislation, the Chemical Products Act gives a responsibility to companies to choose the least harmful chemical for a specific purpose and strive systematically to substitute less hazardous chemicals for hazardous ones. The widespread implementation of comparative assessment and the substitution principle would provide a means to drive down exposures to the lowest levels practicable, and would stimulate the innovation of greener, cleaner chemicals.

Comparative assessment and the substitution principle provide a clear, transparent, and rational way out of the current logjam that is apparent on both sides of the Atlantic, where many substances are under suspicion, but few are taken off the market, or even put under tighter controls.

5. Base the Quantification of Risk on Worst Case Assumptions

In order to take account of some of the uncertainties in

†In the United Kingdom in 1997 there were around 3,000 deaths per year resulting from the use of asbestos (House of Commons, FAQ Briefing, 28 April 1997). Furthermore, in 1995 it was estimated that there were up to a quarter of a million deaths still to come (The Economist, 25 February 1995). Therefore, it could be argued that more people could have been saved if alternative methods of fire prevention and life saving options had been used instead of asbestos.

the EU risk-assessment process, certain "safety" or "assessment" factors are incorporated into the method used to derive the PECs and PNECs. These are laid down in a Technical Guidance Document. However, at many stages in the risk-assessment process, there is room for expert judgement to play a part, and hence the outcome of the process is subjective.

Even a Working Paper drafted by the Commission's Industry Directorate acknowledges the uncertainties of risk assessment and underlines that conclusions may vary depending on the judgment of the person performing the exercise. It states:

> . . . uncertainties during any previous step strongly compromise the reliability of the last phase, the risk characterisation. The exercise does include many choices and judgements by the person performing it (e.g. selection of underlying data, models and assumptions).[4]

This highlights the need for a legal commitment that at any stage in a risk-assessment process, the assumption should be that reasonable worst case scenarios are included. Currently, the technical experts of the Member States of the EU, who are charged with the responsibility of assessing the environmental risks of high-priority existing industrial chemicals, do seem to be guided to a large extent by a desire to consider the worst case scenario. However, this is not written in stone and could change. Also, of course, these experts are still constrained by the framework in which risk assessment currently operates.

In summary, risk assessment seeks to provide science-based guidance to indicate when risk reduction is needed for individual substances, in particular applications. This guidance is based on several assumptions that should always respect an overarching precautionary principle.

APPLICATION OF THE PRECAUTIONARY PRINCIPLE AND POSSIBLE FUTURE TRADE WARS

One of the potential problems with regard to the implementation of the precautionary principle is how non-EU governments will react if the EU progresses in seeking to deliver a higher level of environmental protection for its citizens than that operating in other World Trade Organization (WTO) member countries. The precautionary principle should not be misused to create unjustified barriers to trade, but it would clearly be unacceptable if all countries had to be bound by the lowest standards of health and environmental protection. There are cultural differences, and some nationalities may be more risk averse, while others may opt for a more crisis-management approach. It is hoped that the EU will not be thwarted from finding a safer way of doing business by the threat of transAtlantic trade wars, and of being accused of disguised economic protectionism.

ACTION TAKEN UNDER THE PRECAUTIONARY PRINCIPLE SHOULD NOT BE SEEN AS ALWAYS POTENTIALLY TRANSITORY

The Commission's Communication suggests that measures imposed under the precautionary principle should be seen as potentially transitory. The Commission appears to have been influenced by the WTO Agreement on Sanitary and Phytosanitary Measures (SPS), which suggests that such measures should be temporary, although the precautionary principle itself is not explicitly referred to in this document. Article 5(7) of the SPS agreement states:

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

According to the SPS agreement, measures taken under the precautionary principle are transitional. However, they are not limited by time per se, but by the time taken to obtain additional information for a more objective assessment of the risk.

In some cases, the uncertainty about the threat of a particular substance may be due to a lack of data that can be obtained within a matter of months. In such cases, it is obviously right and proper for precautionary action to be taken temporarily. The requirement to consider new scientific information is consistent with the precautionary principle.

However, it should not be assumed that measures imposed under the precautionary principle are always potentially transitory. For example, it is the authors' view that elimination of exposures to biologically active, bioaccumulative, and/or persistent substances should be permanent, irrespective of their current known toxicities. This is because, given the diversity of species and the complexities of ecosystems, it will impossible to predict, from a few shorter-term tests on a few selected species, the effects of chronic exposure on all species. It would also be an enormous task to accurately determine the effects of concurrent exposures to the many bioaccumulating substances likely to be found as co-contaminants. Therefore, it would be both impractical and unethical to conduct the necessary number of tests to try to show beyond reasonable doubt the safety of a bioaccumulative and/or persistent compound. The possible subtle effects of a chemical on the functioning of the human central nervous system is also particularly difficult to predict from selected tests on animals with less developed brain

structures. In making decisions about whether or not precautionary measures should be deemed permanent, it should be remembered that within the EU, there is already legislation in place that seeks to reduce the numbers of animals used in toxicity testing.

Apart from the difficulties regarding extrapolation of tests to other species, it should also be recognized that it is impossible to test for effects that have not yet been conceived, and of which there is therefore a total ignorance, as was the case with the stratospheric ozone depletion. Furthermore, due to the very properties of persistence and bioaccumulation, if effects due to these substances do become evident, it will be impossible to remedy the situation in the short term. This provides a compelling argument for suggesting that precautionary action on persistent‡ and/or boaccumulative substances should be permanent.

Giving industry lead times to adapt to progressive tightening of controls over persistent and bioaccumulative substances will in many cases significantly reduce costs. This means that it is important to set down the direction of future regulation, because this in itself can lead to more cost-effective solutions. There are winners and losers, and if one chemical goes, a safer alternative will be found and new jobs created.

Many of the substances that have been controlled, such as TBT (tributyltin), the PCBs (polychlorinated biphenyls), and CFCs (chlorofluorocarbons), are bioaccumulative and/or persistent. However, it took many years for the increased sensitivities of some species, or their toxic effects at low levels, or their effects in general, to become apparent. There is a need to learn from these past mistakes, and to recognize that we cannot be confident that toxicity-testing regimens will necessarily predict all effects.

A Case Study: EU Action against a Breast Milk Contaminant

The recent EU decision to regulate penta brominated diphenyl ether (penta-BDE) created a landmark precedent, and further developed the accepted method for risk assessment of chemicals in the EU. Unfortunately, however, marketing restrictions may be only temporary.

Penta-BDE is persistent and bioaccumulative, and it can disrupt the normal functioning of the thyroid hormones,[5-7] which are responsible for brain development. It is used almost exclusively as a flame retardant in polyurethane foams, especially flexible foams used in cars. It is now found in the body fat of many aquatic animals, including dolphins, seals, sea birds, and whales of the open oceans. Penta-BDE and its breakdown product, tetra-BDE, are also found in mothers' breast milk, and a Swedish study shows that the levels of poly-BDEs increased sixfold in the 25 years up to 1997.[8]

‡Unless durability is a desired property (as may be the case for construction materials) and losses to the environment can not occur.

At the EU Technical Meetings in early 1999, experts of the Member States evaluated the data on penta-BDE. They agreed:

> . . . it has been detected, albeit at relatively low levels, in human breast milk, the levels increasing with time. [Furthermore] with the available information it is not possible to say whether or not on a scientific basis there is a current or future risk to human health. However, it would be of concern if by the time the future information has been gathered, the analysis indicated a risk to breast feeding infants.[12]

The technical experts therefore considered that there should be a political decision (taken by Competent Authorities [CAs]) as to whether or not there was an agreed need to reduce the risks from this substance without waiting for further research.

The need for a precautionary approach was finally agreed at the meeting of Competent Authorities in Helsinki on November 23–24, 1999. This was an important milestone, as it shows the implementation of the precautionary approach, and illustrates how the political machinery in EU is willing to respond to the knowledge that no mother on earth wants her breast milk to be contaminated with a man-made flame-retardant chemical. The current proposal is that there will be widespread marketing and use restrictions. However, in line with the Commission's paper on the precautionary principle, this action may be temporary. Thus, the minutes of the CA meeting illustrate that the conclusion was that further information was required, but that "because there was great concern on the unknown potential long-term effects on breast-fed infants, the CAs underlined the need to start Risk Reduction activities immediately."[10]

In contrast, the present authors believe that marketing restrictions should be deemed permanent, and no further information required. No amount of further testing can adequately predict the subtle effects that might result from the in-utero exposure to this chemical, particularly as this substance is persistent and bioaccumulative, and is able to affect brain development in animals.[11]

CONCLUSION

In conclusion, setting the precautionary principle as an overarching guiding principle and attempting to deliver a high level of protection is really just an admission that without some formalized framework to reduce risk, humans and wildlife may be sentenced to suboptimum health. By moving towards a system that has precaution at its heart it is possible to balance the dual societal expectations of a clean and healthy environment and access to technologic developments that increase quality of life.

The views expressed in this paper are personal views held at this point in time and should not be seen to be those of the WWF.

References

1. Commission of the European Communities. Communication from the Commission on the Precautionary Principle, 02.02.2000. COM (2000)1, Brussels, Belgium, 2000.
2. Allanou R, Hansen BG, van der Bilt Y. Public availability of data on EU high production volume chemicals. EUR 18996. European Chemicals Bureau, Italy, 1999.
3. Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. Official Journal of the European Communities. L123/1. 24.4.98.
4. European Commission. III.Doc97/RiMaO2. Belgium, Brussels, 1997.
5. Fowles JR, Fairbrother A, Baecher SL, Kerkvliet NI. Immunologic and endocrine effects of the flame-retardant pentabromodiphenyl ether (DE-71) in C57BL/6J mice. Toxicology. 1994;86:49–61.
6. Darnerud PO, Sinjari T. Effects of polybrominated diphenyl ethers (PBDEs) and polychlorinated biphenyls (PCBs) on thyroxine and TSH blood levels in rats and mice. In: Dioxin 1996, Organohalogen Compounds. 1996;29:316–9.
7. Olsson P-E, Borg B, Brunstrom B, Hakansson H, Klasson-Wehler E. Endocrine disrupting substances. Report 4859. ISBN 91-620-4859-7. Swedish Environmental Protection Agency, Stockholm, Sweden, 1998.
8. Meironyte D, Bergman A, Noren K, Analysis of polybrominated diphenyl ethers in human milk. In: Dioxin 1998, Organohalogen Compounds. 1998;35:387–90.
9. European Commission. Doc X1/14168/99. Brussels, Belgium, 1999.
10. European Commission. Doc ENV/800979/00. Brussels, Belgium, 2000.
11. Eriksson P, Jakobsson E, Fredriksson A. Developmental neurotoxicity of brominated flame-retardants, polybrominated dipheyl ethers and tetrabromo-bis-phenol A. In: Dioxin 1998, Organohalogen Compounds. 1998;35:375–7.

Precautionary Approaches to the Appraisal of Risk: A Case Study of a Genetically Modified Crop

ANDY STIRLING, PHD, SUE MAYER, PHD

There are strong scientific reasons for holding the broader scope of precautionary approaches to be more consistent with the scientific foundations of rational choice and probability theory than are conventional narrow risk-assessment techniques. The imperatives both of science and precaution can be seen to pull in the same direction. The regulatory appraisal of risk should become more systematic and broader in scope. In particular, a set of criteria can be developed concerning the need for greater humility, completeness, transparency, and participation in regulatory appraisal, with specific attention to the comparison of different options (including mixtures of options), the consideration of benefits and justifications, and the systematic "mapping" of the ways in which different framing assumptions lead to different pictures of performance. A case study of a pilot exercise applying a multi-criteria mapping method to the regulatory appraisal of a genetically modified crop is reported. The results are more complete than orthodox risk assessment, in that they embody consideration of an unlimited array of issues and include consideration of a wide range of different strategic alternatives to the use of GM technologies. It is concluded that conventional regulatory appraisal might be adapted to better address the imperatives of both science and precaution. *Key words*: precautionary principle; risk assessment; probability theory; regulatory appraisal; genetically modified crops; multi-criteria mapping.

INT J OCCUP ENVIRON HEALTH 2000;6:296–311

The precautionary principle is an increasingly prominent theme in the debate over technologic risk. Many questions are raised over the implications for policy making. In particular, concerns have been expressed over the relationship between precautionary and more traditional science-based approaches to decision making such as cost–benefit and risk analyses. Fears are sometimes raised that—unlike risk assessment—a precautionary approach is too ambiguous and impractical to serve as a basis for real decision making, that it is somehow antagonistic to science, and even that it threatens to stifle technologic innovation and economic growth.

The first part of this article takes a close look at some of the key practical and theoretical issues bearing on the relationship between 'science' and 'precaution' in the management of technologic risk. It is found that—far from being in tension—these two concepts are entirely consistent and even mutually reinforcing. The real distinction is found to lie between narrow risk-based concepts of regulatory appraisal and broader precautionary approaches. A series of eight criteria are developed against which appraisal techniques can be evaluated in terms both of their scientific and their precautionary validity.

The second part of the article reports on a recent pilot exercise that attempted to apply these criteria to the specific case of the regulatory appraisal of a genetically modified (GM) crop. The main features of the new multi-criteria mapping method are outlined. Key findings are reported, with particular attention to the extent to which the method conforms to a set of scientific and precautionary quality criteria.

SCOPE AND COMPLEXITY OF ENVIRONMENTAL AND HEALTH RISKS

Risk is a complex concept. Even under the most narrowly defined of quantitative approaches, it is recognized that risk is a function of at least two variables—the *likelihood* of an impact and its *magnitude*. However, it is only very rarely the case that a series of technology, policy, or investment options is seen to present only one form of hazard. Normally, the characterization of risks associated with any individual option requires the consideration of a wide variety of disparate risks. In the energy sector, for example, risks can take forms including greenhouse gas emissions, radioactive wastes, heavy metals, persistent organic pollutants, soil erosion, thermal discharges, ambient noise, ecologic disturbance, or aesthetic intrusion in the landscape. All of these risks manifest in different ways, with different physical, biologic, social, cultural, and economic connotations.[1]

The conventional analytic response to this breadth and diversity of issues in regulatory appraisal is to identify a single major yardstick of performance and seek to measure all the various aspects of risk using this as a metric. The chosen unit of measurement in conventional

Received from SPRU—Science and Technology Policy Research, University of Sussex, Brighton, East Sussex, United Kingdom (AS); and GeneWatch UK, Tideswell, Buxton, Derbyshire, United Kingdom (SM).

Address correspondence and reprint requests to: Andy Stirling, PhD, SPRU, Mantell Building, University of Sussex, Brighton, BN1 9RF, United Kingdom.

risk assessment is usually human mortality or morbidity rates. In some areas, the techniques of cost–benefit analysis are employed in seeking to subject a wider range of impacts to measurement under a common monetary metric and so allow comparison with the associated benefits. It is hoped that in this way the multiplicity of magnitudes typically confronted in the regulation of environmental and health risk may usefully be reduced to a single key factor, thus apparently simplifying the process of appraisal. This process of reduction is an essential element in what is sometimes described as a science-based approach to the regulatory appraisal of risk.

Of course, one crucial consequence of this artificial narrowing and conflation of the full diversity of technologic risks is effectively to exclude from consideration many classes of effects. For instance, it is clear that only a minority of the types of energy risks mentioned above is meaningfully addressed by a mortality, morbidity, or even a monetary metric. Moreover, even with respect to the single issue of human health, risk is an inherently multidimensional concept. For instance, are exposures voluntary or controllable? Do they manifest as disease, injuries, or deaths? How familiar are the risks? How immediately are they realized and how reversible once identified? To what extent are they concentrated in large events or dispersed in small routine incidents? How are they distributed across space, time, and society? Mortality, and even morbidity, indices fail to capture these important contextual features.[2]

Beyond this, further scope for divergent approaches to regulatory appraisal lies in the characteristics of the assessment process itself. Should appraisal take account of social, economic, cultural, and ethical issues, as well as environmental and health factors? With respect to the more narrowly defined physical factors, to what extent should appraisal seek to address the potential additive, cumulative, synergistic, and indirect effects associated with particular environmental and health risks? With how wide an array of potential alternatives should each individual technologic or policy option be compared in appraisal? Should attention be confined simply to the *operation* of the options concerned, or should it extend to the manufacture, decommissioning, and disposal of plant, as well as to the various inputs (such as energy and materials) and associated risks at each stage? To what extent should the relative *benefits* of different options be taken into account in appraisal so that they can be offset against the associated risks?

In an ideal world, the appropriate response to factors such as these is easy to determine. All else being equal, the regulatory appraisal of risk should be as *complete* and as *comprehensive* as possible. However, aspirations to completeness concerning the different classes and dimensions of risk and benefit and comprehensiveness concerning the different types of options provide only a rather loose operational guidance in the practical regulation of risk. Moreover, even were appraisal to be fully complete and comprehensive, in some hypothetical sense, then there would still remain the problem of how the different aspects of risk should be framed and prioritized in analysis. For instance, what assumptions should be made about adherence to best practice in the various activities under appraisal? What relative *priorities* should be attached to different effects such as toxicity, carcinogenicity, allergenicity, occupational safety, biodiversity, and ecologic integrity? What weight should properly be placed on impacts on different groups, such as workers, children, pregnant and breastfeeding mothers, future generations, disadvantaged communities, foreigners, those who do not benefit from the technology in question, or even animals and plants as beings in their own right? Even if they were practically feasible, objectives such as completeness and comprehensiveness do not assist in addressing issues of framing and prioritization of this kind. No one set of assumptions or priorities may be claimed to be uniquely rational, complete, or comprehensive.

It is here that we come to a classic and well-explored dilemma in the field of social choice theory, but one that is frequently forgotten in risk assessment and regulatory appraisal. The disciplines of risk assessment, economics and decision analysis have developed no single definitive way of addressing the problems of comparing apples and oranges. Even the most optimistic of proponents of rational choice acknowledge that there is no effective way to compare the intensities of preferences displayed by different individuals or social groups.[3] Indeed, even where social choices are addressed simply in relative terms, the economist Kenneth Arrow went a long way towards earning his Nobel Prize by demonstrating formally that it is *impossible* definitively to combine relative preference orderings in a plural society.[4]

Put simply, the point is that it takes all sorts to make a world. Different cultural communities, political constituencies, or economic interests typically attach different degrees of importance to the different aspects of environmental risk and look at them differently. Within the bounds defined by the domain of plural social discourse, no one set of values or framings can definitively be ruled more rational or well informed than can any other. Even were there to be complete certainty in the quantification of all the various classes and dimensions of risk, it is entirely reasonable that fundamentally different conclusions over environmental risk might be drawn under different—but equally legitimate—perspectives. It is a matter of the science of risk assessment itself, then, that *there can be no analytic fix for the scope, complexity, and intrinsic subjectivity of environmental and health risks.* The notion that there can be a single unambiguous "science based" prescription in the regulatory appraisal of risk is not only naïve and misleading; it is a fundamental contradiction in terms.

THE DEPTHS OF INCERTITUDE

This problem may seem serious enough. Unfortunately,

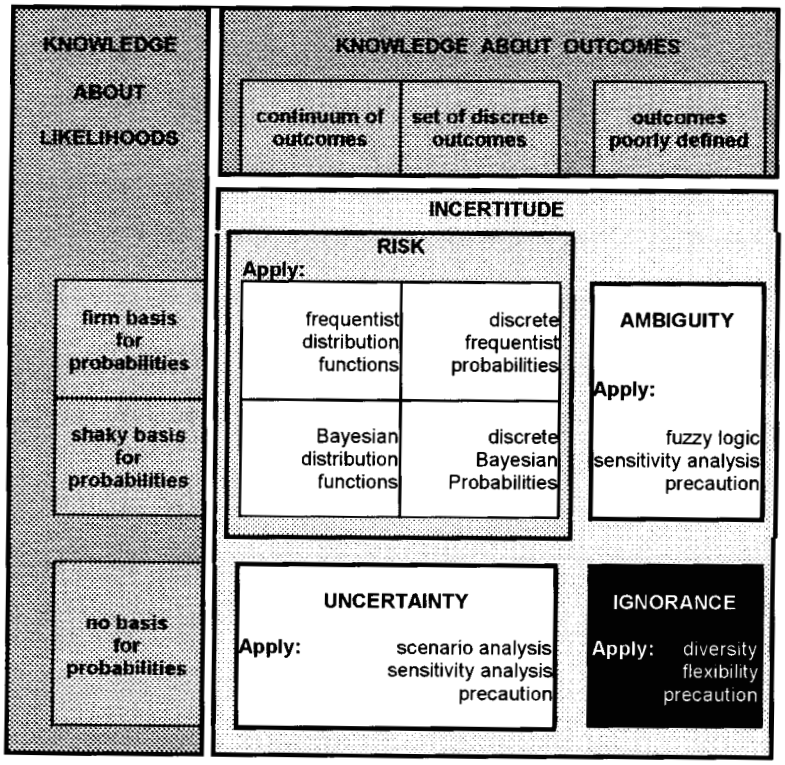

Figure 1—The formal definitions of risk, uncertainty, ambiguity, and ignorance.

the difficulties encountered in the regulatory appraisal of risk are even more intractable than this. Thus far we have considered only the issues associated with the characterization of the magnitude aspects of risk. What of the likelihoods? Here we come upon some profound limitations to the applicability and robustness of probabilistic approaches that are as seriously neglected in regulatory appraisal as are the difficulties discussed above concerning the comparison of magnitudes.

In economics and decision analysis, the well-established formal definition of *risk* is that it is a condition under which it is possible both to define a comprehensive set of all possible outcomes *and* to resolve a discrete set of probabilities (or a density function) across this array of outcomes. This is illustrated in the top left corner of the diagram in Figure 1. This is the domain under which the various probabilistic techniques of risk assessment are applicable, permitting (in theory) the full characterization and ordering of the different options under appraisal. There are a host of details relating to this picture (such as those hinging on the distinction between frequentist and Bayesian understandings of probability), but none of these alters the formal scientific definition of the concept of risk.[5-7]

The strict sense of the term *uncertainty*, by contrast, applies to a condition under which there is confidence in the completeness of the defined set of outcomes, but where there is acknowledged to exist no valid theoretical or empirical basis confidently to assign probabilities to these outcomes. This is found in the lower left corner of Figure 1. Here, the analytic armory is less well developed, with the various sorts of scenario analysis being the best that can usually be managed.[8] While the different options under appraisal may still be broadly characterized, they cannot be ranked even in relative terms without some knowledge of the relative likelihoods of the different outcomes.

Both risk and uncertainty, in the strict senses of these terms, require that the different possible outcomes be clearly characterizable and subject to measurement. The discussion in the previous section has already made it clear that this is often not the case—the complexity and scope of the different forms of environmental risk and the different ways of framing and prioritizing these can all too easily render *ambiguous* the definitive characterization of outcomes. This may be so even where there is relatively high confidence in understandings of the likelihood that at least some form of impact will take place (top right corner of Figure 1). An illustrative example here might be the prospects for regional climatic, ecologic and socioeconomic impacts arising from the human-enhanced greenhouse effect.

Where these problems are combined with the difficulties in applying the concept of probability, we face a condition that is formally defined as *ignorance* (bottom right corner of Figure 1).[9-13] This applies in circumstances where there not only exists no basis for the assigning of probabilities (as under uncertainty), but where the definition of a complete set of outcomes is also problematic. In short, recognition of the condition of ignorance is an acknowledgement of the possibility of surprises. Under such circumstances, not only is it impossible definitively to rank the different options, but even their full characterization is

difficult. Under a state of ignorance (in this strict sense), it is always possible that there are effects (outcomes) that have been entirely excluded from consideration.

Figure 1 provides a schematic summary of the relationships between these formal definitions for the concepts of risk, uncertainty, ambiguity, and ignorance. It is quite normal, even in specialist discussion, for the full breadth and depth of these issues to be rolled into the simple concept of 'risk' (and sometimes 'uncertainty'), thus seriously understating the difficulties involved. In order to avoid confusion between the strict definitions of the terms risk and uncertainty as used here and the looser colloquial usages, the term 'incertitude' is used to cover all four subordinate conditions. Either way, it is not difficult to see that it is the formal concepts of ignorance, ambiguity, and uncertainty—rather than mere risk—that best describe the salient features of regulatory decision making in areas such as energy technologies, toxic chemicals, and genetically modified organisms. Indeed, many of the most high-profile technologically-induced "risks" of recent years—such as stratospheric ozone depletion, endocrine-disrupting chemicals, and BSE, for instance—are all cases where the problem lay not so much in the determination of likelihoods, but in the anticipation of the very possibilities. They were surprises!

The crucial point is that intractable uncertainties, ambiguities, and ignorance are routinely treated in the regulatory appraisal of technology simply by using the probabilistic techniques of risk assessment. This treatment of uncertainty and ignorance as if they were mere risk effectively amounts to what the economist Hayek dubbed (in his Nobel acceptance speech) "pretence at knowledge."[14] Far from displaying a respect for science in regulatory appraisal, the effect of such scientistic oversimplification is actually to ignore and undermine the scientific principles on which risk assessment itself purports to be based. Given the manifest inapplicability—in their own terms—of probabilistic techniques under uncertainty and ignorance, this is a serious and remarkable error. The self-contradictions in aspirations to a "science based" approach reliant solely on quantitative risk assessment, already noted in the last section, are thus further underscored and reinforced.

PRACTICAL CONSEQUENCES FOR RISK ASSESSMENT

The problems discussed so far—the multidimensionality of environmental and health risks and the conditions of uncertainty, ambiguity, and ignorance—may all seem a little abstract and theoretical. It is perhaps also partly for this reason that they remain relatively neglected in the business of regulatory appraisal. Unfortunately, however, they have some important practical consequences that, though often concealed, hold profound implications for the interpretation of orthodox risk-assessment results in all fields, extending from the regulation of energy options through chemicals and industrial hazards to genetic modification technologies.

In all these areas, the typical response to these difficulties in regulatory appraisal is to reduce and simplify—focussing on those aspects that are either the most tractable or the most reasonable under certain dominant perspectives. In this way, individual studies can construct a picture of environmental risks, which appears to be quite unambiguous and precise. The scale of the discrepancies becomes evident only on occasions when attention is extended to a series of different appraisal studies, all applying subtly different—but equally "reasonable" and "legitimate"—framing assumptions concerning the different dimensions of appraisal discussed here. When this takes place, it becomes clear that the apparent relative riskiness of different options can vary quite radically, depending on the framings and priorities attached to the hidden variables during the process of appraisal.

Figure 2 illustrates this by showing the results obtained in 32 large-scale risk assessments of eight different energy technologies conducted in industrialized countries over the past two decades. Here, environmental and health effects are characterized using the techniques of cost–benefit analysis as monetary external costs expressed in standardized form per unit of electricity production.[2] This case is taken as an example because both the techniques employed, and this particular field of application, might arguably be seen as being among the most mature and intensively explored areas of application of comparative risk assessment. The picture is not specific to these techniques or this field. A similar pattern may be found in a variety of other regulatory fields, including transport, toxic chemicals, and food safety. The same pattern is also evident in the underlying physical and mortality indices on which these monetary results are based. A number of salient features can be seen.

First, individual studies present their results with great precision—often as a single value rather than a range and sometimes expressed with as many as four significant figures (one part in ten thousand). Yet, the variability in the results obtained in the literature as a whole for any one option is radically larger. For instance, the uppermost values of the highest range assessing the risks associated with coal power amount to the equivalent of some 20 dollars per kilowatt-hour of electricity production. The lowest values of the bottom range in Figure 2 are less than four hundredths of a cent per kilowatt-hour. The difference is more than four orders of magnitude—a factor of more than fifty thousand! Detailed analysis of the reasons for these discrepancies show that they do not arise as a result of any single factor. It is not a simple matter of some studies' being more accurate or reasonable than others in any definitive sense. Instead, the variability is the cumulative consequence of the adoption of divergent assumptions and priorities concerning the whole range of the different dimensions of appraisal identified in the preceding sections.[2]

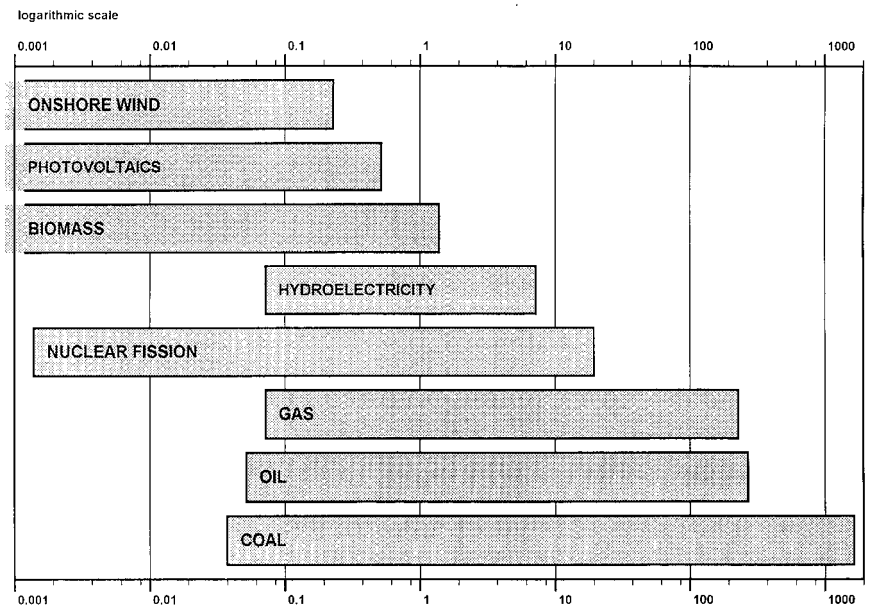

Figure 2—Variability in technologic risk assessments (an example from energy technologies): stated external environmental cost (bars represent range over a variety of studies). 1995 c/kWh.

The second crucial feature that is illustrated in Figure 2 concerns the ambiguities in the ordering of the different options under appraisal. The lowest values obtained for the worst-ranking option (coal) are lower than the highest values obtained for the apparently best-ranking option (wind). Since the effect of the particular assumptions adopted in individual studies is to produce results at the high end of the overall range for some options but lower in the distributions for others, the overall picture yielded by the literature as a whole would accommodate virtually any conceivable ranking order for these eight options! By the judicious choice of framing assumptions, then, radically different conclusions can be justified for regulation.

This evident disjuncture between precision and accuracy in supposedly science based risk assessment paints a rather negative picture. One of the first and most basic tasks in the management of risk is to construct some robust overall notion of the relative merits of the different options under consideration from the point of view of society as a whole. This then serves as a basis for regulatory intervention, market-based measures or investment initiatives. Where this cannot be achieved in any absolute (or even relatively robust) sense, then the value of appraisal lies in systematic exploration of the relationships between different assumptions in analysis and the associated pictures of the relative importance of different options. Where aspirations to the science based appraisal of risk lead to the assertion of the intrinsic authority of narrow risk-assessment procedures, then these crucial exogenous factors typically remain unacknowledged and unexplored. In this event, the problem is not simply one of a lack of rigor concerning the theoretical contradictions noted in the previous sections. The difficulties are also very concrete and pragmatic. For, without a robust appreciation of the assumptions under which appraisal yields differing pictures of performance, serious questions must be raised over whether the associated results—no matter how confidently and precisely expressed—are of any practical policy use at all.

"SCIENCE" AND "PRECAUTION" IN THE REGULATORY APPRAISAL OF ENVIRONMENTAL RISK

It is with increasing realization of these practical and theoretical limitations to the value of orthodox risk assessment in regulatory appraisal that interest in complementary and alternative approaches is growing. In particular, the precautionary principle is becoming an ever-more-prominent feature of the regulatory debate on environmental risks and of national and international legislation.[15-17] A precautionary approach acknowledges the difficulties in risk assessment by granting greater benefit of the doubt to the environment and to public health than to the activities that may be held to threaten these things. A host of different practical instruments and measures are variously proposed in different contexts as embodiments of a precautionary approach or as means to implement a precautionary principle. For present purposes, attention will concentrate on the way in which a precautionary approach offers a direct response to the practical and theoretical problems in regulatory appraisal that have been discussed so far.

One key theme in the debate on these matters surrounds the frequent assertion (and sometimes assumption) that—whatever form it takes—a precautionary approach to the management of environmental risk is somehow in tension with (or even antithetical to) the generally uncontroversial aspiration that regulatory decision making should be based on sound science. Of course, this does not address the extent to which orthodox "scien-

tific" approaches such as comparative risk assessment may themselves be claimed to yield sound results. The thrust of the discussion thus far has been to raise serious doubts over this. Nevertheless, the important question remains as to what exactly the relationship between so-called science-based and precautionary approaches to the regulation of environmental risk is?

A necessary starting point for this analysis is a clear characterization of exactly what is meant by "science" and "precaution" in the context of decision making relative to environmental risk. Drawing on a wide literature, Figure 3 displays some idealized attributes of scientific approaches to regulatory appraisal.[18] A scientific approach to the management of risk should, ideally and at minimum, be *transparent* in its argumentation and substantiation, *systematic* in its analytic methods, *sceptical* in its treatment of knowledge claims, subject to *peer review*, *independent* from special interests, professionally *accountable,* and continually open to *learning* in the face of new knowledge. These aspirations may not always be realized, but they represent fundamental, and relatively uncontroversial, principles guiding any "science-based" approach to regulatory appraisal.

Likewise, it is possible broadly to characterize the essential features of a precautionary approach to the management of risk. A precautionary approach involves the application of principles that *prevention is better than cure*, that *the polluter should pay*, that options offering simultaneously better economic and environmental performance should always be preferred (*no regrets*), that options should be appraised at the level of *production systems* taken as a whole and that attention should be extended to the intrinsic value of non-human life in its own right (a '*biocentric ethic*'). In effect, this means a certain *humility* about scientific knowledge and an acknowledgement of the *complexity* and *variability* of the real world. It implies recognition of the *vulnerability* of the natural environment and living organisms and the prioritizing of the *rights* of those who stand to be adversely affected. It requires scrutiny of claims to *benefits* and *justifications* as well as risks and costs, with full account given to the available *alternatives*. Finally, a precautionary approach involves the adoption of *long-term, holistic, and inclusive* perspectives in regulatory appraisal.[19]

In many ways, these attributes of a precautionary approach concern different aspects of the *breadth* of the regulatory appraisal process. A broad regimen is one that takes account of a wide range of different types of impacts, including qualitative as well as quantitative issues; including indirect as well as direct effects; accommodating a diverse array of different points of view (including, importantly, those of potential victims); and anticipating a wide range of possibilities in the face of uncertainty and ignorance. It extends consideration to

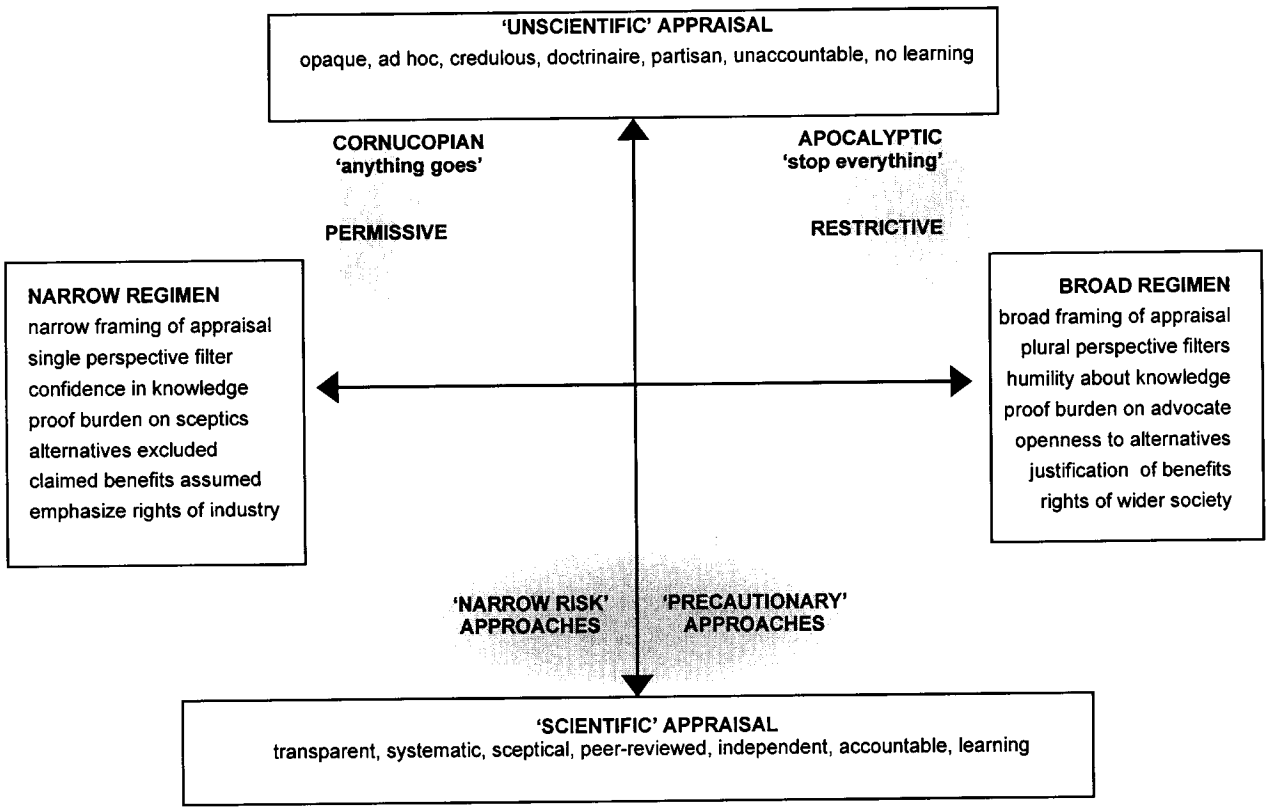

Figure 3—Model of the relationships between risk, science, and precaution.

the benefits and justifications associated with the introduction of the technology in question and examines a variety of alternative ways in which the benefits of a regulated technology might be realized at lower levels of risk. Taken together, these features constitute a more precautionary approach because they increase the number and intensity of the constraints that any technologic option must satisfy in order to be approved by the regulatory process, thus making it more difficult for certain innovations to pass through the regulatory "filter." At the same time, however, such measures might equally serve to encourage other technologic innovations that might otherwise remain neglected.

What is interesting about this characterization of precaution in terms of the breadth of the associated regulatory regimen, is that it reveals a consistent—and in many respects complementary—relationship between precaution and science in the management of technologic risk. Figure 3 distinguishes between different approaches to risk management based on the degree to which each embodies the respective characteristics of 'scientific appraisal' and 'breadth of framing' identified here.

Although the broad/narrow and the scientific/unscientific dichotomies drawn here are highly stylized and simplified, the general picture revealed in Figure 3 is at least richer and more realistic than the prevailing one-dimensional dichotomy between science and precaution. The combination of these two dichotomies generates a fourfold array of idealized permutations. The adoption of a "narrow" regimen without reference to scientific understandings or disciplines in appraisal might be described as a *permissive* position. Taken to an extreme, this would amount to an entirely uncritical anything-goes approach to the regulation of technology of the kind associated with caricature 'cornucopian' visions of technologic progress. Likewise, a broad-based regimen might be similarly unscientific. The resulting *restrictive* position might be associated with a caricature 'apocalyptic' vision of technology. In the extreme, it would lead to a situation of paralysis under which no new technologic innovation that offends in the slightest respect would ever be approved for deployment. The crucial point is that neither the permissive (cornucopian) nor the restrictive (apocalyptic) position as defined here would be subject to challenge or reversal by the disciplines of scientific discourse associated with the vertical axis.

It is clear that neither the established procedures of risk regulation (based on relatively narrowly framed risk-assessment methods) nor the emerging precautionary approach (based on broader perspectives and considerations) actually resemble these stylized permissive or restrictive caricatures. Existing risk-assessment–based regulation includes a host of effective checks and balances. It certainly does not necessarily provide for the uncritical approval of any new technology that may be developed. Likewise, even the most progressive formulations of a precautionary principle are circumscribed in their scope, admit an incremental series of instruments, and allow for regulatory approval under a host of favorable conditions. Both approaches are compatible—at least in principle—with the requirements of systematic method, scepticism, transparency, accountability, quality control by peer review, professional independence, and an emphasis on learning, which are held here for the purposes of this discussion to be among the key aspirations of a science-based approach.

It is at this point that it is useful to return to the earlier discussion of the profound importance of the conditions of uncertainty, ignorance and multidimensionality in risk assessment. It is shown in earlier sections of this article that questions over the scope of appraisal, the plurality of different value positions and framing assumptions, the diversity of different anticipated possibilities, and the degree of confidence placed in the available knowledge are all matters that are central to the scientific status of the appraisal process. As was shown, it flows directly from the theoretical foundations of risk assessment, cost–benefit analysis (and, indeed, all 'rational choice' approaches to decision making on risk) that probabilistic approaches are inapplicable under strict uncertainty and ignorance. It also follows equally directly from these fundamental theoretical principles that different priorities, framing assumptions, and value systems cannot be definitively aggregated across different groups. For both these reasons, it is clear that there can be no analytic fix for the definitive ranking of different technology or policy options in the social appraisal of risk. All that can be done to maximize scientific rigor in appraisal is to ensure that the process is as broadly framed as possible in terms of the value systems and framing assumptions that are included and the options and possibilities that are addressed. Seen in this way, then, key elements of the breadth of the regulatory regimen themselves become issues of sound science in the management of environmental risk, as well as institutional features of the wider regulatory regimen. Precaution, in this sense, is not just entirely consistent with science—it is a necessary prerequisite for as truly scientific approach to the regulatory appraisal of risk.[18]

IMPLEMENTING A PRECAUTIONARY APPROACH TO APPRAISAL

In the discussion so far, environmental and health risks have been treated at a high level of generalization. Of course, it is obvious that at a greater level of detail, different technologic and policy options will vary radically in the magnitude and character of the risks that they present. Likewise, the ranges of different possible regulatory interventions do not fall neatly into permissive or restrictive categories, but lie along a series of continuums, and range between being more and less precautionary in their effects. With respect to both precautionary and other approaches to the regulation of risk, then,

different measures will be appropriate in different contexts. This general picture is the subject of a vast literature.[15-18,20] Here, however, the purpose is to focus specifically on some key implications for regulatory appraisal.

It is possible to construct a series of eight evaluative criteria against which the regulatory appraisal of risk can be assessed in terms of both its scientific rigour and its precautionary qualities.[18]

- *Humility*. Maintain a culture of humility in the face of the many sources of uncertainty, ignorance, and subjectivity in appraisal. Avoid claims to complete or otherwise definitive knowledge.
- *Completeness*. Broaden the scope of the regulatory appraisal of technologic risk to address cumulative, additive, complex, synergistic, and indirect effects as well as more direct causal processes.
- *Benefits and justifications*. Include systematic consideration of the claimed benefits and justifications as well as adverse effects, in order to allow determination of net benefits under different contexts.
- *Comparison*. Conduct appraisal on a comparative rather than a case-by-case basis, including account of a variety of technologic and policy options and the cumulative effects across different cases.
- *Participation*. Ensure full engagement by all interested and affected parties, both to elicit all relevant knowledge and to include consideration of all pertinent priorities and framing assumptions.
- *Mapping*. Express appraisal results not as discrete numerical values, but using sensitivity analysis systematically to map the consequences of different value judgments and framing assumptions.
- *Transparency*. Use the most straightforward of methods. Minimize the number of hidden variables. Provide for detailed auditing of how particular results derive from particular inputs.
- *Diversity*. Extend appraisal to address the ways that diverse mixes of different options may help to hedge against uncertainty and ignorance and help accommodate divergent social perspectives.

These are the considerations that have informed the development of the multi-criteria mapping technique employed in the present case study.[21,22] The motivation behind this approach is to seek to combine the openness and qualitative flexibility of participatory deliberation with the clarity and focus of quantitative assessment. The specific case study with which this method has been piloted concerns the hotly contested debate over the use of genetically modified (GN) crops in U.K. agriculture.

THE UK DEBATE OVER THE REGULATION OF GENETICALLY MODIFIED CROPS

The agricultural use of GM technologies is held in some quarters to promise great benefits. On the other hand, there is general agreement that there exists at least the potential for serious, irreversible harm. In the United Kingdom, formal regulatory appraisal of GM crops has centered on the question of whether or not they are safe for the environment and for human consumption. However, there is considerable scientific incertitude over the form and magnitudes of the possible effects and, as yet (by contrast with chemical or nuclear risks), little accumulated practical experience to draw upon. This has led to the evolution of a set of controls that are intended to be precautionary in nature—where it is accepted that action to avoid harm may be taken in the absence of scientific proof—with the conduct of risk assessment being required *before* experimental or commercial use of a particular genetically modified organism is allowed.

Despite this somewhat precautionary approach to risk regulation enshrined in the European Commission's Deliberate Release Directive (90/220/EC) and the Novel Foods Regulation, the regulatory appraisal process has failed to gain confidence, either of nongovernmental organizations (NGOs), private industry,[23] or the general public.[24,25] This lack of confidence arises, among other reasons: because the scope of the regulatory appraisal is still held in many quarters to be too narrow; because there is a general lack of trust in official reassurances of safety (particularly in the wake of BSE); and because justifications and benefits are not explicitly included in the evaluation process. Industry and regulators have expressed frustration, believing that the precautionary approach is being invoked in too burdensome a fashion, with unrealistic demands being made concerning absolute proof of safety.

It has also been almost impossible to gain agreement between European Member States over whether particular commercial releases of GM crops are environmentally safe, despite a supposedly common approach to their risk assessment.[26,27] Disputes routinely emerge over the appropriate scope of regulatory appraisal. Even where there is agreement over the possibility that effects will occur, notions of what constitute *adverse* effects remain strongly contested.

These sorts of problems with the current regulatory appraisal of GM crops are typical of those that beset the use of conventional risk assessment and cost–benefit analyses in other areas. Taken together, these characteristics of the U.K. debate over the application of GM technologies in agriculture make it a challenging candidate for a case study concerning the application of the general principles of scientific and precautionary appraisal enunciated above.

THE MULTI-CRITERIA MAPPING PILOT STUDY

The details of the multi-criteria mapping method and this particular application in the GM field in the United Kingdom are described at length elsewhere.[22,27] Only those features bearing on the examination of the quality

TABLE 1 The Definitions of the "Basic Options" Appraised by All Participants in the Pilot Study

Option	Definition
Organic agriculture	All farming and food production conducted under present-day organic standards
Integrated pest management	All farming and food production conducted using systems designed to limit but not exclude chemical inputs and with greater emphasis on biologic control systems than conventional systems
Conventional agriculture	All farming and food production conducted under present-day intensive systems
GM* oilseed rape with segregation and present systems of labeling	Labeling based on the presence of foreign DNA or protein in the final product
GM* oilseed rape with post-release monitoring	Monitoring for effects (mainly environmental) conducted on an ongoing basis after commercialization.
GM* oilseed rape with voluntary controls on areas of cultivation	Areas of growing of GM oilseed rape restricted on a voluntary basis to avoid unwanted effects such as gene-flow and cross fertilization of non-GM crops
Up to six additional options to be specified by participant	Any option of participant's choice, including combinations of the above if desired

*Genetically modified.

criteria given above are outlined here. The pilot study took place between April 1998 and September 1999. It was funded by the transnational food firm Unilever, but was entirely independent in its conception, design, implementation, and reporting. The two authors come from an academic and NGO background, and the project was overseen by a steering group comprising a wide range of environmental, consumer, farming, and food industry representatives. The specific topic chosen for the study was the production of oilseed rape in the United Kingdom. Six basic options were identified in advance for the purposes of comparison (Table 1).

In consultation with the steering group, 12 individual high-profile protagonists in the GM food debate were selected as participants. These individuals came from a variety of backgrounds, including academics and government regulators, environmental, consumer, and religious organizations, and representatives from the farming, food, and biotechnology industries. Of course, it is impossible to claim any statistically representative status for such a small sample. However, care was taken that, between them, the group of participants covered a full envelope of specialist and sociopolitical perspectives—ranging, for instance, from strongly opposed to strongly in favor of the use of GM crops. Given the character of the U.K. GM debate at the time of the study (1998–99), it was necessary to give undertakings of anonymity in order to secure participants' involvement. However, the viewpoints of the participants are reproduced individually, each being identified by a code letter and an affiliation with one of four general groupings of perspectives: academic, NGO, industry or 'government' (Table 2).

TABLE 2 The Participants in the Pilot Study

Area	Code*
Agriculture and food industry	B, L, H, K
Academic scientists	C, J
Government safety advisors	E, F
Religious and public interest groups	A, D, G, I

*Each letter represents an individual participant.

During a two-to-three-hour individual interview, each participant undertook a four-stage process: 1) the identification of additional options; 2) the defining of appraisal criteria under which the options should be assessed; 3) the scoring of the performance of each option under each criterion; and 4) the weighting of each criterion in terms of its relative importance. A straightforward linear additive multi-criteria procedure (Figure 4) was employed using a simple spreadsheet model mounted on a portable computer in order to display to the participant the results of the scoring and weighting process as it developed. The process then iterated cyclically until the participant was satisfied that the results accurately reflected his or her own personal perspective and professional judgment relative to the issues at hand.

One crucial feature of the scoring process was the deliberate eliciting of a range of performance scores for each option under each criterion. Rather than providing a single best guess, this allowed consideration of a range of optimistic and pessimistic assumptions under each perspective. The discussion of the associated issues was then carefully documented and provided an interesting reflection of the importance of technical uncertainties in the final picture of performance derived under each perspective.

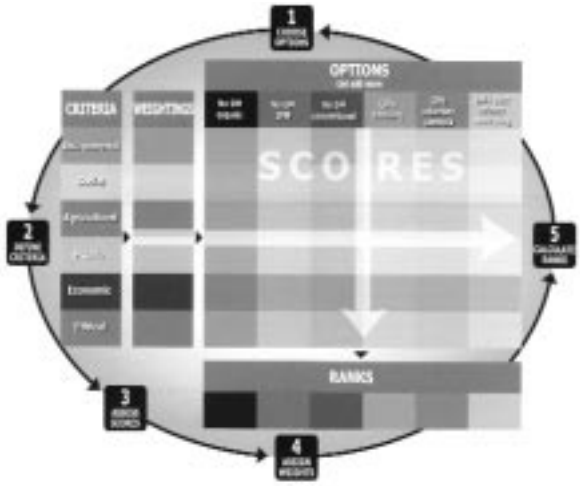

Figure 4—The multi-criteria mapping process.

In the period following the interviews, the participants were contacted and asked to consider the role of deliberate diversification among options as a means to implement two crucial features of the precautionary approach discussed above: the desire to hedge against intractable uncertainties and ignorance and to accommodate a variety of sociopolitical viewpoints. For this purpose, a simple index of diversity was borrowed from mathematical ecology and information theory in order to model different tradeoffs between the value attached to the performance of individual options and the value attached to diversity in the mix of options. The details of this method are described in more detail elsewhere.[21,22,29] In short, participants can choose to assign a zero, low, medium or high weighting to diversity. Where it takes a zero value, then only the best-performing option is included in the favored mix. Where higher weightings are placed on diversity, progressively greater contributions are included from lower-performing options—drawn on in proportion to their relative performances under the perspective in question. In this way, the study was able to elicit a crude notion of the importance of ignorance and pluralism under the different perspectives.

As analysis proceeded, the participants were asked to review the results of a thorough sensitivity analysis conducted on their own sets of weightings. Along with an invitation that participants retain the spreadsheet model and freely experiment with it at their leisure, this provided a further means to verify that the final results represented a robust reflection of the different viewpoints. Finally, all participants were invited to a concluding workshop, at which the results were again confirmed and used as a basis for wider-ranging discussion.

FINDINGS

The procedure summarized above generated a rich body of empirical material, reflecting a very wide range of issues bearing on the regulatory appraisal of GM technologies in agriculture. This is reported in more detail elsewhere,[22,28] but the key points can be summarized here.

TABLE 3 Additional Options Defined by the Participants

Labelling and/or other controls	
GM crops with segregation, full labeling and post-release monitoring and legally binding growing contracts	A*
GM crops with segregation, current labeling and post-release monitoring	F
GM crops with segregation, full labeling and post-release monitoring	H
GM crops with segregation and labeling according to means of production and source of gene, plus post-release monitoring	G
GM crops with segregation, comprehensive labeling based on process and generic restrictions on some classes, e.g., in center of origin	I
GM crops within controlled sectors (compulsory control)	A
GM crops with legally binding threshold for gene transfer to non-GM stream	A
Agricultural system	
GM crops, IPM system	G
GM crops, IPM system	J
No GM crops—conventional and organic as now	K
GM crops in conventional and organic systems	K
GM crops, organic agricultural system, plus segregation, labeling and other regulations as required	J
Assessment criteria	
GM crops with quality	B
GM crops with assessment of indirect agricultural impact and assessment of need	I
Other	
GM crops only in USA	A
No GM commodity crops	A
Complete public control over choice	C

*Letters represent individual participants (see Table 2).

TABLE 4 Broad Groupings of Criteria Defined by the Participants

Environment	
	Biodiversity, e.g., field boundary ecology, other environmental risks
	Chemical use, e.g., reduction in use of existing herbicide sprays, benefits of contact herbicides versus soil-acting residuals, longer-term pollution of air and water
	Genetic pollution, e.g., gene flow to other crops and native flora
	Wildlife effects, e.g., Impact of enhanced weed-control efficiency on wildlife, other practices affecting wildlife value of agricultural systems
	Unexpected effects, e.g., potential for effects not foreseen under this scheme
	Visual, e.g., amenity impacts
	Aesthetics, e.g., feelings about environment
Health	
	Allergenicity, e.g., from food consumption
	Toxicity, e.g., human or animal health
	Nutrition, e.g., to consumers
	Unexpected effects, e.g., unexpected interactions between ingredients, stability of genetic insert
	Ability to manage , e.g., traceablility and ease of recall
Agriculture	
	Weed control, e.g., invasive volunteers and weedy relatives
	Food supply stability, e.g., sustainability, tendency to monocultures, global food security
	Agricultural practice, e.g., farmers' rights, choice and quality of life, land requirements
Economy	
	Consumer benefit, e.g., retail price
	Producers' benefit, e.g., shorter-term costs, yield or longer-term value added
	Benefit to processor, e.g., profitability
	Socioeconomic impact , e.g., welfare of small farmers, substitutions for developing countries
Society	
	Individual impacts, e.g., consumer choice, transparency, accessibility, participation, pluralism
	Institutional impacts, e.g., concentration of power, institutional trust, regulatory complexity
	Social needs, e.g., new opportunities, opportunity costs, misuse of science, employment, quality of life
Ethics	
	Fundamental principles , e.g., animal welfare, taking care of nature
	Knowledge base, e.g., hubris about scientific knowledge

Options

In addition to the six basic options, a further 18 alternative agricultural strategies were identified and evaluated by participants. These included many different labeling and control regimens and the application of a series of different regulatory assessment procedures and criteria. They also involved a variety of different agricultural strategies, including a focus on hypothetical strategies using GM technologies under an organic farming regimen. Interestingly these tended to perform relatively well under the perspectives of participants from both sides of the GM debate (Table 3).

Criteria

A total of 117 appraisal criteria were defined by different participants. Although some of these are apparently closely related, all embody important differences of emphasis or framing. It is interesting that the criteria typically reflect not only issues of consumer choice but also issues of citizenship and wider questions of participation and agency. Collectively they cover a very wide range of considerations, including environmental, agricultural, health, economic, social, and ethical issues. Most of these issues are very remote from the factors included in orthodox risk assessment. Indeed, for no participant was it true that the full range of his or her concerns is fully addressed by existing regulatory appraisal procedures in the United Kingdom (Table 4).

Performance Scores

The pattern of the performance scores assigned by the participants under the various groups of criteria shows that the differences between perspectives are not simply due to variations in the weightings placed on different criteria. Instead, the picture yielded in this exercise is very similar to that illustrated above with respect to risk assessment of energy technologies (Figure 3). The participants adopted a variety of different framing assumptions, resulting in significant differences in the scores assigned by different participants under the same criteria. This has implications for conventional multi-criteria analysis, in which scoring is often conducted by a separate body of experts, with an assumption that different value judgments can be captured simply in the weightings. Despite these differences, however, the patterns evi-

dent in the scoring do allow certain general conclusions. For instance, under all perspectives the organic option tended to perform well under environmental criteria. Also, the evident divergence between the patterns of performance under health and environmental criteria challenges conventional assumptions that these aspects of performance will *necessarily* be well correlated.

Weightings

Notwithstanding the complications raised above with respect to scoring, the patterns evident in the weightings do illuminate some interesting, if rather unsurprising, features. Perspectives drawn from the biotechnology industry and food supply chain are conspicuous in their relative underemphasis of the social and/or environmental and safety considerations that are prominent under all other perspectives. The perspectives adopted by government advisers have the distinctive characteristic of being at the same time relatively narrow in scope while emphasizing environmental and safety considerations. The perspectives expressed by the non-industry participants share a markedly lower emphasis on economic or agricultural considerations.

Rankings

Perhaps the most important output of the multi-criteria mapping procedure is the patterns in the final rankings obtained under the various participants' perspectives. Indeed, it is this picture that constitutes the "map" referred to in the name of the technique, reflecting the way that final results vary with starting assumptions. Figure 5 displays the results obtained in the present exercise for the ten participants from whom it was possible to elicit all the necessary quantitative inputs (the remaining two expressed difficulties either with the scoring or with the weighting process). Each chart represents the rankings elicited from a single participant. The sequence of basic options is the same in each case, running left to right from organic farming through integrated pest management and conventional intensive agriculture to GM crops with (respectively) segregation and labeling, monitoring, and voluntary controls. The height of each vertical bar reflects the overall performance of the option under that perspective—the higher the bar the better the performance. The scale is in arbitrary subjective linear units of performance. Each option is represented by a pair of bars, with the left bar expressing the ranking of that option under pessimistic assumptions and the right bar expressing the ranking under optimistic assumptions. The pessimistic and optimistic scales have been normalized in order more clearly to show the relative orderings.

A number of features can be distinguished in this picture. First, it is clear that there exist profound differences between the practical implications of the perspectives adopted by different participants. In an orthodox regulatory appraisal procedure (such as risk assessment) such variability would typically be concealed by the emphasis on a single aggregated position. In the present analysis, on the other hand, the idiosyncrasies of each individual position are clearly displayed. Second, it is clear that the differences between rankings obtained under optimistic and pessimistic scores are generally rather small compared with the differences between perspectives. This suggests that it is not generally the technical dimensions of uncertainty that are the key issue, but rather more intangible qualitative aspects concerning the divergent interests, values, and framing assumptions adopted by different participants. Third, despite the variability in the evaluations of different participants, there emerges a series of consistencies. With only a few exceptions, the organic option tended to perform relatively well. Conventional intensive agriculture tended to perform uniformly badly. The voluntary-controls regimen for GM crops was regarded rather poorly by industry, academic, and NGO participants alike, being viewed favorably only by the government advisers.

Diversity

The final issue concerns the merits of diversification. Figure 6 shows the diverse mixes of agricultural strategies that were favored by the seven participants who responded to this part of the analysis. The partitioning of the pie charts represents some arbitrary measure of importance, such as "share of output" or "share of land in production." For present purposes, the details do not affect the broad-brush conclusions. What is interesting is that six of these participants—drawn from all sides of the debate—favored the deliberate pursuit of some degree of diversity. The remaining participant—a senior U.K. government safety adviser—displays a uniquely high degree of confidence in the validity and robustness of his own perspective. Together with the idiosyncrasies evident in the rankings displayed in Figure 5, this is, in itself, an informative result. Taken as a whole, this part of the multi-criteria mapping analysis might be taken to raise questions over the extent to which R&D and regulatory policy making should be geared towards active encouragement of a variety of techniques rather than assuming or emphasizing a single particular trajectory. Given the broad support expressed from all sides of the debate for the principle of diversity, questions might also be raised over how to treat options that display characteristics that militate against diversity.

In summary, this pilot multi-criteria mapping exercise permits a series of quite subtle and specific observations to be made concerning the character of the debate and the positions of the different protagonists. However, it also provides a basis for some general normative conclusions concerning the options under appraisal. These findings are all the more robust for being set firmly in the context of systematic exploration and acknowledgement

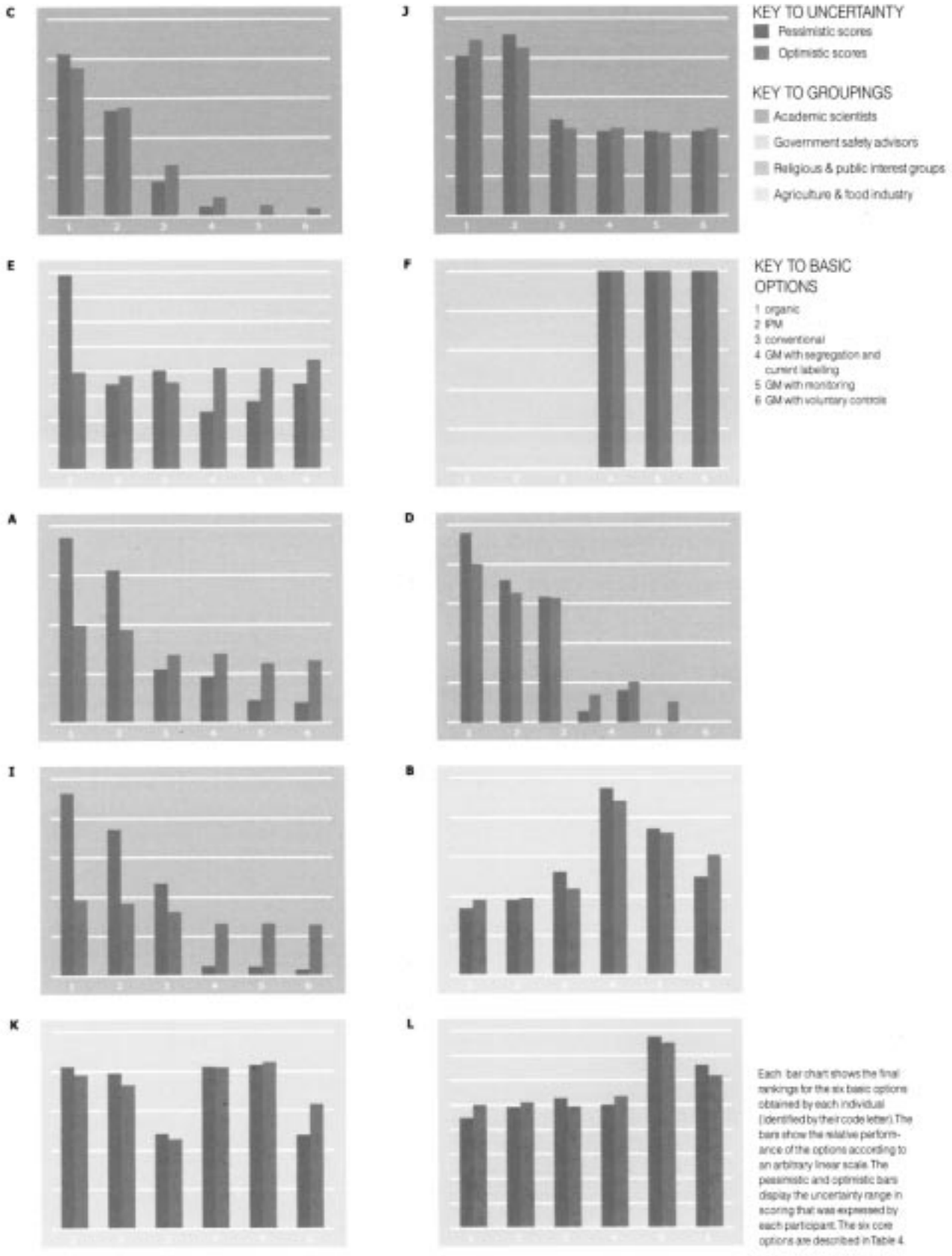

Figure 5—Final rankings for the basic options under the perspectives of individual participants.

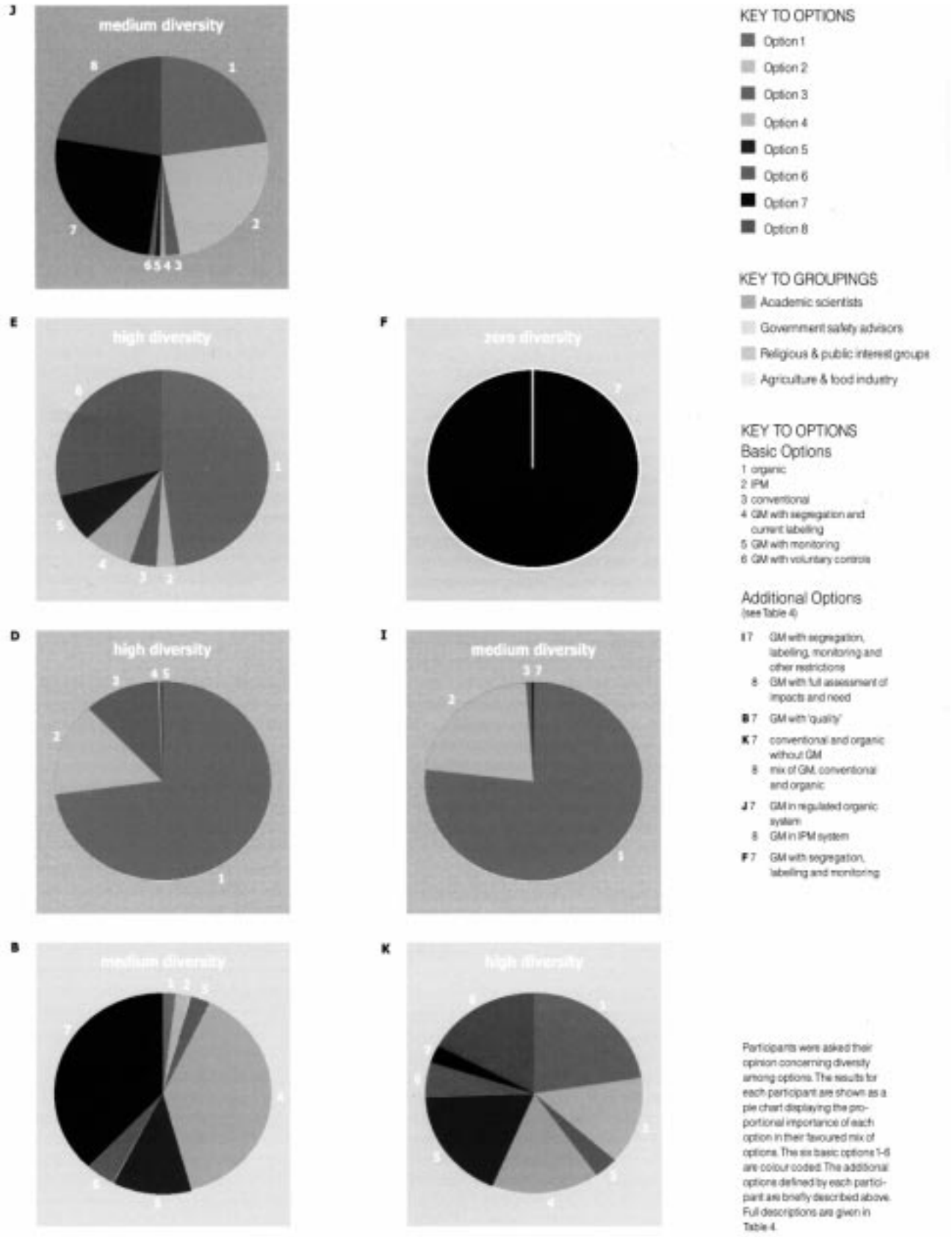

Figure 6—Diverse mixes of options favored by individual participants.

of the underlying variability and dissent. In particular, in the present case, the picture is quite unequivocal with respect to the relatively negative performances of conventional intensive farming and voluntary controls on the use of GM crops. If equal attention is paid to each perspective, then it is clear that the organic-farming and integrated-pest-management options tended to perform significantly better overall.

CONCLUSIONS

This article shows significant theoretical, methodologic, and practical grounds for concern over the utility of orthodox narrow risk-assessment techniques in the regulatory appraisal of risk. The frequently cited dichotomy between science-based and precautionary approaches to regulatory appraisal is shown to be unfounded and misleading. Indeed, there exist strong scientific reasons for holding the broader scope of precautionary approaches to be *more* consistent with the scientific foundations of rational choice and probability theory than are conventional narrow risk assessment techniques. The imperatives both of science and precaution can therefore be seen to pull in the same direction. The regulatory appraisal of risk should become more systematic and broader in scope. In particular, a set of criteria can be developed concerning the need for greater humility, completeness, transparency, and participation in regulatory appraisal, with specific attention to the comparison of different options (including mixtures of options), the consideration of benefits and justifications, and the systematic "mapping" of the ways in which different framing assumptions lead to different pictures of performance.

In order to explore how these criteria might be practically operational, the second part of the article examines as a case study a pilot exercise applying a novel multi-criteria mapping method to the regulatory appraisal of a genetically modified (GM) crop. The results of this exercise are more complete than orthodox risk assessment, in that they embody consideration of an unlimited array of issues. They also include consideration of a wide range of different strategic alternatives to the use of GM technologies. The same attention is given to the justifications and benefits as to the impacts and costs associated with the various options. The appraisal is inherently participatory, in that the results fully reflect the perspectives of a wide range of different socioeconomic and cultural interests. The relative simplicity and auditability of the weighting and scoring approach retain a high degree of transparency. A central feature is the focus on the systematic mapping of the way in which specific results relate to specific assumptions in appraisal. This, together with the explicit attention given to more diverse mixes of options, embodies a greater degree of humility in the face of ignorance and pluralism than is normally seen in risk assessment.

In this way, it may be concluded that there seems no reason in principle why conventional regulatory appraisal might not be adapted to better address the imperatives of both science and precaution. The present pilot exercise was not prohibitive in scale, being conducted by two researchers over a period of 18 months. Although necessarily provisional, the consistencies displayed in the results show that it is possible—despite the breadth of the process—to draw some quite robust conclusions over the relative performances of options such as organic farming, conventional intensive agriculture, and voluntary control regimens for the use of GM crops. Although the techniques of risk assessment continue to offer essential tools in addressing specific aspects, there seems to be no compelling theoretical, methodologic or practical reason for persisting in basing the entire business of regulatory appraisal on these inherently constrained and limited methods.

References

1. European Commission. Externe: Externalities of Energy. Vol 1–6, EUR 16520 - 16525 EN, Brussels, Belgium, 1995.
2. Stirling A. Limits to the value of external costs. Energy Policy. 1997; 25:5.
3. Bezembinder T. Social choice theory and practice. In: Vlek C, Cvetkovitch G. Social Decision Methodology for Technological Projects. Dordrecht, The Netherlands: Kluwer, 1989.
4. Arrow K. Social Choice and Individual Values. New Haven, CT: Yale University Press, 1963.
5. Knight F. Risk, Uncertainty and Profit. Boston, MA: Houghton Mifflin, 1921.
6. Luce R, Raiffa H. Games and Decisions. New York: Wiley, 1957.
7. Morgan M, Henrion M, Small M. Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis. Cambridge, U.K.: Cambridge University Press, 1990.
8. Funtowicz S, Ravetz J. Uncertainty and Quality in Science for Policy. Amsterdam, The Netherlands: Kluwer, 1990
9. Loasby B. Choice, Complexity and Ignorance: An Inquiry into Economic Theory and the Practice of Decision Making. Cambridge, U.K.: Cambridge University Press, 1976.
10. Smithson M. Ignorance and Uncertainty: Emerging Paradigms. New York: Springer, 1989.
11. Wynne B. Uncertainty and environmental learning: reconceiving science and policy in the preventive paradigm. Global Environmental Change. 1992; 111–27.
12. Faber M, Proops J. Evolution, Time, Production and the Environment. Berlin, Germany: Springer, 1994.
13. Stirling A. Risk at a Turning Point?, J Risk Res. 1998;1:97–110.
14. von Hayek F. New Studies in Philosophy, Politics, Economics and the History of Ideas. Chicago, IL: University of Chicago Press, 1978.
15. O'Riordan T, Cameron J. Interpreting the Precautionary Principle. London, U.K.: Earthscan, 1993.
16. Harding R, Fisher E. Perspectives on the Precautionary Principle. Anandale, CA: Federation Press, 1999.
17. Raffensberger C, Tickner J. Protecting Public Health and the Environment: Implementing the Precautionary Principle. New York: Island Press, 1999.
18. Stirling A. On Science and Precaution in the Management of Technological Risk: Vol 1—a synthesis report of case studies. Institute for Prospective Technology Studies. Sevilla, Spain, EUR 19056 EN, 1999.
19. Stirling A. On Precautionary and Science Based Approaches to Risk Assessment and Environmental Appraisal. Vol 2. Institute for Prospective Technology Studies. Sevilla, Spain, 1999.
20. Renn O, Klinke A. Risk Evaluation and Risk Management for Institutional and Regulatory Policy., Vol 2. Sevilla, Spain: Institute for Prospective Technology Studies, 1999.
21. Stirling A. Multicriteria mapping: mitigating the problems of environmental valuation? In Foster J (ed). Valuing Nature: Economics, Ethics and Environment. London, U.K.: Routledge, 1997.

22. Stirling A, Mayer S. Rethinking Risk: A Pilot Multi-criteria Mapping of a Genetically Modified Crop in Agricultural Systems in the UK. Sussex, U.S.: SPRU, 1999.
23. Mayer Sm Hill J, Grove-White R, Wynne B. Uncertainty, precaution and decision making: the release of genetically modified organisms into the environment. Global Environmental Change Programme Briefings Number 8. Global Environmental Change Programme: University of Sussex, Brighton, East Sussex, U.K., 1996.
24. Biotechnology and the European Public Concerted Action Group. Europe ambivalent on biotechnology. Nature. 1997;387:845–7.
25. Grove-White R, Macnaghton P, Mayer S, Wynne B. Uncertain World. Genetically Modified Organisms, Food and Public Attitudes in Britain. Centre for the Study of Environmental Change, Lancaster University, United Kingdom, 1997: Lancaster, 64 pp.
26. Von Schomberg R. An Appraisal of the Working in Practice of Directive 90/220/EEC on the Deliberate Release of Genetically Modified Organisms. STOA, European Parliament, Luxembourg, Belgium, 1998.
27. Wynne B, Mayer S. The Release of Genetically Modified Organisms to the Environment. In: EU 98. European Environment Agency, Copenhagen, Denmark, 1999 (in press)
28. Stirling A. Mayer S. Forthcoming, 2000.
29. Stirling A. Diversity and ignorance in electricity supply investment: addressing the solution rather than the problem. Energy Policy. 1994; 22, 3.

Risk Assessment in a Third-world Reality: An Endosulfan Case History

ROMEO F. QUIJANO, MD

The author describes the chain of frustrated attempts to regulate the use of the toxic pesticide endosulfan in the Philippines in the face of opposition from its internationally powerful manufacturer. Risk assessment, although purportedly a science-based system to protect public health and the environment, has failed to do so, particularly in vulnerable third-world countries. The precautionary principle, based on preventing risk rather than assessing established risk, holds hope for resolution of the problem. *Key words*: toxic pesticides; Philippines; legislation; corporate influence; public health; international corporations.

INT J OCCUP ENVIRON HEALTH 2000;6:312–317

Since the early 1980s, risk assessment has been the basis of environmental and health risk management in most countries of the world. Basically, risk assessment is the process by which scientific data are analyzed to describe the characteristics of the likelihood of harm to humans and the environment. It involves four main areas of analysis:

1. hazard identification—to determine whether the available scientific data describe a causal relationship between a chemical product and demonstrated injury to human health or the environment;
2. dose–response relationship—to establish the quantitative relationship between exposure and response where adverse health or environmental effects have been observed;
3. exposure analysis—to identify and characterize exposure in potentially exposed populations; and
4. risk characterization—to fully describe the expected risk by examining the exposure predictions taking into account the dose–response and other relevant information.

Ostensibly, the main objective of risk assessment is to establish a science-based evaluation system that would protect public health and the environment while at the same time providing access to potentially harmful chemical products.

Real-world experience, however, reveals that the risk-assessment process has failed to protect public health and the environment, especially in third-world countries, where financial, technical, human, and other resources are sorely lacking and where sociopolitical circumstances are conducive for powerful chemical companies to exert influence and manipulate the market. In fact, risk assessments have been used to legitimize the sale of largely unnecessary pesticides and have facilitated public misinformation regarding the real risks people face when exposed to these toxic chemicals. The case history of endosulfan in the Philippines, a developing country, is an illustrative example of the reality that risk assessment, as currently practiced, is not workable and is easily distorted and manipulated by powerful chemical manufacturers.

ENDOSULFAN REGISTRATION

Endosulfan was first made available for use in most countries in the 1950s, when risk assessment, or any safety evaluation procedure for that matter, as a requirement for pesticide registration was not yet in place. In the Philippines, even at the time that the Fertilizer and Pesticide Authority (FPA) was created in 1977, endosulfan was registered with the assumption of safety without any rigorous evaluation of potential risks. In the early 1980s, risk assessment began to be considered in pesticide regulation, coinciding with the establishment of the Pesticide Technical Advisory Committee (PTAC) to the FPA. When the "Dirty Dozen" campaign was launched internationally by nongovernmental organizations led by the Pesticide Action Network International, risk assessment became the basis for the banning of most "Dirty Dozen" pesticides in the Philippines, although it was probably more to the credit of a determined senior medical toxicologist–pediatrician on the technical committee that the risk-assessment process successfully led to the banning of the said pesticides.

Sometime in 1990, endosulfan was noticed to have become the most frequent cause of death among pesticide-related poisoning cases reported to National Poison Control Center established by the lone medical expert sitting on the PTAC. A review of endosulfan was undertaken by the toxicology subcommittee of PTAC using the same risk-assessment principle used in evaluating the "Dirty Dozen" pesticides. As a result, the FPA ordered a ban on endosulfan 35%, allowing only the 5% formulation, and severely restricted its use. Immediately, Hoechst, the major manufacturer of endosulfan, took the

Received from the Department of Pharmacology and toxicology, College of Medicine, U.P. Manila, Philippines.

Address correspondence and reprint requests to Dr. Quijano.

FPA to court and was able to obtain an injunction (on procedural grounds) that allowed it to continue selling endosulfan 35%. In April 1993, Hoechst slapped a lawsuit of more than US $800,000 on a medical pharmacologist–toxicologist for reportedly stating in a conference that "thiodan [trade name of endosulfan] causes cancer," as quoted in three major newspapers. The feature service and the journalist who wrote the story were also sued. At the same time, Hoechst also sought out and confronted the female farmer who had testified in the conference about the harmful effects of a Hoechst pesticide product. The confrontation left the farmer frightened. In September 1993, the FPA issued a new order reiterating the ban and restriction on endosulfan, together with four other highly toxic pesticides. Again Hoechst vigorously contested the order through a restraining order from a judge who was later exposed to have a close relationship with the company's lawyer. The company exerted every effort to negate the ban order, including seeking the intervention of the President, warning of serious and undesirable consequences with respect to the government policy of attracting foreign investors, and instructing its dealers not to cooperate with the FPA in its effort to obtain a market inventory of the endosulfan products. In January 1994, the Philippine Supreme Court ordered the suspension of the proceedings at the Regional Trial Court, effectively lifting the restraining order against the ban on endosulfan. Hoechst continued to advertise Thiodan without mentioning restrictions on the use of the pesticide and without warning of adverse effects. The FPA found the ad to be "false, misleading and deceptive" and ordered the company to stop the ad. Subsequently, the ban took effect in June 1994.

An exemption to the ban of endosulfan 35%, however, was granted on a temporary basis by the FPA for use in growing pineapples, under supposedly strict monitoring guidelines. Recent information reveals that these guidelines were wantonly violated with impunity, and extension of temporary use has been granted without reasonable justification. It was also observed that although the use of endosulfan has been dramatically reduced, continued use has been reported and documented in various parts of the country, particularly in Mindanao. The explanation was that endosulfan was probably coming in from the "back door," but there is suspicion from knowledgeable sources that the supply was probably coming also from the excess inventory of stocks at the time of the effectivity of the ban. The post-ban inventory has never been accounted for properly.

HEALTH RISKS

Despite clear evidence that endosulfan was presenting significant risks to human health and safety, especially under conditions of use in third-world countries. Hoechst has been claiming that "Consumer safety (was) proven" and that endosulfan was "a relatively safe, effective, user-beneficial insect and environment friendly pesticide."[1] This claim is utterly false and grossly dishonest. Several studies and review documents from different sources consistently show that endosulfan is highly poisonous and easily causes death and severe acute and chronic toxicity to various organ systems, including mental impairment, neurologic disturbances, immunotoxicity, reproductive toxicity, maternal and developmental toxicity, liver and kidney damage, cardiac disorder, blood disorder, respiratory depression, skin irritation, and many others.[2,3] In addition, endosulfan has been reported to be an endocrine disruptor.[4,5] In the Philippines, endosulfan accounted for the largest number of deaths due to pesticide poisonings reported to the National Poisons Control and Information Center in 1991[6] and continued to be one of the most common causes of pesticide poisonings until it was banned. The company makes much use of the document "Endosulfan 91-115 JMPR 1989"[7] published by the WHO, claiming that the document "clearly and categorically stated that endosulfan has no indication whatsoever for causing cancer."[1] Again, this claim is patently false. The carcinogenicity studies reviewed were in fact limited by inadequate reporting and survival and, therefore, no valid conclusion of no effect can be derived from them.[8] Looking at the raw data of the carcinogenicity studies submitted by the company, there is in fact valid reason to suggest that endosulfan is carcinogenic. For example, one study showed high incidences of lymphosarcoma in both the control group and the endosulfan exposed group.[9] Although there was no statistically significant difference between the two groups, the high incidence of lymphosarcoma by itself gives a warning that endosulfan possibly causes cancer of the lymphatic system and that the similarly high incidence of the disease in the control group is highly unusual and could have been the result of a methodologic error resulting in undue exposure of the control group also to the carcinogenic agent. Furthermore, other studies show that endosulfan can cause cancer. For example, one study[10] showed that endosulfan was carcinogenic in male and female rats at all sites examined. It also induced liver tumors in female mice. Another study[11] found that endosulfan promoted the growth of altered hepatic foci in rats in a way similar to the action of the structurally related chlorinated insecticides chlordane, aldrin, and heptachlor, indicating that endosulfan is a potential liver-tumor promoter.

The company also claims that endosulfan is nonmutagenic and nongenotoxic based on the negative findings indicated by the company-sponsored studies. The 1989 WHO document[7] echoed these negative findings, which became the basis of subsequent erroneous characterization in various publications that endosulfan was non-genotoxic. However, several independent studies have shown that endosulfan is genotoxic. Data from in-vitro and in-vivo mutagenicity studies generally provide evidence that endosulfan is mutagenic, is clastogenic, and induces effects on cell-cycle kinetics. For example,

endosulfan was found to be mutagenic in various assay systems, including the Ames test, the micronucleus test, and the yeast gene conversion test.[12-14] Endosulfan was also found to cause chromosomal aberrations in hamster and mouse, sex-linked recessive mutations in Drosophilia, and dominant lethal mutations in mice.[15,16] Studies in human cells both in vitro and in vivo also showed that endosulfan caused the occurrence of sister chromatid exchanges, indicating chromosomal damage.[17,18] Very recently, a team of researchers in Japan found further evidence of endosulfan genotoxicity using sister chromatid exchanges, micronuclei, and DNA-strand breaks as detected by single-cell gel electrophoresis as biomarkers.[19]

Another issue that has not been given due attention is the inappropriate hazard classification of endosulfan by the WHO. The WHO has classified endosulfan as a Class II or "moderately hazardous" pesticide based mainly on the LD_{50} value taken from company-generated acute toxicity data. However, closer examination of available data, including data from independent sources, clearly shows that endosulfan should belong to at least Class Ib, the "highly hazardous" category, since most of the LD_{50} values fall within the Class Ib category range and other acute toxicity data[3] clearly indicate that endosulfan's acute toxicity profile is comparable to or even worse than the toxicity profiles of other pesticides in Class Ib. In fact, the European Union has classified endosulfan as a Class Ib[8] pesticide in its labeling requirements, and the U.S. Environmental Protection Agency (EPA) has also classified endosulfan as highly toxic and has listed endosulfan on the Extremely Hazardous Substances List under the Environmental Standards.[20] Using the criteria recommended by the WHO itself[7] in classifying pesticides, endosulfan should have been classified as Class Ib. It appears that the WHO technical committee gave more weight to company-generated data and apparently ignored independent data. Given the fact that the chemical industry actively lobbies international bodies and these bodies at times have been shown to be influenced by the chemical industry, it is quite possible that the erroneous classification of endosulfan was a result of chemical industry lobbying.

It is worth noting that the studies reviewed in the document "Endosulfan 91-115 JMPR 1989," often cited by Hoechst as its basis for claiming the innocuousness of endosulfan, were the submissions of the company itself, and there was hardly any independent study included in the review. In addition, many of the studies commissioned by Hoechst were found (1983) to have been performed by Industrial Biotest (IBT), of Chicago, which was convicted for fraudulent practices, including fabrication of data that became partly or wholly the basis of approval of endosulfan in many countries. As late as the early 1990s, Hoechst was still submitting data obtained from IBT to the Philippine pesticide regulatory agency when the company was required to submit scientific data for the purpose of risk-assessment review by the Pesticide Technical Advisory Committee.

ENVIRONMENTAL RISKS

Endosulfan is extremely toxic to aquatic life, particularly fish. Endosulfan can cause fish kills even when used at recommended application rates. In august 1995, runoff from cotton fields contaminated with endosulfan resulted in the death of more than 240,000 fish along a 25-km stretch of a river in Alabama. Investigations showed that the pesticide had been sprayed according to label instructions. In the Sudan, in 1988, barrels washed in irrigation canals caused fish death. Three people died after drinking water from the canal.[21]

Bioaccumulation of endosulfan and the metabolite endosulfan sulfate is significant in aquatic species. Combined residues had been found to have concentrated after 96 hours from 81–245× to as much as 1,000–1,344× in grass shrimp, pinfish, spot, and striped mullet. After 28 days, the combined residues had concentrated 2,249× in edible tissues and 2,755× in whole fish. Endosulfan also accumulated 600× in the pelecypod Mytilus edulis after 50 hours. There was also slight concentration in two species of mussels exposed to the chemical for 36 days.[22-24]

In a report by the IPCS, endosulfan was considered of moderate to low toxicity to honeybees and was only moderately toxic to birds, particularly mallard ducks and ring-necked pheasants.[25] However, the National Wildlife Federation (U.S.) states that endosulfan is extremely toxic to wildlife and acutely toxic to bees. It also warns that birds feeding in treated areas could be killed.[26] The Danish government also classified endosulfan as acutely toxic to birds, with an LD_{50} of 28–42 mg/kg.[27]

Some toxic effects of endosulfan on plants have also been reported. It was found that endosulfan changed the permeability of root membranes, resulting in coiling of the root radical, inhibition of root growth, stunting of shoots, and burning of the tips and margin of leaves.[25] Endosulfan has also been found to be toxic to a wide variety of microorganisms. Some reports have indicated that endosulfan affects the membrane components of the yeast Rhodotorula Endosulfan was also found to reduce the productivity in a natural phytoplankton community by 86.6% during a four-hour exposure, and has been reported to be one of the organochlorines most toxic to soil algae, actinomycetes, and bacterial colonies.[25]

Endosulfan is also highly persistent in soil. In one study, it was found that the half-life of alpha endosulfan was about 60 days and that of beta endosulfan was about 800 days after incorporation of technical endosulfan into soil at 6.7 kg/ha.[28] In another study, when 0.38 ppm of endosulfan was applied to Colorado soil, it was found that 0.04 ppm remained after three years.[29] Other studies done under varying soil conditions showed persistence profiles ranging from 42 days to 100 days, with percentage recoveries ranging from 17% to 54% for alpha

endosulfan and 65% to 91% for beta endosulfan.[30] It must be noted that the persistence of toxicity is actually longer, since the major degradation product, endosulfan sulfate, is as toxic as the parent compound.[2]

When released to water, alpha endosulfan was found to have a degradation half-life of 35.4 days to 150.6 days and beta endosulfan, 37.5 days to 187.3 days at pH 7 and pH 5.5, respectively.[31] Endosulfan has been found in surface water outside the spraying season. A survey of 11 agricultural watersheds located in Southern Ontario revealed that endosulfan, together with atrazine and simazine, persisted long enough to appear in water throughout the year. In 14% of water samples, endosulfan levels exceeded the water-quality criteria established by the International Joint Commission for the Great Lakes.[32] Endosulfan also persisted in groundwater at deep soil layers in concentrations ranging from 0.009 μg/L to 0.053 μg/L up to 20 days after last spraying.[33] The potential for endosulfan to contaminate groundwater was also demonstrated by a study on pesticide residues in selected well waters in major rice-producing areas in the Philippines, wherein endosulfan residue levels ranged from 0.002 μg/L to 0.03 μg/L.[34]

Volatization of endosulfan is expected to be significant. Endosulfan was detected in 2.11% of ambient air samples obtained from 14 states (U.S.) in 1970 and from 16 states in 1971–72, with a mean concentration of 111.9 ng/m^3 (with a maximum of 2,256.6 ng/m^3) for alpha endosulfan.[35] Endosulfan can be transported over long distances in air. Samples of precipitation collected in the Great Lakes ecosystem contained endosulfan concentrations of 1–12 parts per trillion.[36] Concentrations of alpha endosulfan in precipitation from Canada ranged from 0.001 ppb to 0.116 ppb; those of beta endosulfan, from 0.001 ppb to 0.031 ppb.[37] Concentrations of endosulfan in rain/snow samples collected in rural and urban areas were 1–10 ppt.[38]

Food contamination with endosulfan is widespread. Several endosulfan residue surveys in various types of food consistently revealed significant contamination with endosulfan. For example, monitoring of pesticide residue levels in food from July 1, 1969, to June 30, 1970, by the U.S. FDA showed that 17 of 240 food composites contained endosulfan concentrations ranging from 0.001 ppm to 0.006 ppm.[39] In another study, an infant food composite contained 0.002 ppm beta endosulfan and 0.004 ppm alpha endosulfan. Two of 110 toddler food composites contained 0.001–0.004 ppm beta endosulfan.[40] In the Philippines, a survey of agricultural crops, including various vegetables and fruits, also revealed significant contamination with endosulfan, at concentrations ranging from 0.01 ppm to 0.11 ppm.[41]

ENDOSULFAN AND THE POPS NEGOTIATIONS

An objective and careful review of the existing data on endosulfan clearly demonstrates that endosulfan belongs to the group of highly toxic persistent organic pollutants (POPs). Endosulfan was in fact in the initial list of POPs being considered for worldwide elimination at the first meeting of experts in Vancouver, Canada, in 1994, jointly convened by the governments of Canada and the Philippines as a response to the growing worldwide concerns about the serious damage to health and the environment that persistent organic pollutants are causing. In the subsequent Manila meeting in 1996, the Philippine delegation strongly recommended the inclusion of endosulfan, together with triphenyltin compounds, in the initial list of POPs that would be subject to worldwide phaseout and elimination through a legally binding international agreement or treaty. This position gained support from many country delegations, including public-interest groups, but was vigorously opposed by the chemical industry representatives, particularly Hoechst's. Eventually, endosulfan disappeared from the initial list of POPs. For some reason, the Philippine government suddenly lost interest in pursuing its position on endosulfan and no longer sent its scientists earlier involved in the POPs issue to subsequent POPs meetings. From an initial list of about 40 POPs, the list was trimmed down to only 12, namely, aldrin, chlordane, dieldrin, endrin, DDT, heptachlor, hexachlorobenzene, mirex, toxaphene, PCBs, dioxins, and furans. The POPs treaty negotiations was then set into motion without endosulfan among the initial POPs targeted for elimination. It is significant to note that all the initial POPs that are not byproducts have already been banned or severely restricted in most countries and not one is still being manufactured by any major chemical company based in developed countries. No major chemical company from the developed countries, therefore, stands to lose profits from a worldwide ban on these chemicals. This is an indication that the intense lobbying of the chemical industry in the initial meetings on the POPs issue was very successful. It was the feeling of the Philippine experts involved in the POPs issue that the active intervention of the chemical industry representatives during the POPs meetings influenced the decision to exclude endosulfan from the initial list of POPs. This was made more evident by the fact that a representative of Hoechst at one point attempted to alter the background document on endosulfan not through open discussion and debate but through direct access to some key people involved in organizing the experts' meetings on POPs.

CONCLUSION

The foregoing account brings to the forefront the question of who really decides on the matter of risk assessment of toxic chemicals such as pesticides and POPs. While it is commonly accepted that health and safety of the people and the environment should be paramount, the reality is that corporate interests and profits are the dominant con-

siderations influencing decisions pertaining to the production, marketing, and use of toxic chemicals. "Science-based" risk assessment is not the decisive factor in determining the regulatory status of toxic chemicals. The reality of "power relations" between the strong and the weak, between the rich and the poor, and between the first world and the third world is very much in the decision-making processes of governments in their attempts to confront the problems related to toxic chemicals.

Corporations often defend their products despite overwhelming evidence of harm to human health and the environment by referring to the extensive testing their products undergo, to the approval of regulatory bodies in many countries based on "risk assessment," and to the tacit approval by international bodies such as the WHO and FAO. However, past experiences clearly show that profit-driven corporations exert all efforts to ensure profitability by attempting to exercise control, through their vast financial resources and political clout, over all factors that may influence the market, including: information and research, scientists and academic institutions, regulatory bodies and governments, judges and politicians, international organizations, and even non-governmental organizations.

This reality makes science and corporations inherently contradictory. Science is about truth and true science means the search for new knowledge in a systematic and logical manner so that people may benefit from it. Science involves astute observation of objects and events, careful formulation of hypotheses, unbiased experimentation and analysis, and logical conclusions. On the other hand, corporate pseudo-science is characterized by manipulation of objects and events, vested-interest–driven and obscured formulation of hypotheses, biased experimentation and analysis, and market-directed, predetermined conclusions. Data are collected, generated, or even fabricated to support corporate objectives and achieve marketing targets. Arguments are not based on human logic but are predetermined by corporate interests. Information is not something that may be true or false but something that is created and packaged to sell a product. Any information that tends to diminish the sales of a product is immediately considered a disparagement (even illegal) and therefore must be suppressed. The corporation would demand "scientific proof" and puts the burden on the victims and complainants. At best, when denial is no longer possible, the corporation would concede that the information "needs further study" and still would resist complete banning of their toxic product.

Very recently, the idea of using the precautionary principle in dealing with toxic chemicals has been pushed strongly by many sectors, especially independent scientists and public-interest groups. Essentially, the precautionary approach attempts to avoid the creation of pollutants in the first place, in contrast to risk-assessment strategies that attempt to manage pollutants to some level of "acceptability" after they have been created. With the precautionary principle, there is recognition that long-term impacts of toxic chemicals are difficult to predict and often impossible to prove. It also accepts the fact that, historically, many toxic chemicals have been shown to cause serious and often irreversible damage to human health and the environment. While the precautionary approach must still rely on science to identify potential risks to human health and the environment, it is not dependent, as risk assessment is, on a system of decision making that demands generation of extensive scientific data and requires exhaustive analysis of risks as pre-conditions to policy formulation and action. This is particularly relevant to third-world countries, where the resources needed to characterize the risks are not readily available. Pollution prevention is the only logical option.

References

1. Pesticide firm defends pestkiller. Philippine Daily Inquirer (PDI). 20 May, 1993: 10.
2. Agency for Toxic Substances and Disease Registry. Toxicological profile for endosulfan. ATSDR, U.S. Department of Health and Human Services, Atlanta, GA, PB93-182558, 1993.
3. Micromedex, Inc., Englewood, CO. Endosulfan. Vol 17, edition expired 1993.
4. Soto A, et al. The pesticides endosulfan, toxaphene and dieldrin have estrogenic effects on human sensitive cells. Environ Health Perspect. 1994;102(4).
5. Japan Offspring Fund. Endocrine Disruptors Threaten Our Offspring. Tokyo, Japan: JOF, Nov 1998.
6. National Poison Control and Information Service. Report on Poisoning Cases. Philippine General Hospital, Manila, Philippines, 1991.
7. World Health Organization. WHO/FAO Joint Meeting on Pesticide Residues, Endosulfan 91-115. Geneva, Switzerland: WHO, 1989.
8. IPCS. Endosulfan Health and Safety Guide. Geneva, Switzerland, World Health Organization, 1988.
9. IBT, 1965.
10. Reuber MD. The role of toxicity in the carcinogenicity of endosulfan. Sci Total Environ. 1981;20:23–47.
11. Fransson-Steen R, et al. Carcinogenesis. 1992;13:2299–303.
12. Syliangco CYL. Mutat Res. 1978;53:271–2.
13. Adams JS. Mutat Res. 1978;53:271–2.
14. Yadav AS, et al. Mutat Res. 1982;105:403–8.
15. Velasquez A, et al. Mutat Res. 1984;136:115–8.
16. Naqvi SM, Vaisnavi C. Bioaccumulative potential and toxicity of endosulfan insecticide in non-target animals. Comp Biochem Physiol (C). 1993;105:347–61.
17. Sobti RC, et al. Cytokinetic and cytogenetic effect of agricultural chemicals on human lymphoid cells in vitro. II. Organochlorine pesticides. Arch Toxicol 1983;52:221–31.
18. Dulout FN, et al. Mutat Res. 1983;143:237–44.
19. Yuquan L, et al. Environ Health Perspect. 2000;108:559–61.
20. Environmental Protection Agency. List of Lists. SARA Title III Consolidated Chemical List. U.S. EPA, Washington, DC, 2 Feb 1990.
21. Dinham B. The Pesticide Hazard. London, U.K.: Zed Books, 1993.
22. Schimmel SC, et al. In: Mayer FL, Hamelink JL (eds). Aquatic Toxicology and Hazard Evaluation. American Society for Testing and Materials. 1977: 241–52.
23. Reish D, et al. J Water Pollut Control Fed. 1979;15:1477–517.
24. Roberts D. Bull Environ Contam Toxicol 1975;13:170–6.
25. IPCS. Environmental Health Criteria Series No. 40, Endosulfan. Geneva, Switzerland: World Health Organization, 1984.
26. National Wildlife Federation. Pesticides: Is Safe Use Possible? Washington, DC: NWF, 1987.
27. Hansen OC. Ecotoxicological Evaluation of Endosulfan. Copenhagen, Denmark: Danish Technical Institute, 1993.
28. Stewart DKR, Cairns KG. J Agric Food Chem. 1974;22:984–6.
29. Rao DMR, Murty AS. J Agric Food Chem. 1974;22:984–6.

30. El Beit IOD, et al. Int J Environ Studies. 1981;16:171–80.
31. Greve PA, Wit SL. J Water Pollution Control Fed. 1971;42:2338–48.
32. Frank R, et al. J Environ Qual. 1982;11:497–505.
33. Paningbatan EP, et al. Movement of monocrotophos and endosulfan in saturated soil. The Philippine Agriculturist. 1993;76:259–68.
34. Medinar JR, et al. Insecticide residues in selected well water in Calamba and Calauan, Laguna. The Philippine Agriculturist. 1991; 74:195–205.
35. Kutz FW, et al. In: Lee RE (ed). Air Pollution from Pesticides and Agricultural Processes. Cleveland, OH: CRC Press, 1976: 95–137.
36. Eisenreich SJ, et al. Environ Sci Technol. 1981;15:30–8.
37. Brooksbank P. Water Quality Bulletin No. 129. The Canadian Network for Sampling Organic Compounds in Precipitation, Environment Canada, Inland Water Directorate, 1983.
38. Miller JM. The potential atmospheric impact of chemicals released to the environment. USEPA-560/5-80-001. Washington, DC: U.S. Environmental Protection Agency, 1981.
39. Duggan RE, et al. Pesticide residue levels in foods in the United States from July 1, 1969 to June 30, 1976. U.S. Food and Drug Administration and Association of Official Agricultural Chemists, 1983.
40. Podrebarac DS. J Assoc Off Anal Chem. 1984;67:166–75.
41. Bureau of Plant Industry. Pesticide residues in food. Department of Agriculture, Quezon City, Philippines, 1995.

Beyond Risk: An Ecological Paradigm to Prevent Global Chemical Pollution

JOE THORNTON, PHD

Since World War II, synthetic chemical pollutants have accumulated in the environment and food webs on a global basis, have damaged wildlife populations, and may pose large-scale hazards to human health. Despite the global nature of this problem, the vast majority of environmental regulations focus on preventing local risks using risk assessment of individual compounds, discharge permits, and control and disposal technologies. The current approach has failed to prevent global contamination and environmental damage because it underestimates the scale, complexity, and diversity of the hazards of chemical pollution. Fundamental shifts in the mode of chemical assessment and policy are required; a new framework should focus on chemical classes rather than individual substances, convert industrial processes to prevent the production and use of persistent and/or bioaccumulative substances, and shift the default state of pollution policy in the face of uncertainty from permission to restriction.* *Key words*: chemical pollutants; global pollution; regulations; risk assessment; public policy; persistent organic pollutants.

INT J OCCUP ENVIRON HEALTH 2000;6:318–330

At the time of this writing, the nations of the world are negotiating the first legally binding instrument to address global contamination by persistent organic pollutants (POPs). Motivated by growing evidence that diverse mixtures of synthetic chemical pollutants are now globally distributed in the environment and food web, have damaged wildlife populations, and have the potential to cause large-scale human health damage,[1,2] the POPs agreement has the potential to establish a framework for effective action on an environmental issue of profound consequence.

The draft agreement,[3] however, manifests a deep tension between the established—and largely ineffective—risk-based framework for environmental policy and a new approach designed to rectify the failures of the current system. On one hand, the agreement, which requires global action to eliminate production of several POPs, represents a fundamental shift from the present use of control and disposal techniques to manage chemicals, after they have been created, on a local scale. On the other, it would initially address just 12 pollutants, most of which have already been restricted by many of the world's nations, ignoring thousands more POPs in commerce or produced accidentally. And for several of the 12 chemicals, whether the treaty will require their generation to be eliminated or merely reduced by improving control and disposal technology remains unresolved and a matter of controversy.

The purpose of this paper is to show that the agreement will adequately address the global POPs problem only if it moves decisively away from the dominant regulatory approach. The goal of the POPs negotiation process should be to establish a framework for a precautionary mode of environmental management focused not on controlling a list of individual substances but on eliminating broad classes of hazardous chemicals and the technologies that produce them.

THE RISK PARADIGM

In the 1970s, industrialized countries adopted a framework for assessing and regulating toxic chemicals that remains largely in force today. I call this approach the risk paradigm, because it views environmental hazards as "risks"—locally bounded, short-term, probabilistic events—and it uses risk assessment as its primary scientific and policymaking tool. It is a paradigm, in the sense of Kuhn,[4] because the scientific and political assumptions, concepts, and tools that make up the risk paradigm determine how data on the sources and impacts of toxic chemicals are collected and interpreted, how conclusions are drawn from them, and what kinds of action will be taken in response.

The modus operandi of the risk paradigm is to manage pollution by permitting chemical production, use, and release, as long as discharges of certain individual substances do not exceed some quantitative standard of acceptable contamination. The belief that health and ecosystems can be protected in this way is founded on two central assumptions: that ecosystems have an "assimilative capacity" to absorb and degrade pollutants with-

Received from The Earth Institute, Columbia University, New York, New York.

Address correspondence and reprint requests to: Joseph Thornton, PhD, Columbia University Department of Biological Sciences, MC-2430, New York, NY 10027, U.S.A.; e-mail: <jt121@columbia.edu>.

*The argument presented here is distilled from a more complete presentation in the author's recent book, *Pandora's Poison: Chlorine, Health, and a New Environmental Strategy* (MIT Press, 2000) and is used with the publisher's permission.

out harm, and that organisms can accommodate some degree of exposure with no or negligible adverse effects, so long as the exposure is below a "threshold" of toxicity.

As implemented, the central artifact of the risk paradigm is the pollution permit—a license that sets maximum legal release rates of individual toxic chemicals from individual facilities. (The same approach is manifest in acceptable pesticide residues in food and legal limits for workplace exposures to individual toxic substances.) These limits are calculated using quantitative risk assessment,[5] a mathematical approach that begins from toxicological studies on laboratory animals, sometimes incorporating safety factors, to estimate the threshold or safe dose for each chemical to be regulated. In the case of cancer, it is generally agreed that no-effect levels are not likely to exist, so the threshold is calculated as the dose that poses some level of risk determined a priori to be acceptable (typically a 10^{-5} or 10^{-6} additional lifetime risk of cancer). Based on an array of assumptions about human behavior and intake, risk assessment is then used to estimate the level of environmental contamination that will cause a hypothetical "most exposed individual" (MEI) not to exceed the acceptable exposure level. With further assumptions about pollutant fate and transport, the next step in risk assessment is to calculate the maximum release rate that will ensure that contamination will not exceed this level in the vicinity of the facility.

This maximum acceptable release rate becomes the permitted discharge level, and industries typically comply with the limit by installing pollution-control devices or improving housekeeping practices. In rare cases, more restrictive action than prescribed by a risk assessment—such as banning a chemical—can be taken, but only when the evidence from epidemiological or ecological studies is overwhelming that a specific substance has caused severe health and environmental damage. Restrictions applied in the 1970s to DDT and the use of lead compounds in gasoline and paint in many nations are prime examples.

In principle, the individual elements of the risk paradigm—prediction of acceptable discharges and exposures, the focus on assessment and regulation of individual substances on a local scale, and the reliance on pollution control and disposal—are separable. In practice, however, they usually appear together, because the system's risk-assessment methods limit the description of hazards to those that can be managed using permits and control technologies. In this way, the elements of the risk paradigm complement and reinforce each other, creating a self-consistent system that, through its own lens, is competent to protect health and the environment.

The fact is that the risk paradigm has failed to prevent global chemical contamination, because the global hazards that synthetic chemicals pose are fundamentally different from the kinds of local, temporary risks for which this approach was designed. In at least six ways, the assumptions of the risk paradigm are deeply at odds with the reality of global toxic pollution. The details of that reality reveal the extent of and reasons for the failure of the dominant approach.

FAILURE 1: ACCUMULATION OF PERSISTENT POLLUTANTS

The first problem with the risk paradigm lies in its assumption that there is an "acceptable" discharge of synthetic chemicals that will not overwhelm the ecosystem's assimilative capacity. Permitting discharges in limited amounts has often worked effectively for the kinds of nonsynthetic pollution to which this approach was originally applied—human and animal waste, oil and grease, acids and bases—because ecosystems can assimilate such substances, so long as they are introduced at rates below the degradation or buffering capacity of the system. It has not been appropriate or effective, however, for the many synthetic pesticides, solvents, refrigerants, chemical feedstocks, intermediates, and unintentional byproducts that are, by design or coincidence, resistant to natural degradation processes. Many of these substances have environmental half-lives measured in years, decades, or centuries (Table 1). Many more are bioaccumulative—oil-soluble substances that accumulate in the fatty tissues of living

TABLE 1 Persistence of Selected Synthetic Compounds in Selected Environmental Media

Substance	Half-life (Years)*	Medium	Reference†
Carbon tetrachloride	24.3	Atmosphere	Montzka et al.[95]
Dichlorodifluoromethane	69.3	Atmosphere	Montzka et al.[95]
Chlorodifluoroethane (HCFC-142b)	13.2	Atmosphere	Montzka et al.[95]
Hexachlorobenzene	7	Atmosphere	Cortes et al.[96]
Hexachlorocyclohexane	13	Atmosphere	Cortes et al.[96]
Chloroform	1,850	Water	Jeffers et al.[97]
1,2-Dichloroethane	72	Water	Jeffers et al.[97]
Hexachloroethane	$1.8 \cdot 10^9$	Water	Jeffers et al.[97]
Trichloroethylene	$1.3 \cdot 10^6$	Water	Jeffers et al.[97]
Perchloroethylene	$990 \cdot 10^6$	Water	Jeffers et al.[97]

*Atmospheric half-lives are derived from actual environmental measurements; aquatic half-lives from hydrolysis constants in pure water.

†For complete reference citations, see the reference list.

TABLE 2 Bioconcentration Potentials of Selected Synthetic Chemicals

Substance*	Fat Solubility† (Kow)
Atrazine	407
Carbon tetrachloride	676
Perchloroethylene	2,512
Monochlorostyrene	3,802
Trichlorophenols	4,898–18,621
g-Hexachlorocyclohexane	5,248
Endosulfan	6,761
Hexachlorocyclopentadiene	9,772
Trichlorobenzenes	10,471–15,488
Tetrachlorobenzenes	50,119
Hexachlorobutadiene	79,433
Pentachlorobenzenes	147,911
Hexachlorobenzene*	
Tetrachlorodibenzofurans*	660,693
Octachlorostyrene	1,949,845
Tetrachlorodibenzo-p-dioxin*	6,309,573

*Of these substances only three (*) are addressed in the draft global agreement on POPs.
†Expressed as the octanol–water coefficient.
Data source: National Library of Medicine.[98]

things and multiply in concentration as they move up the food chain (Table 2). Some bioaccumulative substances reach concentrations in upper trophic wildlife, including humans, that are tens of millions of times greater than their levels in the ambient environment.[6,7]

Because of their tendency to build up rather than break down, releases of persistent and/or bioaccumulative substances since the expansion of synthetic chemical manufacturing after World War II have resulted in the global accumulation of a large number of POPs. These chemicals are distributed long distances on currents of wind and water and have therefore accumulated, sometimes in very high levels, in the ambient environment and food web in areas remote from any known sources of these substances, including the high Arctic,[8-10] the isolated rainforests of South America and Africa,[11] and the deep and open oceans.[6,12] In the Arctic, where long residence times, cold temperatures, and long food chains combine to enhance the persistence and bioaccumulation of organic chemicals, body burdens of humans and wildlife are as much as an order of magnitude greater than they are in industrialized regions at temperate latitudes.[13,14]

Although research and policy have focused primarily on a handful of substances—PCBs, dioxin, and about a dozen organochlorine pesticides, global contamination cannot be reduced to a few "bad actors." In the Great Lakes, 362 synthetic chemicals have been "unequivocally identified" in the water, sediments, and food chain; the list includes the most infamous organochlorines, but it also contains a full spectrum of less familiar substances, from simple solvents to a host of complex industrial chemicals and byproducts.[15] Polychlorinated terphenyls are widespread in the water, sediment, and biota of Northern Europe,[16] and pesticides presumed to be relatively non-persistent—atrazine, chlorpyrifos, endosulfan, chlorothalonil, metolachlor, and terbufos—can now be measured in Arctic air, water, and fog.[10] Industrial byproducts, including chloroanisoles, chloroveratroles, and octachlorostyrene, are present in measurable quantities in the Canadian Arctic[10] and over the remote Atlantic ocean,[17] and a variety of chlorinated benzenes are ubiquitous components of rain and snow.[18] Atrazine, alachlor, and chlorpyrifos are widespread in air, fog, groundwater, and surface water throughout large parts of North America, even in areas remote from the places where they are used.[19,20] And halogenated solvents, refrigerants, and their haloacetate breakdown products have become truly ubiquitous contaminants of the troposphere, stratosphere, and vegetation.[21-23]

With the environment and food web ubiquitously contaminated, it should come as no surprise that the bodies of human beings are, as well. An estimated 700 xenobiotic organic chemicals are present in the adipose tissues of the general population of the United States.[24] At least 188 organochlorine pesticides, solvents, plastic feedstocks, specialty chemicals, byproducts, and metabolites have been specifically identified in the blood, fat, milk, semen, urine, and/or breath of the general U.S. and Canadian population—people with no special workplace or local exposures to these substances (Table 3). For bioaccumulative substances, the vast majority of the average individual's exposure—in excess of 90%—comes through the food supply, primarily from animal products.[25] For some of the best-studied substances, the general public's average body burden is already at or near the ranges at which health impacts have been documented in laboratory animals.[25-27]

The now-ubiquitous global presence of myriad synthetic chemicals, in large-scale production for just over half a century, supports a simple inference: substances that persist or bioaccumulate cannot be integrated into natural cycles. Discharged in even very small amounts,

TABLE 3 Synthetic Organochlorines Detected in the Adipose Tissue, Blood, Milk, Breath, and/or Urine of the General Human Population of the United States and Canada

Substance Class	Substances Identified
Chloromethanes	12
Chloroethanes	9
Chloroethylenes	3
Other chloroaliphatics	10
Chlorobenzenes	12
Chlorophenols	3
Chlorodiphenyl ethers	6
PCBs	86
Polychlorinated dibenzodioxins	8
Polychlorinated dibenzofurans	10
Other chlorinated aromatics	8
Pesticides	21

Source: Thornton.[1]

these chemicals build up gradually in the environment and in living things. Given enough time, even very small "acceptable" discharges ultimately reach unacceptable levels. The ecosystem's assimilative capacity for persistent or bioaccumulative substances is therefore zero, and the only "acceptable" discharge is also zero. Any amount greater than zero must be expected to lead to some degree of long-term, global contamination.

FAILURE 2: CUMULATIVE GLOBAL POLLUTION

The second problem with the current approach to chemical pollution is that the focus on individual facilities and the local environments around them is fundamentally at odds with the global, cumulative nature of chemical pollution. When a facility is granted a permit to discharge pollutants into the air or water (or when the regulations that provide the guidance for these permits are formulated), the risk assessments on which these decisions are based consider only local and immediate exposures through one or a few exposure routes. The central construct of a risk assessment is a "most exposed individual" (MEI), a hypothetical person who suffers very high local exposures. In the simple case of an air-emissions permit, for example, the MEI stands at the edge of the facility grounds, breathing deeply, 24 hours a day for 20 years or more. The risk assessor uses data and assumptions about the height of the smokestack, the direction and speed of the wind, the amount of air a person breathes, and the toxicity of each substance to "back-calculate" a maximum permissible emission rate.

By this method, any quantity of the pollutant not ingested by the most exposed individual simply disappears. These dispersed and ignored emissions in fact represent the vast majority of pollutant releases, since no MEI takes into his or her body more than a tiny fraction of the chemicals released from the facility. In the risk paradigm, whatever quantity of a pollutant is taken up by wind or water currents and transported long distances is of no consequence. If a facility builds a higher smokestack or a longer discharge pipe, ensuring that emissions will be diluted in the air or water, then risks to the MEI will be reduced, and larger quantities of pollutants can be permitted. In this way, risk-based discharge permits allow—and even encourage—global pollution.

Moreover, when the risk paradigm assesses and permits releases of a chemical from a single facility, it takes no account of the fact that there may be hundreds of other facilities emitting the same chemical, in the same region or around the world. There are thousands of individual sources permitted to release thousands of pollutants. Even if releases from each of these facilities are locally acceptable, their emissions are dispersed together across the planet, contributing to a total chemical load that the local view never even considered. Preventing even extreme local contamination from myriad individual facilities, each permitted to operate simultaneously, year after year, does nothing to prevent the slow accumulation of a global pollution burden.

The problem is not only with facility-based permitting but also with risk assessment as a mode of hazard evaluation. There is no accepted method to evaluate the impacts of individual or multiple pollution sources in the context of the total, worldwide exposure burden. By relying on a model that pollutants travel directly and predictably from their discharge point to a single most exposed individual or local ecosystem, risk assessment as currently practiced and applied inherently precludes consideration of the global effects of the entire universe of pollution sources.

FAILURE 3: TOXICOLOGICAL COMPLEXITY

The third reason that the risk paradigm is inadequate to prevent global pollution is that the complex biological impacts of chemical mixtures cannot be adequately predicted or prevented with assessments and management strategies that focus on individual substances. There are 70,000 synthetic chemicals in commerce,[28] and, as we have seen, many hundreds have already accumulated in the bodies of the human population. In the current policy framework, each chemical is assessed and regulated individually. Acceptable discharge and exposure levels for each substance are extrapolated from laboratory studies using a classic reductive approach to reveal causality: animals are exposed to varying doses of a single pollutant, and the effect of that pollutant can be clearly discerned because all other factors are held constant. The assumption is that assessments of the toxicity of a substance at a given dose level will also hold when exposure occurs in the context of a chemical mixture.

This assumption has been resoundingly falsified by repeated findings that pollutants interact to modulate each other's toxicity in surprising and extreme ways. Although additive and inhibitive interactions occur, the most common effect of binary mixtures is a multiplicative or exponential effect by which the whole is greater than the sum of its parts.[29] The pesticide fenarimol, for example, greatly increases the mutagenicity of trichloroethylene,[30] and trichloropropene oxide and dioxins both amplify the carcinogenicity of certain polyaromatic hydrocarbons.[31,32] The magnitude of the synergistic effect can be extreme: exposure to a usually nontoxic dose of the pesticide chlordecone increases the death rate 67-fold among rats exposed to an "otherwise inconsequential" dose of carbon tetrachloride.[33] When a dose of PCBs that causes a 1.5-fold increase in liver porphyrin levels in rats is combined with a dose of dioxin that in isolation causes no measurable porphyrin elevation, porphyrin levels increase by 650 times.[34]

Single-chemical predictions of toxicity are therefore not reliable, and exposures predicted to be safe based on risk assessment may cause considerable health damage.

In a classic study, rats exposed to a mixture of 25 common groundwater pollutants, all at levels well below the doses that produce any measurable effects in isolation, exhibited statistically significant immunosuppression and increased susceptibility to several kinds of infectious diseases.[35] When this same mixture was applied along with ionizing radiation, it substantially amplified the toxicological potency of radiation to rat bone marrow.[36] Indicating that it is not only chemicals that interact with each other but biologically active agents of entirely different classes.

The real-world impacts of chemical pollution therefore cannot be predicted with confidence based on single-chemical assessments. Even the use of comparative risk assessment to prepare priority lists of individual chemicals fails to take account of the true modes by which chemicals disrupt biological systems. It is the total chemical burden—the complete set of environmental hazards of all types, in fact—that poses potential health hazards; single-chemical studies, conducted completely out of this context, offer little insight into the hazards that the components of these mixtures actually pose. Single-chemical studies clearly have scientific value: with their simplified exposure regimens, these experiments are indispensable for clarifying the mechanisms by which individual components evoke their toxic effects. But value for science is not the same as value for policy, and the inescapable conclusion is that discharges or exposures cannot be approved based on risk assessment with confidence that health will not be damaged.

This problem is intrinsic to the risk-based approach. One might reasonably suggest that toxicological testing and risk-assessment methods should focus on the effects of individual chemicals in the context of chemical mixtures. But evaluating the role of each individual compound in a mixture and its interactions with all the others would require a multifactorial design that examines all possible combinations of the chemicals. Such studies are astronomically demanding of time and resources. According to scientists at the National Toxicology Program, an abbreviated single-species, 13-week toxicity evaluation of all the interactions in a mixture of just 25 chemicals would require over 33 million experiments at a cost of about 3 trillion dollars. A similar study of just 1% of the chemicals in commerce would require an unimaginable 10^{210} experiments.[36]

In practice, gaining insight into the effects of chemical mixture does not really require probing the roles of individual substances in all possible combinations. It is much more practical and revealing to pluck a real-world mixture of chemicals from some corner of the environment and compare the effects it causes with those of a mixture from some less-contaminated place. For example, several studies have compared the health of animals fed fish from large contaminated ecosystems such as the Great Lakes or the Baltic Sea with the health of those fed fish from less contaminated environments, and they have found that the chemical mixtures in fish have adverse effects on immunity, reproduction, and behavior.[37-40] But these studies do not indicate *which* compounds in the mixture are causing the effects, so their results become irrelevant and inadmissible when decisions are required to focus on single chemicals. We do not lack evidence that the low-level chemical mixtures present in the environment can cause health damage; rather, the problem is that the current regulatory system is blind to data that cannot be reduced to a simple cause–effect, single-chemical model.

FAILURE 4: INADEQUATE DATA

The fourth problem with risk-based regulations on individual substances is that the data to support them simply do not exist. According to a 1984 National Research Council report, data for a complete health-hazard assessment were not available for a single industrial chemical, and there were no data whatsoever for 78%.[41] A 1997 update of that study found that the situation had not improved: even among the subset of high-volume chemicals that had already been the subject of specific regulatory attention—those expected to have been the most thoroughly studied—70% still lacked even minimal chronic toxicity data; no reproductive toxicity tests were available for 53%, no neurotoxicity information for 67%, and no immunotoxicity data for a whopping 86%.[42] As for the thousands of additional substances formed as byproducts, environmental transformation products, or metabolites, toxicological data are likely to be even less ample for these substances than for those that are officially on the market.

New toxicological data can be obtained, but we cannot hope to amass the information base to effectively regulate synthetic substances individually any time soon. The U.S. National toxicology program conducts assessments for 10 to 20 substances per year,[43,44] but the chemical industry brings 500 to 1,000 new chemicals into commerce annually.[36] Our knowledge base is constantly falling further and further behind the diversity of chemicals introduced into the environment.

This lack of data fundamentally undermines the ability of the risk paradigm to protect health. In the current system, synthetic chemicals are presumed harmless until demonstrated hazardous. In a risk assessment, a chemical for which there are no toxicological data is assigned a risk of zero, and a substance with a zero risk is subject to no restrictions whatsoever. The result is that the current system operates primarily on ignorance rather than knowledge, and the vast majority of chemicals receive laissez-faire treatment simply because they have been studied superficially, if at all. Predictions that the public's exposures are safe have no empirical basis in observation or even extrapolation. Chemicals are often left off priority lists not because they are less hazardous than other substances but because we know little or nothing about them.

The question is, how severe are the hazards we have not yet detected? At the time of their introduction in the late 1920s, chlorofluorocarbons were considered absolutely safe; some 50 years later, they were found to cause severe damage to the stratospheric ozone layer.[45] More recently, tris(4-chlorophenyl)methanol (TCM), an exotic industrial specialty chemical and by-product that had not been the subject of previous scientific or regulatory attention, was sought and found at levels up to the parts per million in wildlife tissues on a truly global basis[46]; toxicological evaluations have just begun, and TCM has been found to be an estrogen receptor agonist,[47] raising the possibility of a variety of reproductive, developmental, behavioral, and pathological impacts. It remains unknown how many other chemicals with the potential to cause severe health damage are globally distributed but presently unrecognized.

FAILURE 5: FORMATION OF CHEMICAL MIXTURES

Even if it were possible to develop data and regulations for each individual organochlorine, chemical-by-chemical regulations and assessments would still fail to address the ways that that synthetic chemicals are produced—always in complex mixtures, many of the components of which are unidentified. Over 300 organochlorine byproducts have been identified, for example, in the effluents of chlorine-bleaching pulp mills, including a tremendous diversity of chemical structures: chlorinated dioxins, furans, phenols, benzenes, thiophenes, methylsulfones, methanes, ethanes, acids, and PCBs.[48,49] The identified substances account for only 3 to 10% of all the organically-bound chlorine in the effluent; the remaining 90 to 97% have not been chemically identified or assessed.[50] Similarly, the emissions of waste incinerators are estimated to contain over 1,000 products of incomplete combustion,[51] including a wide range of chemical structures, from carbon tetrachloride to chloronaphthalenes and dioxins.[51-53] The most ambitious studies have identified just 40 to 60% of the total mass of unburned hydrocarbons in the stack gas.[54,55] In the disinfection of water with chlorine gas, scores of byproducts have been identified, ranging from chloromethanes to chlorophenoxyphenols and chlorodibenzofurans,[56-59] and unidentified compounds represent 50 to 75% of the total organically-bound chlorine in the water.[59-61]

Even in more carefully controlled chemical synthesis processes, mixtures are always produced. Byproducts account for almost 20% of commercial DDT preparations, and about one sixth of this is unidentified compounds.[62] All lesser chlorinated benzenes are contaminated with considerable quantities of the highly persistent and bioaccumulative hexachlorobenzene, because the chlorination of benzene inevitably proceeds, in part, to the saturated form.[63] In the production of short-chain chlorinated hydrocarbons by chlorinolysis, 1% to 7% of the total yield consists of highly persistent and bioaccumulative organochlorine byproducts.[63] And in the reactions by which vinyl chloride is synthesized, 10% of the yield consists of organic byproducts,[63] including the very hazardous hexachlorobenzene, hexachlorobutadiene, hexachloroethane, PCBs, dioxins, and furans; the wastes from this process are over 60% chlorine by weight, and about 30% of the contents are unknown compounds.[63-65]

If synthetic chemicals are always produced in diverse mixtures, it is unrealistic to think we can regulate and control them individually. Even trying to assess these substances on a chemical-by-chemical basis fails to provide the kind of knowledge necessary to make effective policy; an assessment that considers only the fate and toxicity of a commercial chemical—and excludes all the byproducts formed in its manufacture, use, and disposal—may radically underestimate the actual health and environmental damage that a substance may cause. Moreover, managing chemicals on a substance-by-substance basis requires us to know what chemicals we are producing. In fact, we do not even know the chemical names or structures of the majority of the byproducts formed in industrial processes, not to mention their toxicity and environmental behavior. We cannot assess and control substances that have not even been identified, so our blindness to the composition of the mixtures produced in chemical-intensive industrial processes fundamentally undermines the chemical-by-chemical approach to environmental regulation.

Suppose society decided to eliminate just a few of the most persistent, toxic, and bioaccumulative substances, such as those on UNEP's list of 12 POPs. Policies targeted specifically at a short list of chemicals would still have to address the production and disposal of entire classes of compounds and technologies, because of the formation of unintentional mixtures. The continuing discharge of tons of PCBs into the environment each year as byproducts of chlorine-based industrial processes, decades after the deliberate production of PCBs was phased out, for example, clearly illustrates this problem.[66] Perhaps the greatest challenge comes from 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), the most persistent, bioaccumulative, and toxic of all synthetic chemicals known. TCDD and/or related compounds have been detected as byproducts in the electrolytic production of chlorine gas; in all direct applications of chlorine; in the manufacture of any and all chlorinated organic chemicals, including plastic feedstocks, solvents, pesticides, intermediates, and specialty chemicals; in some uses of chlorine-based substances; and in the purposeful or accidental combustion of any and all organochlorines (Table 4). The conclusion is that dioxin formation appears to be endemic to the industrial use of chlorine chemistry. No organochlorine can go through its life cycle of manufacture, use, and disposal without producing dioxin along the way. If we want to stop the production of the single most hazardous substance, it is nec-

TABLE 4 Selected Industrial Processes in Which the Generation of Polychlorinated Dibenzo-p-dioxins or Related Compounds Has Been Identified

Category	Dioxin-generating Process	Reference*
Production of chlorine gas	Chlor-alkali with graphite electrodes	Rappe et al.[99]
	Chlor-alkali with titanium electrodes	Environment Agency[64]
Direct chlorine applications	Pulp bleaching	U.S. EPA[68]
	Water treatment	Rappe et al.[57]
	Metallurgy	Oehme et al.[100]
	Production of inorganic chlorides	Hutzinger and Fiedler[101]
Synthesis of organochlorines	All chloroaromatics (pesticides, intermediates, specialty chemicals)	U.S. EPA,[68]Hutzinger and Fiedler[101]
	Chlorinated solvents	Environment Agency,[64] Heindl and Hutzinger[102]
	Aliphatic plastic feedstocks	Environment Agency,[64] Heindl and Hutzinger[102]
Uses of organochlorines	Synthesis with organochlorine intermediates	Hutzinger and Fiedler[101]
	Solvent use in alkaline environment	Hutzinger and Fiedler[101]
	Lumber treatment with pentachlorophenol	Rappe and Marklund[103]
	Scavengers for lead in gasoline	Marklund et al.[104]
Disposal of organochlorines	Waste combustors	U.S. EPA[68]
	Copper-recycling smelters	U.S. EPA[68]
	ferrous metal smelters	U.S. EPA[68]
	Open-barrel waste combustion	U.S. EPA[68]
Accidental combustion of organochlorines	Building fires with PVC plastic	U.S. EPA[68]
	Vehicle fires with PVC plastic	U.S. EPA[68]
	Landfill and warehouse fires	U.S. EPA[68]
Environmental transformation of organochlorines	Transformation of substances in sewage sludge	Oberg et al.[105]
	Photolytic transformation of airborne chlorophenols	Baker and Hites[106]

*For complete reference citations, see the reference list.

essary to address the entire class of industrial substances and technologies derived from the use of chlorine gas and organochlorine compounds.

FAILURE 6: POLLUTION CONTROL AND DISPOSAL

The final reason that the risk paradigm has failed is that the technological effort to control pollutants rather than prevent their generation inevitably leads to global accumulation. Devices for pollution control and disposal can help a facility to meet discharge limits and thereby reduce local contamination, so they have become the technological centerpiece of the risk paradigm. But these technologies do little or nothing to prevent global pollution. The predominant effect of control and disposal devices is to shift chemicals from one environmental medium or chemical form to another. The most effective precipitators, scrubbers, filters, evaporation tanks, and landfill liners merely change the time or place in which persistent pollutants enter the environment; immediately or eventually, captured pollutants make their way into the ecosystem in one place or another, in one form or another.

As for incinerators, these devices not only shift pollutants from one medium to another but convert them to new forms; the desired products are carbon dioxide and water, but even properly operated facilities convert a considerable portion of the wastes they burn into persistent and toxic products of incomplete combustion (PICs). PICs are the inevitable result of the random combustion reactions and post-combustion processes; improved operating conditions can reduce their formation but cannot prevent them.[55,67] Further, metallic pollutants such as lead, mercury, and cadmium cannot be destroyed by burning at all, and incinerators serve simply as dispersion points for these pollutants. Ironically, it is incinerators—the centerpiece of the pollution-control infrastructures in most industrialized countries—that are the largest identified sources of dioxin and leading sources of many metallic pollutants.[68-71]

Pollution-control strategies are further undermined by the fact that many chemicals, such as pesticides, paint

strippers, and plastics, are deliberately dissipated into the environment or the economy. When the goal is to prevent local contamination, dissipation of this sort is of little consequence, but it contributes considerably to global contamination. Once a pesticide is sprayed onto agricultural land, a paint stripper sold to a handyman, or PVC pipes installed in a building that may one day catch fire and thus generate dioxins,[72] even the most efficient devices attached to factories become irrelevant. In these cases, the hazard comes from the product, not a waste, and the only way to prevent the release of these substances or their ultimate byproducts into the environment is not to produce and use them at all.

Further, control and disposal technologies seldom perform as well in reality as they are supposed to. Human error, aging equipment, and fluctuations in operating and environmental conditions can all result in unexpectedly large releases of chemicals to the environment during capture or disposal. Landfill liners decay and leak, incinerators undergo upset conditions and explosions, chemicals are spilled, and so on. With the use of synthetic products expanding globally, especially in developing countries where regulatory and technological infrastructures are less developed, the scenario of optimally designed, operated, supervised, and maintained control and disposal technologies becomes highly unrealistic.

Finally, the goal of pollution control is to reduce the quantity of emissions per unit product, economic growth in the rate of production eventually overwhelms improvements in the rate of emissions per unit product. In theory, perpetual increases in pollution-control efficiency could avoid this problem. In reality, however, after an initial reduction in discharges, the cost of improved control increases exponentially, so it quickly becomes prohibitively expensive to achieve further reductions, and companies must spend more and more on control just to maintain a constant rate of environmental pollution.

BEYOND RISK

These six issues show why the current system for chemical assessment and regulation is intrinsically ill-suited to preventing global pollution. At the heart of the risk paradigm's failure is an inappropriate model of nature on which risk assessment and its pretense of predictive management of environmental hazards are based. Quantitative risk assessment was adapted from the methods used by engineers and economists to predict the probability that a bridge will collapse or an investment fail. These predictions are reasonably reliable, because the system has been built by humans and is thus well characterized, and only a limited number of factors affect the integrity of the bridge. The system is classically mechanical and linear: the effect of weakness in one part of the bridge on another part is well understood, and the probabilities of individual events can be added or multiplied to yield the probability of an overall outcome. Although there are always uncertainties, these too can be defined and even quantified. Finally, the impacts of failure are local and immediate, and each risk can be considered in isolation, since the collapse of a bridge at one location has no effect on the integrity of a bridge elsewhere. The same model underlies environmental risk assessment's attempt to quantify the risks of specific forms of health damage caused by individual chemicals.

This mechanical, probabilistic model is inappropriate for ecosystems and organisms, which are not built objects but are alive, unpredictable, densely interconnected, hierarchical, and largely uncharacterized complex systems.[73] In systems such as this, quantitative predictions are unreliable. The first barrier to reliable prediction is missing data; when the initial values that should be put into a predictive model are not known, we can have no confidence whatsoever in the output.

Second, we cannot predict the impacts of perturbing a system unless the system itself is well characterized, but knowledge of the specific fundamental mechanisms (at molecular, cellular, organismal, population, and community levels) by which organisms and ecosystems develop and function remains partial at best. For example, new molecular components of the vertebrate endocrine system are continually discovered, and the physiological functions of many potential hormone receptors remain unknown.[74] The dynamics of relationships among species in an ecosystem also remain largely uncharacterized.[75] Without relatively complete knowledge of how organisms and ecosystems function, there is no way we can reliably predict or manage the effects of the multiple, simultaneous changes we inflict upon these systems.

Finally, prediction works well in simple physical systems with determinate, linear paths of causality: that is, each cause produces one effect, and the total result of numerous small causes is simply the sum of all their individual impacts. Organisms and ecosystems, in contrast, are characterized by multifactorial and circular causality—negative and positive feedback loops, redundancy, multiple functions, critical periods of high sensitivity, and so on. Circular webs of causality mean that the system is buffered against some changes, but it is extremely sensitive to others. Multiple tiny changes can cause runaway or synergistic effects, resulting in a major reorganization or breakdown of the system. Other impacts may be more subtle, degrading the performance or adaptability of the system without the obvious signs of failure. The ability of tiny, one-time doses of endocrine-disrupting chemicals during early development to cause delayed multigenerational damage to reproductive and cognitive function is powerful testament to this dynamic.[76,77]

The impossibility of making reliable quantitative predictions of the impacts of individual substances on ecosystems and organisms falsifies the risk paradigm's most basic assumption: that humans have the knowledge and technology to manage these impacts at the fine level of control implied by approving discharges and regulat-

ing individual substances. The very concept of "risk," ultimately, is inappropriate for the kinds of health and environmental damage that POPs can cause. A risk is by definition the quantifiable probability that something bad will occur. The long-term hazards of chemical pollution, in contrast, are not discrete "either–or" events that may or may not happen, the risk of which can be expressed probabilistically. Instead, pollutant exposure has the potential to modify the distribution of functional ability throughout the entire population; virtually everyone exposed will be affected to a greater or lesser degree.[78] Further, the injury emerges slowly in the subtle and diverse symptoms of global environmental decay, so these hazards cannot be reduced to probabilities and are difficult to quantify in any fashion. Global contamination causes universal side-effects and systemic damage, not individual risks. By focusing on discrete local impacts and individual activities, the assessment of "risks" establishes a lens that is largely blind to the slow emergence of global damage, which occurs as the cumulative result of all the technological activity in society.

Finally, the risk paradigm's methods for dealing with environmental damage once it occurs also break down in the face of the global reality of POPs. Persistent, global contamination cannot be cleaned up, and multigenerational health damage cannot be repaired. The inability to trace causality to individual actors means that it is difficult if not impossible to hold individual firms accountable for the damage caused by global contamination. And the risk paradigm is without an effective mechanism for detecting and correcting its errors. Before more severe restrictions than a risk assessment justifies can be applied to a substance, the risk paradigm requires a specific causal link to be demonstrated. But epidemiology and eco-epidemiology are limited in their ability to establish such specific causal links for subtle, transgenerational health impacts that may emerge decades after exposures to mixtures of interacting chemicals, especially when there is nowhere on earth an uncontaminated control or comparison group.[79] Current institutions therefore become paralyzed by their own unrealistic standards of proof and are left without an effective mechanism to detect and stop the damage they may be doing to health and the environment.

AN ECOLOGICAL PARADIGM FOR GLOBAL POLLUTION

To cope with this new kind of hazard, we need a new scientific and institutional model that is designed specifically to address synthetic chemical pollution on a global scale. I call this approach the "ecological paradigm," because it is based on a view of nature that derives not from engineering but from ecology: organisms and ecosystems are complex, integrated, and only partially understood systems in which causality is generally nonlinear and prediction therefore unreliable.

First and foremost, the ecological paradigm recognizes the limits of science, which provides important clues about nature but can never completely predict or diagnose the impacts of individual chemicals on natural systems. The implications for policy are obvious: since science leaves so much unknown, we cannot afford to make risky bets on its predictions or wait to protect health and the environment until we have proof of specific causal links. Instead, we should avoid practices that have the potential to cause severe damage, even in the absence of proof. This perspective embodies the principle of precautionary action in the face of scientific uncertainty: when the potential impacts of a mistake are severe and irreversible, we should err on the side of caution by anticipating and preventing environmental damage.[80] Precaution implies that substances and technologies that may be reasonably presumed to pose hazards should be avoided, whether or not scientists can prove that damage has already been done.

The precautionary principle tells us not to wait for proof before taking action, but it does not specify what kind of action to take, so the ecological paradigm relies on four other principles, which are formulated specifically to address the limits of the risk paradigm.

- First is the principle of zero discharge: to prevent the accumulation of persistent and bioaccumulative substances, these chemicals are considered incompatible with ecological processes, and releases in any quantity are considered a potential hazard. The goal of policy becomes not the licensing of "acceptable" discharges but eliminating releases of such substances altogether.[81]
- To accomplish this goal, the ecological paradigm takes a new technological approach with clean production.[82] In contrast to the after-the-fact strategy of pollution control and disposal, clean production emphasizes front-end solutions, particularly the redesign of products and processes to eliminate the use and generation of toxic chemicals, before they need to be managed. For example, a clean production approach to emissions of the solvent perchloroethylene from dry cleaners replaces the old process with a new generation of machines that use water, steam, or liquid carbon dioxide to clean clothes.[83] The principle of clean production says simply that we should always use the cleanest available technology to fulfill society's needs. Assessment of alternatives rather than approval of pollution becomes the centerpiece of environmental management.[84]
- To address the overwhelming lack of information that undermines the chemical-by-chemical approach, the ecological paradigm shifts the burden of proof, an idea called "reverse onus." In the current system, chemicals are presumed to be harmless until demonstrated hazardous. As a result, a lack of data is misconstrued as evidence of safety, and all the untested and unidentified chemicals are assumed to be safe. In

the ecological paradigm, the burden of proof shifts to those wanting to produce or use a synthetic chemical, who must demonstrate in advance that their actions are not likely to pose a significant hazard and that there is no safer alternative available. This is the same standard that is supposed to be applied to pharmaceuticals in the United States before they are brought on the market, and there is no reason chemicals that enter our bodies indirectly and involuntarily via the environment should be subject to any less scrutiny.

- Finally, to cope with the impossibility of micromanaging the diversity of hazards produced by modern technologies, the scale of preventive measures in the ecologic paradigm shifts from micromanagement of individual sources and substances to large classes of chemicals and the processes that produce them. Priority in environmental policy is given to those classes whose members tend to have the most hazardous qualities. Organohalogens and metallic pollutants are obvious choices for immediate action.

Based on these principles, the ecologic paradigm would require progressive reductions in the use of all synthetic chemicals—a gradual process to transform current industrial technology, with its countless individual hazards, into an economic base that is compatible with ecological processes. It is clear that safer alternatives exist already for most applications of POPs; although many require investment, they are economically and technically feasible.[1,85,86]

Implementation of the ecological paradigm involves a carefully planned process called "chemical sunsetting."[87] Sunsetting begins by reversing the onus for classes of chemicals and processes for which a prima facie case can be established that their members may be hazardous; members of these classes are treated as candidates for phase-out, and specific exceptions are made for uses that can be demonstrated non-hazardous to a reasonable degree of certainty or to fulfill an important need for which no alternative is available. The goal of environmental policy becomes zero discharge of these substances, and progress is made towards that goal by converting the sources of priority substances to cleaner materials and technologies.

Because the problem is global, the policy should be implemented on an international scale. And because persistent synthetic chemicals are used in a wide variety of industrial processes, the complete conversion to safer technologies will take decades. Chemical sunsets require priorities and timelines to be established, exceptions to be granted, and the safest and most effective substitutes to be chosen; these decisions should be made democratically and be specifically tailored to each nation or region, preferably through a transition planning board that is representative in its makeup and held accountable to the public at all stages of the process.

Some critics have argued that treating classes of substances from a precautionary perspective is radical and unscientific.[88,89] But in making public policy decisions, society always chooses the appropriate level of intervention. We do not try to address insect infestations by targeting individual bugs or traffic problems by regulating individual cars. In these cases, society has decided that it is more effective to focus on systemic causes rather than their individual manifestations, which are too numerous and dispersed to be micromanaged. Ozone-depleting compounds, PCBs, and lead compounds all represent chemical classes whose members have been addressed as together, based on a recognition of their common sources or their contributions to a common problem. Addressing all synthetic chemicals according to their broad classes would extend this precedent to a much larger group of substances. There are thousands of members of the class of organohalogens, for example: although most have not been well studied, virtually all of those that have been tested have turned out to be hazardous,[1,90] often at extremely low doses, and their hazardous qualities can be understood as the expected outcome of the impacts at the molecular level of halogenating organic substances.[1,91] For diverse and generally hazardous classes of chemicals such as this, macromanagement is well justified.

TOWARD GLOBAL ACTION

Although the risk paradigm dominates contemporary environmental policy, alternative approaches have been used in various times and places. Indeed, aspects of the ecological paradigm have been implemented on an ad-hoc basis, and these actions have been far more successful at reducing global pollution than risk-based regulations. For example, restrictions in many nations on the production and use of such pollutants as DDT, PCBs, and CFCs, and major uses of lead and mercury have led to drastic reductions in releases of these compounds, and environmental levels and human exposures have gradually followed suit. In contrast, permit and control regulations during the 1970s and 1980s yielded little or no decrease in the environmental concentrations of numerous major pollutants in the United States.[92]

More recently, the Swedish Government has instituted the Chemicals Action Programme,[93,94] which will phase out several dozen of the most hazardous solvents, pesticides, and bleaching agents. This program effectively implements the principles of clean production and zero discharge by changing the inputs of materials into such processes as agriculture, industrial cleaning and coating, and pulp bleaching. But because it focuses on a relative short list of individual substances, the Chemicals Action Program still addresses only a small fraction of the thousands of chemicals that pose potential health and environmental hazards. Moreover, for all its virtues, the program is national and cannot address the global distribution of POPs and their sources.

The most critical development in the present period is

unquestionably the negotiation of the POPs agreement, now in its final stages under the auspices of the United Nations Environmental Program. Because this instrument represents the first international action to stop the accumulation of persistent toxic substances in the global environment, it represents a significant step forward beyond the local and national efforts of the present. As currently conceived, however, the agreement is not nearly adequate to its task. First, it is unclear whether it will require releases of POPs—particularly those that are produced as accidental byproducts—to be eliminated at the source or simply reduced under a risk-based pollution-control approach. Further, the agreement addresses only 12 "priority" pollutants, and provisions for adding more chemicals to the list of targets at a future date are also a matter of controversy.

As I have shown here, the POPs treaty will effectively address global pollution only if it moves decisively away from the risk-based strategy of prediction, reduction, and control of single chemicals toward a preventive approach focused on converting industrial production systems to eliminate hazardous classes of chemicals entirely. There is no doubt that the very existence of an international instrument to confront toxic pollution on a global scale is a major step forward. The challenge now is to establish a conceptual and legal framework that can effectively and promptly address the thousands of hazardous substances not slated for action in the initial agreement.

References.

1. Thornton J. Pandora's Poison: Chlorine, Health, and a New Environmental Strategy. Cambridge, MA: MIT Press, 2000.
2. Colborn T, Dumanoski D, Myers JP. Our Stolen Future. New York: Dutton, 1996.
3. United Nations Environment Programme. Final Report: UNEP/POPS/INC.4/5—Report of the Intergovernmental Negotiating Committee for an International Legally Binding Instrument for Implementing International Action on Certain Persistent Organic Pollutants on the Work of Its Fourth Session; Bonn, 20–25 March 2000. Geneva, Switzerland, 2000.
4. Kuhn TS. The Structure of Scientific Revolutions. Chicago, IL: University of Chicago Press, 1970.
5. Covello VT, Merkhofer MW. Risk Assessment Methods: Approaches for Assessing Health and Environmental Risks. New York: Plenum, 1993.
6. Tatsukawa R, Tanabe S. Fate and bioaccumulation of persistent organochlorine compounds in the marine environment. In: Baumgartner DJ, Dudall IM (eds). Oceanic Processes in Marine Pollution. Vol 6. Malabar, FL: R. E. Krieger, 1990:39–55.
7. Allan R, Peakall D, Cairns V, et al. Toxic Chemicals in the Great Lakes and Associated Effects. Vol I: Contaminant Levels and Trends. Ottawa, ON, Canada: Environment Canada, 1991.
8. Gregor D, Gummer W. Evidence of atmospheric transport and deposition of organochlorine pesticides and polychlorinated biphenyls in Canadian Arctic snow. Environ Sci Technol. 1989;23:561–5.
9. Patton GW, Walla MD, Bidleman TF, Barrie LA. Polycyclic aromatic and organochlorine compounds in the atmosphere of northern Ellesmere Island, Canada. J Geophys Res. 1991;96 (D6): 10867–77.
10. Barrie L, Macdonald R, Bidleman T, et al. Chapter 2: Sources, occurrence and pathways. In: Jensen J, Adare K, Shearer R (eds). Canadian Arctic Contaminants Assessment Report. Ottawa, ON, Canada: Indian and Northern Affairs Canada, 1997.
11. Simonich SL, Hites RA. Global distribution of persistent organochlorine compounds. Science. 1995;269:1851–4.
12. Ono M, Kanna N, Wakimoto T, Tatsukawa R. Dibenzofurans: a greater global pollutant than dioxins? Evidence from analyses of open ocean killer whale. Marine Poll Bull. 1987;18:640–3.
13. Dewailly E, Ayotte P, Bruneau S, Laliberte C, Muir DCG, Norstrom RJ. Inuit exposure to organochlorines through the aquatic food chain in Arctic Quebec. Environ Health Perspect. 1993;101:618–20.
14. Norstrom RJ, Simon M, Muir DCG. Polychlorinated dibenzo-p-dioxins and dibenzofurans in marine mammals of the Canadian North. Environ Poll. 1990;66:1–19.
15. Great Lakes Water Quality Board. 1987 Report on the Great Lakes Water Quality. Windsor, ON, Canada: International Joint Commission, 1987.
16. Wester PG, Deboer J. Determination of polychlorinated terphenyls in biota and sediments with gas chromatography/mass spectrometry. Organohalogen Compounds. 1993;14:121–4.
17. Fuhrer U, Ballschmitter K. Bromochloromethoxybenzenes in the marine troposphere of the Atlantic Odean: a group of organohalogens with mixed biogenic and anthropogenic origin. Environ Sci Technol. 1998;32:3308–15.
18. Brun GL, Howell GD, ONeill HJ. Spatial and temporal patterns of organic contaminants in wet precipitation in Atlantic Canada. Environ Sci Technol. 1991;25:1249–61.
19. Glotfelty DE, Seiber JN, Lilhedahl LA. Pesticides in fog. Nature. 1987;325:602–5.
20. Goolsby D, Thurman EM, Pomes ML. Herbicides and their metabolites in rainfall: origin, transport and deposition patterns across the midwestern and northeastern United States, 1990–1991. Environ Sci Technol. 1997;31:1325–33.
21. DeLorey D, Cronn D, Farmer J. Tropospheric latitudinal distributions of CF2Cl2, CFC13, N20, CH3CCl3 and CCl4 over the remote Pacific Ocean. Atmos Environ. 1988;22:1481–94.
22. Makhijani A, Gurney KR. Mending the Ozone Hole. Cambridge, MA: MIT Press, 1995.
23. Plumacher J, Schroder P. Accumulation and fate of C2-chlorocarbons and trichloroacetic acid in spruce needles from an Austrian mountain site. Organohalogen Compounds. 1993;14:301–2.
24. Onstot J, Ayling R, Stanley J. Characterization of HRGC/MS Unidentified Peaks from the Analysis of Human Adipose Tissue. Vol I: Technical Approach. Washington, DC: U.S. Environmental Protection Agency Office of Toxic Substances (560/6-87-002a), 1987.
25. U.S. Environmental Protection Agency. Exposure and Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) and Related Compounds [review draft]. Washington, DC: U.S. EPA Office of Research and Development, 2000.
26. DeVito MJ, Birnbaum LS, Farland WH, Gasiewicz T. Comparisons of estimated human body burdens of dioxinlike chemicals and TCDD body burdens in experimentally exposed animals. Environ Health Perspect. 1995;103:820–31.
27. Tryphonas H. Immunotoxicity of PCBs (Aroclors) in relation to Great Lakes. Environ Health Perspect. 1995;103, suppl 9: 35–46.
28. U.S. Environmental Protection Agency. Chemical testing and information gathering. Washington, DC: U.S. EPA Office of Pollution Prevention and Toxics, 1998. Available at: <www.epa.gov/oppintr/chemtest/index.htm>.
29. Simmons JE. Nephrotoxicity resulting from multiple chemical exposures and chemical interactions. In: Yang RSH (ed). Toxicology of Chemical Mixtures. New York: Academic Press, 1994:335–60.
30. Hrelia P, Maffei F, Vigagni F, et al. Interactive effects between trichloroethylene and pesticdes at metabolic and genetic level in mice: mechanism-based predictions of interactions. Environ Health Perspect. 1994; 102, suppl 9: 31–4.
31. Oesch F, Oesch-Bartlomowicz, Arens J, et al. Mechanism-based predictions of interactions. Environ Health Perspect. 1994; 102, suppl 9: 5–10.
32. Daly AK, Cholerton S, Armstrong M, Idle JR. Genotyping for polymorphisms in xenobiotic metabolism as a predictor of disease susceptibility: mechanism-based predictions of interactions. Environ Health Perspect. 1994; 102, suppl 9: 55–62.
33. Mehendale HM. Amplified interactive toxicity of chemicals at nontoxic levels: mechanistic considerations and implications to public health: mechanism-based predictions of interactions. Environ Health Perspect. 1994; 102, suppl 9: 139–50.
34. van Birgelen APJM, Fase KM, van derk Kolk J, et al. Synergistic effect of 2,2',4,4',5,5'-hexachlorobiphenyl and 2,3,7,8-tetrachloro-

dibenzo-p-dioxin on hepatic porphyrin levels in the rat. Environ Health Perspect. 1996;104:550–7.
35. Germolex DR, Yang RSH, Ackermann MP, et al. Toxicology studies of a chemical mixture of 25 groundwater contaminants: immunosuppression in B6C3F mice. Fund Appl Toxicol. 1991;13:377–87.
36. Yang RSH. Toxicology of chemical mixtures derived from hazardous waste sites or application of pesticides and fertilizers. In: Yang RSH (ed). Toxicology of Chemical Mixtures. New York: Academic Press, 1994:99–117.
37. Daly HB, Stewart PW, Lunkenheimer L, Sargent D. Maternal consumption of Lake Ontario salmon in rats produces behavioral changes in the offspring. Toxicol Ind Health. 1998;14:25–38.
38. de Swart RL, Ross PS, Vos JG, Osterhaus ADME. Impaired immunity in harbour seals (*Phoca vitulina*) exposed to bioaccumulated environmental contaminants: review of a long-term feeding study. Environ Health Perspect. 1996;104, suppl 4: 823–8.
39. Reijnders PJH. Reproductive failure in common seals feeding on fish from polluted coastal waters. Nature. 1986;324:456–7.
40. Brouwer A, Reinjders PJH, Koeman JH. Polychlorinated biphenyl (PCB)-contaminated fish induces vitamin A and thyroid hormone deficiency in the common seal (*Phoca vitulina*). Aquat Toxicol 1989; 15:99–106.
41. National Research Council. Toxicity Testing: Strategies to Determine Needs and Priorities. Washington, DC: National Academy Press, 1984.
42. Roe D, Pease W, Florini K, et al. Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States. New York: Environmental Defense Fund, 1997.
43. Greisemer RA, Eustis SL. Gender differences in animal bioassays for carcinogenicity. J Occup Med. 1994;36:855–9.
44. Lucier GW, Schecter A. Human exposure assessment and the National Toxicology Program. Environ Health Perspect. 1998;106: 623–7.
45. World Meteorological Organization and United Nations Environmental Programme. Report of the Third Meeting of the Ozone Research Managers. Geneva, Switzerland: World Meteorological Organization, 1996.
46. Jarman WM, Simon M, Norstrom RJ, et al. Global distribution of tris(4-chlorophenyl)methanol in high trophic level birds and mammals. Environ Sci Technol. 1992;26:1770–4.
47. Lascombe I, Beffa D, Ruegg U, Tarradellas J, Wahli W. Estrogen activity assessment of environmental chemicals using in vitro assays: identification of two new estrogenic compounds. Environ Health Perspect. 2000;108:621–9.
48. Suntio LR, Shiu WY, Mackay D. A review of the nature and properties of chemicals present in pulp mill effluents. Chemosphere. 1988; 17:1249–90.
49. MacDonald RW, Ikonomou MG, Paton DW. Historical inputs of PCDDs, PCDFs, and PCBs to a British Columbia interior lake: the effects of environmental controls on pulp mill emissions. Environ Sci Technol. 1998;32:331–7.
50. Bonsor N, McCubbin N, Sprague J. Municipal Industrial Strategy for Abatement: Kraft Mill Effluents in Ontario. Toronto, ON, Canada: Environment Ontario, 1988.
51. U.S. Environmental Protection Agency. Background Document for the Development of PIC Regulations from Hazardous Waste Incinerators. Washington, DC: U.S. Environmental Protection Agency, Office of Solid Waste, 1989.
52. Wienecke J, Kruse H, Huckfeldt U, Eickoff W, Wasserman O. Organic compounds in the flue gas of a hazardous waste incinerator. Chemosphere. 1995;30:907–13.
53. Green AES, Wagner JC. toxic products of medical waste incineration. In: Green AES (ed). Medical waste incineration and pollution prevention. New York: Van Nostrand Reinhold, 1993:1–36.
54. Jay K, Stieglitz L. Identification and quantification of volatile organic components in emissions of waste incineration plants. Chemosphere. 1995;30:1249–60.
55. U.S. Environmental Protection Agency. Standards for owners and operators of hazardous wastes incinerators and burning of hazardous wastes and boilers and industrial furnaces; proposed and supplemental proposed rule, technical corrections, and request for comments. Fed Reg. April 27, 1990;55:82–211.
56. Onodera S, Ogawa M, Yamawaki C, Yamagishi K, Suzuki S. Production of polychlorinated phenoxyphenols predioxins by aqueous chlorination of organic compounds. Chemosphere. 1989;19:675–80.
57. Rappe C, Swanson S, Glas B, Kringstadt K, de Sousa P, Abe Z. Formation of PCDDs and PCDFs by the chlorination of water. Chemosphere. 1989;19:1875–80.
58. Stevens A, Moore L, Slocum C, Smith L, Seeger D, Ireland J. Byproducts of chlorination at ten operating utilities. In: Jolley RL, Condie LW, Johnson JD, et al. (eds). Water Chlorination: Chemistry, Environmental Impact and Health Effects, Vol 6. Chelsea, MI: Lewis, 1990:579–604.
59. Jolley RL. Basic issues in water chlorination: a chemical perspective. In: Jolley RL, Bull RJ, Davis WP, Jatz S, Roberts MH, Jacobs VA (eds). Water Chlorination: Chemistry, Environmental Impact, and Health Effects, Vol 5. Chelsea, MI: Lewis, 1985:19–38.
60. Amy G, Greenfield J, Cooper W. Correlations between measurements of organic halide and specific halogenated volatile organic compounds in contaminated groundwater. In: Jolley RL, Condie LW, Johnson JD, et al. (eds). Water Chlorination: Chemistry, Environmental Impact and Health Effects, Vol 6. Chelsea, MI: Lewis, 1990:691–702.
61. Ventresque C, Bablon G, Legube B, Jadas-Hecart A, Dore D. Development of chlorine demand kinetics in a drinking water treatment plant. In: Jolley RL, Condie LW, Johnson JD, et al. (eds). Water Chlorination: Chemistry, Environmental Impact and Health Effects. Vol 6. Chelsea, MI: Lewis, 1990:715–28.
62. U.S. Environmental Protection Agency. Ambient Water Quality Criteria Document: DDT. Washington, DC, 1980.
63. Rossberg M, Lendle W, Togel A, et al. Chlorinated hydrocarbons. In: Gerhartz W (ed). Ullman's Encyclopedia of Industrial Chemistry. 5th ed. New York: VCH Publishers, 1986: A6:233–398.
64. Environment Agency. Regulation of dioxin releases from the Runcorn operations of ICI and EVC. Warrington, U.K., 1997.
65. Dow Chemical. Waste Analysis Sheet: heavy ends from the distillation of ethylene dichlorine in ethylene dichloride production. Plaquemine, LA: Dow, February 21, 1990.
66. Alcock RE, Behnisch PA, Jones KC, Hagenmaier H. Dioxin-like PCBs in the environment—human exposure and the significance of sources. Chemisphere. 1998;37:1457–72.
67. Hutzinger O. Dioxin danger: incineration status report. Analyt Chem. 1986;586:633–42.
68. U.S. Environmental Protection Agency. The Inventory of Sources of Dioxin in the United States. Washington, DC: EPA, 1998.
69. Agency for Toxic Substances and Disease Registry. Public Health Statement: Lead, Atlanta, GA: U.S. Centers for Disease Control, 1990.
70. Lindqvist O, Johansson K, Aastrup M, et al. Mercury in the Swedish environment: recent research on causes, consequences and corrective methods. Water Air Soil Poll. 1991;55:1–32.
71. Pacyna JM, Munch J. Anthropogenic mercury emission in Europe. Water Air Soil Poll. 1991;56:51–61.
72. Fiedler H, Hutzinger O, Hosseinpour J. Analysis and remedial actions following an accidental fire in a kindergarten. Organohalogen Compounds. 1993;14:19–23.
73. Wynne B. Uncertainty and environmental learning. In: Jackson T (ed). Clean Production Strategies: Developing Preventive Environmental Management in the Industrial Economy. Boca Raton, FL: Lewis, 1993:63–84.
74. Kliewer SA, Lehmann JM, Willson TM. Orphan nuclear receptors: shifting endocrinology into reverse. Science. 1999;284:757–60.
75. Roughgarden J, May RM, Levin SA (eds). Perspectives in Ecological Theory. Princeton, NJ: Princeton University Press, 1989.
76. Theobald HM, Peterson RE. Developmental and reproductive toxicity of dioxins and other Ah receptor agonists. In: Schecter A (ed). Dioxins and Health. New York: Plenum, 1994:309–46.
77. Seegal RF, Schantz SL. Neurochemical and behavioral sequelae of exposure to dioxins and PCBs. In: Schecter A (ed). Dioxins and Health. New York: Plenum, 1994:409–48.
78. Landrigan PJ, Graham DG, Anger WK, et al. Environmental Neurotoxicology. Washington, DC: National Academy Press, 1992.
79. Rose G. Environmental factors and disease: the man made environment. BMJ. 1987;294:963–5.
80. Raffensperger C, Tickner J (eds). Protecting Public Health and the Environment: Implementing the Precautionary Principle. Washington, DC: Island Press, 1999.
81. International Joint Commission. Fifth Biennial Report on Great Lakes Water Quality. Windsor, ON, Canada, 1990.
82. Jackson T. Principles of clean production—an operational approach to the preventive paradigm. In: Jackson T (ed). Clean Production Strategies: Developing Preventive Environmental Management in the Industrial Economy. Boca Raton, FL: Lewis, 1993:143–64.

83. U.S. Environmental Protection Agency. Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes. Washington, DC: U.S. EPA Office of Pollution Prevention and Toxics (EPA/744-B-98-001), 1998.
84. O'Brien M. Making Better Environmental Decisions: An Alternative to Risk Assessment. Cambridge, MA: MIT Press, 2000.
85. Plimke E, Schessler R, Kaempf K. Konversion Chlorchemie. Wiesbaden, Germany: Prognos AG and Hessiches Umweltministerium, 1994.
86. Chem-Info Services. A Technical and Socio-Economic Comparison of Options to Products Derived from the Chlor-alkali Industry. Burlington, ON, Canada: Environment Canada, 1997.
87. International Joint Commission. Sixth Biennial Report on Great Lakes Water Quality. Windsor, ON, Canada, 1992.
88. Willes RF, Nestmann ER, Miller PA, Orr JC, Munro IC. Scientific principles for evaluating the potential for adverse effects from chlorinated organic chemicals in the environment. Regul Toxicol Pharmacol. 1993;18:313–56.
89. Karol MH. Toxicological principles do not support the banning of chlorine. Fund Appl Toxicol. 1995;24:1–2.
90. American Public Health Association. Resolution 9304: Recognizing and addressing the environmental and occupational health problems posed by chlorinated organic chemicals. Am J Public Health. 1994; 84:514–15.
91. Henschler D. Toxicity of chlorinated organic compounds: effects of the introduction of chlorine in organic molecules. Angewandte Chemie Int Edi. 1994;33:1920–35. [In English]
92. Commoner B. Making Peace with the Planet. New York: Pantheon, 1990.
93. Wahlstrom B, Lundqvist B. Risk reduction and chemicals control—lessons from the Swedish chemicals action programme. In: Jackson T (ed). Clean Production Strategies: Developing Preventive Environmental Management in the Industrial Economy. Ann Arbor, MI: Lewis, 1993:237–60.
94. Swedish Ministry of the Environment. Sweden's offensive policy on chemicals (Factsheet 6.1). Stockholm, Sweden, 1998.
95. Montzka SA, Butler JH, Elkins JW, Thompson TM, Clarke AD, Lock LT. Present and future trends in the atmosphere burden of ozone-depleting halogens. Nature. 1999;398:690–4.
96. Cortes DR, Basu I, Sweet CW, Brice KA, Hoff RM, Hites RA. Temporal trends in gas-phase concentrations of chlorinated pesticides measured at the shores of the Great Lakes. Environ Sci Technol. 1998;32:1920–7.
97. Jeffers P, Ward L, Woytowitch L, Wolfe N. Homogenous hydrolysis rate constants for selected chlorinated methanes, ethanes, ethenes and propanes. Environ Sci Technol. 1989;23:965–9.
98. National Library of Medicine. Hazardous Substances Databank (online database). Available at: <www.toxnet.nlm.nih.gov>.
99. Rappe C, Kjeller LO, Kulp SE. Levels, profile and pattern of PCDDs and PCDFs in samples related to the production and use of chlorine. Chemosphere. 1991;23:1629–36.
100. Oehme M, Mano S, Bjerke B. Formation of poly-chlorinated dibenzofurans and dibenzo-p-dioxins by production processes for magnesium and refined nickel. Chemosphere. 1989;18:1379–89.
101. Hutzinger O, Fiedler H. Formation of Dioxins and Related Compounds in Industrial Processes. Pilot Study on International Information Exchange on Dioxins and Related Compounds #173. Brussels, Belgium: NATO Committee on the Challenges of Modern Society, 1988.
102. Heindl A, Hutzinger O. Search for industrial sources of PCDD/PCDF: III. Short-chain chlorinated hydrocarbons. Chemosphere. 1987;16:1949–57.
103. Rappe C, Marklund S. Formation of polychlorinated dibenzo-p-dioxins and dibenzofurans by burning or heating chlorophenates. Chemosphere. 1978;8:269–81.
104. Marklund S, Anderson R, Rappe C, et al. Emissions of PCDDs and PCDFs in gasoline and diesel fueled cars. Chemosphere. 1990; 20:553–61.
105. Oberg LG, Wagman N, Andersson R, Rappe C. De novo formation of PCDD/F in compost and sewage sludge—a status report. Organohalogen Compounds. 1993;11:297–302.
106. Baker J, Hites R. Is combustion the major source of polychlorinated dibenzo-p-dioxins and dibenzofurans to the environment? A mass balance investigation. Environ Sci Technol. 2000;34:2879–86.

Announcement

The Collegium Ramazzini celebrated the 300th anniversary of the publication of Ramazzini's *De Morbis Artificum Diatriba* at its annual meeting in Carpi, Italy, on October 27–29, 2000. The celebration was followed by meetings discussing "Present Priorities in Occupational Carcinogenesis."

The Ramazzini Award, occupational medicine's most prestigious recognition, was presented by the Collegium Ramazzini to Dr. Eula Bingham, of the University of Cincinnati. Dr. Bingham presented the Ramazzini Lecture, "The Regulation of Carcinogens: The History and the Future."