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### The Precautionary Principle in Environmental Science

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Environmental scientists play a key role in society's responses to environmental problems, and many of the studies they perform are intended ultimately to affect policy. The precautionary principle, proposed as a new guideline in environmental decision making, has four central components: taking preventive action in the face of uncertainty; shifting the burden of proof to the proponents of an activity; exploring a wide range of alternatives to possibly harmful actions; and increasing public participation in decision making. In this paper we examine the implications of the precautionary principle for environmental scientists, whose work often involves studying highly complex, poorly understood systems, while at the same time facing conflicting pressures from those who seek to balance economic growth and environmental protection. In this complicated and contested terrain, it is useful to examine the methodologies of science and to consider ways that, without compromising integrity and objectivity, research can be more or less helpful to those who would act with precaution. We argue that a shift to more precautionary policies creates opportunities and challenges for scientists to think differently about the ways they conduct studies and communicate results. There is a complicated feedback relation between the discoveries of science and the setting of policy. While maintaining their objectivity and focus on understanding the world, environmental scientists should be aware of the policy uses of their work and of their social responsibility to do science that protects human health and the environment. The precautionary principle highlights this tight, challenging linkage between science and policy. Key words: environmental science, foresight, planning, precaution, risk assessment, science policy. Environ Health Perspect 109:871-876 (2001). [Online 15 August 2001] http://ehpnet1.niehs.nih.gov/docs/2001/109p871-876kriebel/abstract.html

There are few pressing social issues that depend as heavily on scientific information as do environmental problems. Most scientists and policy makers agree on the importance of science in environmental policy debates, even when they can agree on almost nothing else about the health of the ecosphere. Thus, environmental scientists play a key role in society's responses to environmental problems, and many of the studies performed by environmental scientists are intended ultimately to affect policy. The precautionary principle has been proposed as a new guideline in making environmental policy (1,2). In this paper we examine the implications of the precautionary principle for environmental scientists. Specific objectives are to define the precautionary principle and illustrate it through three brief examples; identify aspects of conventional science that may inhibit precautionary policies; identify new directions for scientific research that would better inform precautionary policies; and promote dialogue among environmental scientists about the usefulness and potential applications of the precautionary principle.

## **Definition of the Precautionary Principle**

A 1998 consensus statement characterized the precautionary 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" (3). The statement went on to list four central components of the principle: taking preventive action in the face of uncertainty; shifting the burden of proof to the proponents of an activity; exploring a wide range of alternatives to possibly harmful actions; and increasing public participation in decision making.

The term "precautionary principle" came into English as a translation of the German word Vorsorgeprinzip. An alternative translation might have been "foresight principle," which has the advantage of emphasizing anticipatory action—a positive, active idea rather than precaution, which to many sounds reactive and even negative. Although the principle has its roots in German environmental policy, over the past 20 years it has served as a central element in international environmental treaties addressing North Sea pollution, ozone-depleting chemicals, fisheries, climate change, and sustainable development (3). Precaution is one of the guiding principles of environmental laws in the European Union.

## The Precautionary Principle in Practice

#### **Historical Links**

The precautionary principle encourages policies that protect human health and the environment in the face of uncertain risks. In this broad sense it is not a new concept, and some may object to giving it a new name, when similar ideas go by different names in other disciplines. For example, public health practitioners use the term primary prevention to mean much the same thing. The physician's obligation to first do no harm is a precautionary approach to treating a sick person. The governments of several Scandinavian countries have made regulatory decisions about electromagnetic fields and other hazards using a concept called prudent avoidance, which is also similar  $(4, \hat{5})$ . The term precautionary principle has the advantage that it provides an overarching framework that links environmental sciences and public health.

#### **Motivating Factors**

The precautionary principle has arisen because of the perception that the pace of efforts to combat problems such as climate change, ecosystem degradation, and resource depletion is too slow and that environmental and health problems continue to grow more rapidly than society's ability to identify and correct them. In addition, the potential for catastrophic effects on global ecologic systems has weakened confidence in the abilities of environmental science and policy to identify and control hazards. There are also the apparent contradictions of our regulatory process: if the laws governing toxic chemical

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release are effective, then why are mercury levels in freshwater fish so high that pregnant women should not eat them (6,7)? How is it possible that human breast milk may not meet U.S. Food and Drug Administration contaminant limits for baby food (8,9)?

The great complexity, uncertainty, and potential for catastrophe from global climate change are among the strongest motivators for those urging precaution in environmental policy. The earth warmed over the twentieth century by an estimated 0.6°C (10). The trend was not uniform, though, and warming is occurring faster during the winter and at night (11), and the winter warming is occurring faster at high latitudes than near the tropics (12). For human populations, the rates of change and wide swings in weather are of chief concern, as ice core records indicate that increased climatic variability may be associated with rapid climate change events and changes in the ocean thermohaline circulation (13). Together, warming and more extreme weather have begun to alter marine life and the weather patterns that affect infectious diseases, their vectors, and hosts. The unprecedented scale of this hazard justifies reexamination of environmental monitoring systems and paradigms (14).

Frustration with policy concerning toxic chemicals has also stimulated interest in the precautionary principle. The risk assessment process is perceived by a growing segment of the population as antagonistic to strong environmental protection and as excessively complex and full of hidden assumptions that have the effect of disenfranchising all but the experts from the decision-making process. Current U.S. environmental policy often seems to be more reactionary than precautionary, requiring a high degree of certainty of harm before preventive action is taken, and emphasizing the management of risks rather than their prevention. The precautionary principle, by calling for preventive action even when there is uncertainty, by placing the onus on those who create the hazard, and by emphasizing alternatives and democracy, is viewed by environmentalists as a way to shift the terms of the debate and stimulate change.

Points of opposition. A lively debate is now underway about the usefulness of the precautionary principle (15–20). Perhaps the most frequently voiced criticisms are a) current regulatory procedures are already precautionary; for example, the safety factors used in risk assessments insure precaution; b) the precautionary principle is not scientifically sound because it advocates making decisions without adequate scientific justification; and c) if it were implemented, the precautionary principle would stifle innovation by requiring proof of safety before new technologies could be introduced. Each of these concerns has

been addressed by proponents of the principle (21–23), and this article is not intended as a comprehensive response to critics. The objective instead is to discuss the implications of the precautionary principle for the work of environmental scientists.

#### **Case Illustrations**

Cellular telephones in airplanes. When the flight attendant explains the safety procedures before takeoff, there is an instruction not to use various electronic devices during takeoff and landing and not to use cellular telephones any time during flight. There is some very limited (anecdotal) evidence that these devices may interfere with the essential navigational and control systems of the aircraft. In 1999, in response to inquiries about the necessity of this ban, the U.S. Federal Aviation Administration (FAA) commissioned a study to gather stronger evidence for or against the hypothesis that consumer electronic devices interfere with aircraft functions (24). The study failed to find any evidence of this interference. Nevertheless, the FAA ruled that, in the absence of strong evidence of safety, the ban would continue in effect. Most people agree that the inconvenience of not being able to talk on the phone in flight is offset by even a small risk of an airplane crash. This illustrates the first component of the principle: taking action in the face of uncertainty. The second aspect of precaution deals with burdens of proof, and here, too, there would probably be little controversy. Most would agree that those who would change the rule on cellular telephone use in flight should have the responsibility to show that the change will not cause unreasonable risk. But suppose concerns about portable electronic devices in airplanes had not been raised initially, and so airline passengers were currently using their cellular telephones in flight. Now suppose that a few isolated malfunctions occurred in the navigational systems of a small number of aircraft while cellular telephones were in use, and concerns were raised. Should cell phone use be banned? At that point there would be a quantifiable economic loss from ending the practice. It seems quite likely that implicitly or explicitly a cost-benefit analysis would be run, and to do this, it would be necessary to estimate the risk—something that would be, and is, very hard to do with any confidence. Some might call this approach more "science based," but it would be a highly uncertain process, and one in which the risks being evaluated might be very small, but the consequences potentially catastrophic. Fortunately, the way events have actually unfolded, it is not necessary to estimate the risk-precautionary action was taken. The availability of an economically viable alternative (in-flight telephones) may have made it easier to act in the absence of strong evidence, which highlights the potential for the precautionary principle to stimulate the search for safer technologies.

Pesticides in schools. Recently the Los Angeles Unified School District, the largest public school system in the United States, announced a new policy on the use of pesticides in schools (25). The policy states unambiguously that pesticides pose risks to the health of children and the environment, that they shall be used only after nonchemical methods have been considered, and that if there is a choice among pest control methods, the least harmful one shall be chosen. There is no mention of balancing risks and benefits, nor a list of banned substances. The precautionary principle is a long-term objective of the policy, according to its authors. Critics worry that the precautionary principle will encourage technology choices based on fear and emotions, rather than on science. But another interpretation would be that the Los Angeles Unified School District is saying that all pesticides should be assumed to be hazardous, while acknowledging a great deal of uncertainty about exactly how hazardous. The intention to prefer nonchemical methods and to choose the least toxic method encourages a search for alternatives, while at the same time not preventing the use of a toxic chemical if it is found to be necessary and irreplaceable. The new policy also requires consideration of the service or function that a pesticide provides. For example, a pesticide being used for aesthetic purposes may be determined to be less important than one that serves a hygienic function. The former may be more readily eliminated than the latter, if no alternative can be found.

Polyvinyl chloride toys. Polyvinyl chloride (PVC) is an extremely versatile material, made into thousands of products. By adding varying amounts of a chemical called a plasticizer, the pliability of PVC can be modified from hard and brittle to soft and almost spongy. There is evidence that several of the plasticizers, members of the phthalate chemical family, are reproductive toxicants in animals. They may also cause reproductive toxicity in humans, although this evidence is quite limited (26-28). Until 1999, many PVC plastic toys specifically designed to be sucked and chewed contained the plasticizer diisononyl phthalate. Many of the manufacturers of toys that formerly contained this chemical have now voluntarily stopped using this plasticizer, or in some instances completely phased out PVC in these toys, in response to consumer and government concerns about toy safety. But the evidence for human health risks is weak and uncertain. Producers of PVC products have argued that there is no evidence of harm from use of their products, given 40 years of use without apparent ill effects.

There is a flaw in this reasoning, however, because the absence of evidence of harm is not the same thing as evidence of the absence of harm. Of course, absolute safety can never be proven. But a lengthy and costly risk assessment, followed by an equally lengthy and acrimonious risk management process would be the likely outcome of the present one-substance-at-a-time approach to chemicals policy.

The precautionary principle seeks to minimize the limitations of a risk assessmentbased regulatory policy by encouraging a search for alternatives whenever a potentially hazardous chemical is identified. If a clearly safer alternative exists, why accept even a small, highly uncertain risk? The Danish Environment Agency used just this logic in taking action to eliminate phthalates from toys (29). They said, in essence, that there is exposure to these compounds, there is animal toxicity data, the exposure is to children who by definition are particularly susceptible to many toxic substances, there are alternatives, and the product serves no necessary function. Considering all these factors, they concluded that the plasticizer should not be used in toys.

#### Limitations of Conventional Scientific Methods

Environmental scientists study highly complex, poorly understood systems. Often the most informative experiments cannot be conducted for logistical or ethical reasons (there is only one Atlantic Ocean to study; potential carcinogens cannot be administered to humans in double-blind trials). At the same time, this work is of great interest to those who seek to balance economic growth and environmental protection. In this complicated and contested terrain, it is useful to examine the methodologies of science and to consider ways that, without compromising integrity and objectivity, research can be more or less helpful to those who would act with precaution. It would, for example, be useful to policy makers if scientists were more explicit about the limits of knowledge and about the nature and amount of uncertainty in research findings.

Presented below are examples of the ways that science is currently conducted that may make it more difficult to set precautionary policies. There may be alternatives to these methods, well within the bounds of good practice, that would be more helpful to policy makers faced with high-stakes decisions and great scientific uncertainty.

#### **Hypothesis Formulation**

Einstein said that the theory decides what can be observed, and at the more practical level, the formulation of specific research hypotheses determines to a large degree the sorts of results that can be found. Where does the particular formulation of a hypothesis come from? Often the hypothesis is formulated in a way that is feasible to test with the time and resources available. There is also a tendency for researchers to refine understanding of old problems rather than risk investigating new ones (30). Greater and greater levels of detail are sought about well-defined problems, rather than the higher stakes enterprise of searching for entirely new phenomena. For example, we refine understanding of the mechanisms of toxicity of asbestos, lead, and polychlorinated biphenyls, rather than evaluating effects of other, less well-studied toxicants. Funding agencies and skeptical peer reviewers reinforce this tendency by favoring tightly focused proposals that repeat or incrementally build upon work in wellestablished areas.

#### Emphasis on Independent Effects, Not Interactions

There is a tendency to assume that the mechanisms underlying the phenomena being studied are driven primarily by the independent actions of a few causal factors. If they interact, this is assumed to be of secondary importance. This implicitly assumes that things are not connected and leads to an atomized worldview. In reality, complex biological systems such as ecosystems, human populations, or individual physiology are composed of feedback loops and other interactions which make cause-effect relationships far from direct or linear. But many times the effects of hypothesized causal factors are considered in research to be decomposable into additive components that are measured individually. For example, when studying a mixture of pollutants, the emphasis is on identifying which component of the mixture is problematic. Interactions are difficult to study, but this should be seen as a challenge to develop more sensitive and complex methods, rather than as an inherent limitation of science.

#### Narrow Definition of Uncertainty

The formal evaluation of error or uncertainty in many environmental science papers is limited to a presentation of *p*-values or confidence intervals for the main results. Beyond this, there may be a qualitative examination of limitations of the findings, which is relegated to the discussion section at the end of the paper. The standard *p*-values and confidence intervals indicate the magnitude of potential error in the statistical parameter estimates due strictly to sampling variability. But in observational studies of complex, poorly understood systems, this may be the least important

source of uncertainty. Potentially more important are errors in the independent variables, errors arising from choice of the wrong form for the model(s) used to analyze and interpret the data, and biases from problems in the conduct of the study.

For example, a study of the effects of an environmental contaminant on reproductive success in fish would typically report the amount of sampling error around the final estimate of the degree of association found between the contaminant and the measure of reproductive behavior. But this would typically not take into consideration the error in measuring the levels of the contaminant in the fish or in the environment and would not investigate the sensitivity of the findings to the choice of statistical models used to link exposure with reproductive outcome.

It is sometimes argued that scientists are trained to read papers critically and that they are able to factor in these other sources of uncertainty in their evaluation of a study. But applied scientists are also communicating to nonscientists who may mistakenly take the limited characterization of sampling error as the best estimate of all the uncertainty.

#### **Setting Type I and Type II Error Rates**

Errors due to sampling variability are routinely quantified. However, standard practice has led to a conservatism that perhaps hinders precautionary action. When a scientific investigation is designed to test a hypothesis, there are two kinds of errors that one seeks to minimize. A Type I error is the mistake of concluding that a phenomenon or association exists when in truth it does not. (Technically, the Type I error is rejecting the null hypothesis when it is really true. The paraphrasing above, while valiantly railed against by statistics teachers everywhere, is the way it is thought of in everyday practice.) By convention, Type I (or alpha) errors are guarded against by setting that error rate low, usually at 5%. In other words, the finding must be so strong that there is less than a 5% probability that this result would have been seen by chance alone in a world in which no such phenomenon actually exists. In this case the result is called statistically significant (with the clear implication that one is supposed to believe it). The Type II error, failing to detect something that actually does exist, is, by convention, often set at 20% (although practical limitations of sample size often result in a substantially higher or lower Type II error). Twenty percent of the time, a real phenomenon will be missed because the data were not strong enough to convincingly demonstrate its existence. There is an implicit bias here: the test is set up to be more cautious about falsely detecting something than about failing to detect something. Should Type I and Type

II error rates be set explicitly and *a priori*, depending on the purposes that the study is meant to serve? Bayesian statistical methods promise a way out of these conundrums by shifting the focus from formal testing to calculating the weight of evidence provided by a particular study and the degree to which this study should shift *a priori* beliefs. At present, Bayesian methods are little used in practice, but research to make them more accessible and practical is now under way (31–33).

#### **Type III Errors**

A Type III error occurs when one provides an accurate answer to the wrong problem (34). The cliche about looking under the street light for the keys lost down the block (because the light is better there) comes to mind to illustrate this common problem. To some degree, this is another aspect of hypothesis formulation discussed above. Citizen groups who ask a scientist for help with a particular environmental concern frequently experience the consequence of Type III errors. The citizens have a broad concern about, for example, potential health effects of a power plant in the neighborhood. The scientist hears the concern, and translates it into a problem that he or she is able to solve with the tools at hand, such as, do the power plant emissions exceed current health standards? This translation almost inevitably narrows the focus to something manageable and solvable. But often the citizens are frustrated with the results because scientitsts did not adequately address the initial concerns. On the other hand, the scientist is puzzled or, worse, concludes that the citizens are "antiscience."

#### **Disciplinary Divisions**

The citizens group's concerns about the power plant would probably be better addressed by an interdisciplinary investigation, using a wide variety of different methods and looking for an integrated understanding of the facility's impacts. Traditional boundaries between academic disciplines make it difficult to bring together the broadest possible set of research tools; combining for example quantitative and qualitative methods.

#### Scientific Methods to Inform Precautionary Policy

As noted at the beginning of this paper, science plays a critical role in environmental policy by providing insights into the normal functioning of natural systems and the ways they are disrupted by technologies and other human activities. Environmental scientists use a wide variety of methods, and these are to a large degree determined by the problem at hand. In some fields, prediction is an essential part of scientific proof. In others, it is useless or impractical. The simple accumulation of

confirming cases is of no use in fields that hold to a high standard of mathematical proof, and in some disciplines controlled experiments are essential. But in many environmental sciences where observational studies are the rule, experiments are often infeasible or unethical, and it is impractical to wait to see if predictions are borne out. Other types of evidence are used, and usually sufficient proof for action comes from the accumulation of plausible inference from independent lines of work. For instance, environmental causes of cancer may be identified from the geographic distributions of cancers; time trends in cancer frequency; the occurrence of cancers in highly exposed working populations; animal experiments; and experimental knowledge of chemical pathways of cancer induction. And once it is demonstrated that a particular molecule is carcinogenic, similar molecules are at least suspect. Any one line of argument is imperfect, and fault can be found with the details of most separate methods. It is the preponderance of evidence that finally prevails. It is never easy to determine the moment in this process when there is sufficient evidence to act as if a causal connection exists, but scientists can and should play an important role in this decision, as they are the ones who know the data and the methods best.

A shift to more precautionary policies creates opportunities and challenges for scientists to think differently about the way they conduct studies and communicate results. The following paragraphs briefly summarize some of the positive implications that such a policy shift might have for the conduct of science.

#### What Is Studied

There is a great need for better methods to study whole systems and the interactions of various causal factors. The cumulative and interactive effects of multiple insults on an organism or ecosystem are very difficult to study. There are often many levels of a system (individuals, families, communities, nations), and hazards often exert effects at multiple levels. Current methods in many disciplines are not well suited to such investigations.

As noted above, multidisciplinary teams will be more likely to find new ways to frame hypotheses that lead to insights not possible from narrow disciplinary viewpoints. The recent recognition of the problem of endocrine disruption provides an example. A review of many different types of evidence on the effects of persistent pollutants on wildlife in the Great Lakes led to the hypothesis that a common mechanism of action might be causing a variety of reproductive and developmental effects (35,36). Because of the fragmentation of scientific disciplines, no single researcher was able to develop a coherent

hypothesis. An interdisciplinary conference (35) provided the opportunity for many different fields to meet and share insights. The conference organizers summarized the outcome (35):

so shocking was this revelation [about the widespread observation of endocrine disruption in wildlife] that no scientist could have expressed the idea using only the data from his or her discipline alone without losing the respect of his or her peers.

#### Research Methods

Uncertainty is a positive aspect of knowledge because it clarifies what is known and unknown and thus stimulates further investigation. But there is also a strong desire on the part of scientists to be precise. This may result from a confusion of uncertainty of information with quality of information; but the two concepts are distinct (37). It is possible to produce high-quality information about greatly uncertain phenomena. Most scientists are aware that their p-values and confidence intervals do not fully capture all of the likely error in their results, but standard methods do not exist for characterizing other aspects of uncertainty. There is a great need for research to find ways to characterize, express, and communicate uncertainty. Scientists develop intuition or professional judgment about the strength of a particular result. The Bayesian view of statistical inference, an increasingly popular alternative to standard frequentist methods, acknowledges that we have beliefs about the phenomena under study and seeks to formalize the role these play in the way we view our data (32). The role of data, according to this perspective, is to shift our a priori beliefs about the phenomena under study. Strong results may shift beliefs a lot, producing a posterior probability that may be far from the prior probability that the researcher had assigned to the hypothesis before conducting the research. But weak data will have little impact, leaving posteriors close to priors. There is increasing awareness that Bayesian statistical methods correspond more closely to common approaches to logical inference in everyday life. Methods development work is still needed in most fields, however, before Bayesian statistics can be routinely applied.

Uncertainties that derive from the choice of research methods and mathematical models should also be more fully investigated and discussed. Formal sensitivity analyses in which the investigator assesses the degree to which results are changed by using different assumptions or analytic methods should become standard practice (38).

Current methods seldom encourage a search for patterns within noisy data and "clusters of clusters" of similar effects in different species. Conservation medicine is a new academic initiative that links human and animal health with ecosystem health and global change (39). It begins from the premise that the health of ecosystems is directly related to the health of species, including humans. The initiative arose from a growing understanding that human impacts on ecosystems were multiple and integrated. Conservation medicine uses interdisciplinary teams of veterinary and medical health professionals to develop a greater understanding of the ecological context of health and advance biodiversity conservation and ecosystem health.

If society chooses to act with incomplete information, it must be acknowledged that one kind of risk is being accepted to avoid another. One risk being accepted is that the policy choice may have been wrong. Fortunately, the effects of a policy can often be evaluated for beneficial or detrimental unintended consequences. Thus a strong environmental monitoring program and formal evaluations of the interventions or controls are essential parts of a policy of precaution (40).

Despite the need for more and better systems research, it remains true that much useful information is learned by taking a system apart and testing its components. The development of new approaches should supplement current scientific methods, not replace them. There is also an important role for those who can synthesize the results of the work of many disparate disciplines to reach insights not possible by the individual researchers. This has been called "joining edge" research (as opposed to "cutting edge").

#### Conclusions and Recommendations

It is important to clearly distinguish between the development of scientific information about an issue and the setting of policy, but in practice, there is not always an unambiguous demarcation. Policy makers set agendas that determine the questions asked of scientists; scientists formulate hypotheses in ways limited by their tools and their imaginations; thus, the information they provide to the policy makers is limited and to a degree socially determined. There is a complicated feedback relation between the discoveries of science and the setting of policy. While maintaining their objectivity and focus on understanding the world, environmental scientists should be aware of the policy uses of their work and of their social responsibility to do science that protects human health and the environment (14). The precautionary principle highlights this tight, problematic linkage between science and policy, which can be summarized in the following seven points:

- Scientific studies can tell us something about the costs, risks, and benefits of a proposed action, but there will always be value judgments that require political decisions.
- The scientific data used for making policy will nearly always be limited by uncertainty. Even the best theory and data will leave much that is not known about estimates of risks, benefits, or costs.
- 3. In conducting their research, scientists must make assumptions, choices, and inferences based on professional judgment and standard practices, that if not known by the public or policy makers, may make scientific results appear to be more certain and less value laden than is warranted.
- 4. Although there are some situations in which risks clearly exceed benefits no matter whose values are being considered, there is usually a large gray area in which science alone cannot (and should not) be used to decide policy.
- 5. In these gray areas, status quo activities that potentially threaten human and environmental health are often allowed to continue because the norms of traditional science demand high confidence in order to reject null hypotheses, and so detect harmful effects.
- 6. This scientific conservatism is often interpreted as favoring the promoters of a potentially harmful technology or activity when the science does not produce overwhelming evidence of harm.
- 7. The precautionary principle, then, is meant to ensure that the public good is represented in all decisions made under scientific uncertainty. When there is substantial scientific uncertainty about the risks and benefits of a proposed activity, policy decisions should be made in a way that errs on the side of caution with respect to the environment and the health of the public.

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