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A Healthy Ecosystem

Definitions of the Precautionary Principle are evolving. An early one: In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities.

Do No Harm: The Precautionary Principle

Precautionary approaches to public health have a long history. The father of the precautionary approach is Hippocrates, who said, "As to diseases, make a habit of two things: to help, or at least to do no harm."

Precautionary actions have been a cornerstone of public health. For example, the physician John Snow mapped cases of London's cholera epidemic of the mid-1800s. He observed that most cases of cholera were grouped around dwellings that used a certain well for drinking water. Until then it was thought that diseases were only transmitted in the air. The possibility of water transmission was hotly debated. While the organism that caused cholera was not identified for another 30 years, the removal of the handle at the Broad Street pump was a precautionary action by Dr. Snow that had a major impact on halting the 1854 cholera epidemic in the Soho district of London.

Origins of the Modern Precautionary Principle

In more modern times, the origins of the Precautionary Principle can be traced to Germany's emerging environmental movement of the 1970s. "Precautionary Principle" is actually the English translation of the German phrase "Vorsorgeprinzip," and the direct translation is "Foresight Principle." There is no one definition of the Precautionary Principle; one of the early definitions was drafted in 1992 at the United Nations Rio Conference on the Environment and Development:

"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, full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Definitions of the Precautionary Principle continued to evolve. A conference that had a major impact on redefining the Precautionary Principle was the 1998 Wingspread Conference held in Racine, Wisconsin. The 32 participants at the conference included scientists, lawyers, treaty negotiators, and activists from the United States, Canada and Europe. The participants drafted statements calling on policy makers, corporations, scientists, and communities to implement Precautionary Principles in making decisions affecting the environment. The principles they drafted at the end of the three-day conference included:

- "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."

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The Precautionary Principle

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The Wingspread Conference added the elements of *reversing the burden of proof* (the "polluter pays" principle), as well as the importance of *open dialogue* and the *democratic process in decision-making.* Another new concept was the *full exploration of alternatives.* The importance of planning and considering alternatives in the decision making process is closer to the original German concept of the "foresight" principle.

Predicting Hazards to Humans

Scientists use a variety of tools to predict hazards in people. One example of harm or irreversible damage detected in laboratory animals before there was "proof" of harm in humans was data on the chemical vinyl chloride. Years before a similar type of liver tumor was observed in plastic manufacturing workers exposed to high levels of vinyl chloride, a rare type of liver tumor was identified in controlled laboratory animal studies.

The National Toxicology Program still oversees a variety of short and long term studies in laboratory animals used to identify potential chemical hazards in humans. Of the 509 chemicals tested so far, 42 (8%) have been identified as causing mammary (breast) tumors in control laboratory animal cancer bioassays.

Court Rulings

Policy makers and regulatory agencies in the United States have had a strong history of precautionary approaches to protect public health even when there is scientific uncertainty of a cause and effect. Unfortunately for our nation's children, the phaseout of lead in gasoline was too long in coming. From 1922 to 1985 more than 15.5 billion pounds of lead were used as a gasoline additive in the United States. With the phaseout of lead in gasoline in the 1970-80s, lead levels in air had been reduced by 80% by the 1990s. But lead still persists in soil since it does not degrade. Public health scientists had testified and protested the use of lead in gasoline as early as 1925. One of the leading public health scientists of that time, Dr. Thompson of the US Public Health Service had stated, "…lead has no business in the human body....Everyone agrees lead is an undesirable hazard and the only way to control it is to stop its use by the public."

Nearly 60 years later we are still struggling with how very low levels of lead affect the body's immune system and cognitive development in children. However, the push to use lead in gasoline in the 1920s was made under the guise of global competitiveness and the industrial supremacy of the United States. We, our children, and generations to come, will pay the price for the decision to use lead in gasoline for more than 50 years.

For the protection of our children's health, the American Public Health Association (APHA) affirmed its endorsement of the Precautionary Principle as a cornerstone of public health. In a 2000 policy statement, the APHA encouraged governments, the private sector and health professionals to promote and use the Precautionary Principle to protect the health of developing children.

US Federal Agencies Take Precautionary Approaches

Examples of landmark federal legislation using a precautionary approach include the Food, Drug and Cosmetic Act. This law requires pharmaceutical manufacturers to demonstrate safety of the drug prior to market approval by the Food and Drug Administration (FDA). The 1970 Occupational Safety and Health Act requires employers to provide workplaces free from recognized hazards.

The EPA requires pesticide manufacturers to submit the results of animal cancer bioassays prior to registration approval to determine if the pesticide is a cancer hazard. Unfortunately, there is a lack of transparency in this process. The cancer bioassay reports are submitted to the EPA, but remain the property of the manufacturer. The results of the reports are rarely published in the open scientific literature, and often can only be obtained though the tedious process of a Freedom of Information Act request. But since proprietary (trade secret) information can be found in the reports, the manufacturer retains the right to edit (black out) parts before they are released if copies are requested under the Freedom of Information Act. While some requests have quick turnaround of one to three months, Breast Cancer and Environmental Risk Factors program staff have waited up to 18 months to get copies of reports evaluating the cancer-causing potential of certain pesticides.

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Criticisms of the Precautionary Principle

Opponents of the Precautionary Principle have argued that many US federal agencies already use a precautionary approach and that we have a history of environmental legislation with a precautionary approach. There are important elements that have been introduced into environmental legislation—including adding extra safety factors—when setting limits on certain chemicals. For instance, an extra 10-fold safety factor can be used when setting maximum levels of pesticide residues, called tolerances, on food.

Much of chemical regulatory policy in the United States is based on a more traditional risk assessment procedure where harm must be proven before a chemical is removed from the manufacturing stream, and steps are then taken to mitigate the risk by limiting exposures. This approach can result in a very lengthy risk assessment procedure that can delay policy decisions. It also does not have the advantage of

Chemical regulatory policy in the United States is based on a more traditional risk assessment procedure where harm must be proven before a chemical is removed from the manufacturing stream, and steps are then taken to mitigate the risk by limiting exposures. A criticism of the Precautionary Principle is that this approach can result in a very lengthy risk assessment procedure that can delay policy decisions.

A second criticism is that a precautionary approach will invoke a "monsters under the bed" syndrome.

The definitions of the precautionary principle have the common element that precautionary action should be taken when there is credible, scientific evidence of harm.

The Precautionary Principle Thus Far: Where It's Been, Where It's Heading

As a tool of public policy-making, the Precautionary Principle has evolved considerably since its earliest incarnations. Its history and current status can be summarized as follows:

- It was used extensively in US environmental decision-making in the 1970s.
- It has been and continues to be the cornerstone of the public health system.
- It is already being used as a cornerstone of environmental decision-making in European nations—especially Denmark, Sweden, and Germany—as well as in Canada.
- It can be used to enhance the collection of cancer risk information on high production volume chemicals.
- It must be science-based.
- It does not eliminate the need for risk assessments.
- It is enhanced by public participation.
- It requires transparency of data on health risks of chemicals.
- It has spurred a debate on whether the principle should embrace the "polluter pays" directive, which places the responsibility for providing risk assessment information with industry. Some advocates of precaution believe that evaluations by independent agencies and researchers are also important.

Recent Legislation in Canada Based on Precautionary Policy

Precautionary Framework Policy Passed

On August 5, 2003, the Canadian Cabinet formally approved policy that will apply the Precautionary Principle to all decisions made by federal policy-makers that "carry a risk of serious or irreversible harm where there is a lack of scientific uncertainty."

Québec Pesticide Laws

In July 2002, Québec enacted a *Pesticide Management Code* which will phase out the use of certain pesticides on lawns in public and municipal areas. Restrictions will be extended to the private lawns of homeowners by 2005. The legislation will change requirements for the training of persons working in retail pesticide sales, and will also broaden requirements that must be met for certification of farmers and forest managers who apply pesticides. The legislation will also specify which chemicals (called the "active ingredients") will be allowed for pest control inside and outside in elementary and secondary schools, and daycare centers.

providing a wealth of scientific data upon which to make decisions. Again, the cost is often time and continued exposure of the chemical to at-risk populations while risk assessment data is being collected. For instance, special review and re-registration assessment of certain pesticides by the EPA may take as long as five to ten years.

The second criticism is that a precautionary approach will invoke a "monsters under the bed" syndrome. As a scientist, I would agree that this is a potential problem. It is important to realize that the precautionary approach does not eliminate the need for assessing harmful effects of chemicals. The definitions of the Precautionary Principle outlined earlier in this article do have the common element that precautionary action should be taken when there is *credible, scientific evidence of harm*. Action should not be taken because of a perceived risk. But, under this principle action can be taken when there is still scientific uncertainty in order to protect public health.

The third argument is that the Precautionary Principle is not science-based. In response, many scientists and policy makers emphasize that the best science must be brought to the table when using the Precautionary Principle to make policy decisions. The decisions cannot be made in a vacuum. They cannot be made without scientific evidence of potential harm. We know very little about the risk of many chemicals. The absence of data does not mean there is an absence of harm, but rather that data must be gathered to provide a basis for decision-making.

The Precautionary Principle, as invoked in the EU REACH program and in a policy framework recently enacted by the Canadian government (see side-bar article), does not require less science. On the contrary, because of the absence of data on so many chemicals, a precautionary approach will require more extensive risk assessments to evaluate if actions are necessary. The question still remains, however, what level of scientific evidence is needed to trigger policy actions based on a precautionary approach. According to John Carins, at Virginia Polytechnic Institute, "... the Precautionary Principle requires scientists to develop and improve methods and procedures for studying complex natural systems." The best elements of a precautionary approach do not demand less science; rather, it is a challenge to the scientific community to improve methods used for risk assessment.

The fourth criticism is that the use of the Precautionary Principle will stifle industry and competitiveness. Yes—and no. It may cause some industries to no longer operate if a chemical is regulated, but at the same time such action may create entirely new industries. For example, "green" industry could produce environmentally friendly products creating a new and viable, market-based industry. For instance, the phasing out of mercury thermometers resulted in an entire digital industry for measuring temperatures in the ears of feverish children. The auto industry survived phasing lead out of gasoline. So did the paint industry. New alternatives for medical tubing without phthalates are now available. This means premature babies and dialysis patients no longer have to be exposed to harmful phthalates that can leach out of plastic tubing. New markets for new products were created that are safer for people and the environment. Seeking alternatives may open up competitiveness for multiple manufacturing streams to replace a single, environmentally toxic product.

A summary of the International Summit on Science and the Precautionary Principle, held in Lowell, Massachusetts in 2001, stated: "Applying the Precautionary Principle can foster innovation in materials, products and production processes. The goal of precaution is to prevent harm—not progress—and support a sustainable future." Our inventiveness can be the best measure of our competitiveness in a global market that will no longer tolerate products that harm human health or the ecology of the earth.

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