

# PRECAUTIONARY PRINCIPLE

*As defined recently, the principle provides a new guide to U.S. environmental policy*

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In late January, a group of experts met in Wisconsin to discuss a new approach to environmental policy-making—the precautionary principle. If this approach, as they defined it, were codified into law in the U.S., it would place the burden of proving the safety of chemicals on the producer. As a result, it could slow the introduction of new chemicals and make it easier for the government to ban old ones.

The precautionary principle, as a general approach to environmental policy, is not entirely new. It already forms the basis of at least a dozen treaties and laws, including the 1987 Montreal Protocol on Substances That Deplete the Ozone Layer, the 1990 Massachusetts Toxics Use Reduction Act, the 1992 United Nations Framework Convention on Climate Change, and the 1994 Maastricht Treaty of the European Union. In these, the principle means that anticipatory steps must be taken to reduce potential risks to human health and the environment from chemicals, products, or processes before cause-and-effect relationships have been fully established.

A number of industry advisers have called the precautionary principle unscientific and dangerous. For example, John O. Mongoven, president of Mongoven, Biscoe & Duchin, a Washington, D.C.-based public affairs firm specializing in issues management for major corporations, believes the principle is antagonistic toward sound science, has its origins in instinct and feeling, and threatens the entire chemical industry.

Nevertheless, many government, industry, and environmental leaders say they subscribe to the precautionary principle. In practice, though, they define it in many different ways. Some leaders would require rigorous risk assessment and cost-benefit analysis before banning a product or choosing one product over another. Others would judge the risks using a weight-of-evidence approach. Some

would place all the onus for damage from a new product on the producer. Others reject this idea.

To iron out these differences and reach a common definition, 32 experts from the U.S., Canada, and Europe—scientists, lawyers, treaty negotiators, legislators, scholars, and activists—met last month at the Wingspread Conference Center in Racine. Noticeably absent from the meeting were representatives from the Chemical Manufacturers Association, who, when contacted by C&EN, stated that they had no official policy on this issue.

The meeting was sponsored by three foundations—the Johnson Foundation, the W. Alton Jones Foundation, and the C. S. Fund—and organized by the Science & Environmental Health Network, a consortium of about 50 environmental groups dedicated to the use of science to protect the environment and public health.

At this conference, the experts agreed on the definition in the following excerpt: "Existing environmental regulations and other decisions—particularly those based on risk assessment—have failed to adequately protect human health and the environment. . . . There is compelling evi-



**Wahlström: Sweden's interpretation**

dence that damage to humans and the worldwide environment is of such magnitude and seriousness that new principles for conducting human activities are necessary. Therefore, it is necessary to implement the precautionary principle: When an activity raises threats to the environment or human health, 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 [of the safety of the activity]."

The most controversial aspect of the definition is that it shifts the burden of proof of safety to the producer. Currently, in the U.S., manufacturers of pharmaceuticals must show that their products are effective and safe for the intended use. "But most existing U.S. laws and regulations focus on cleaning up and controlling damage rather than preventing it," Carolyn Raffensperger, cochair of the meeting and coordinator of the Science & Environmental Health Network, told the attendees.

For the vast majority of the 1,000 or so new chemicals introduced into commerce each year, little or no testing is required. The manufacturer submits a premanufacture notification to the Environmental Protection Agency, and if, after 90 days, EPA does not require additional testing, the manufacturer is free to produce the chemical. Consequently, basic toxicological information is lacking for the majority of high-volume chemicals. "The precautionary principle, as defined at Wingspread, would require the manufacturer to demonstrate safety for all new chemicals and to be held responsible if damage occurs," Raffensperger explained. "This requirement would probably slow the introduction of new chemicals, but give us a chance to understand the public and environmental consequences," she said.

Another controversial aspect of the Wingspread definition is that it places much less emphasis on risk assessment and cost-benefit analysis than does current practice. The group decided that in some situations, when not enough is known about a proposed product or activity and its alternatives to do rigorous risk assessments and cost-benefit analyses, the precautionary principle can nevertheless be applied by using a weight-of-evidence approach. This takes into account the cumulative evidence from many studies, often in several species, that address whether a product or activity will cause injury or is likely to cause injury, explained Joel A. Tickner, cochairman of the conference

Photo by Bette Hileman

and researcher in the Work Environment Program at the University of Massachusetts, Lowell.

But using the precautionary principle does not usually mean "throwing out risk assessment and cost-benefit analysis," Tickner said. Rather than employing these techniques to quantify an acceptable risk, he explained, they are used to compare alternatives. This is a "much less complex and often more clear-cut activity, requiring less rigorous quantitative analyses," he said.

In their attempt to reach a consensus, speakers at the conference discussed current laws and policies that embody the precautionary principle and interpreted how these work to protect the environment. They also described strategies to implement the principle and explained chemical issues that could be resolved more easily with this approach.

The Massachusetts Toxics Use Reduction Act aggressively applies the precautionary principle, said Kenneth Geiser, director of the Toxics Use Reduction Institute at the University of Massachusetts, Lowell. It involves "redesigning the processes of production so as to reduce pollution by substituting less hazardous materials, by optimizing production technologies, and by redesigning products." It requires companies to report annually on their use of toxic chemicals and prepare comprehensive plans showing how they are going to reduce their use of these substances, he explained.

The law does not ask what levels of exposure to toxic chemicals are safe, Geiser said, but rather how to redesign production to avoid their use altogether. The law also calls for companies to perform assessments of alternatives, evaluating what activities can be undertaken to reduce or eliminate hazards. According to the Massachusetts Department of Environmental Protection, toxic by-products in Massachusetts—which include all wastes and releases as well as recycled or treated waste materials—declined 30% between 1990 and 1995 under the law.

Several European countries are instituting this approach. Sweden, for example, takes a precautionary approach to much of its chemicals management, Bo Wahlström of Sweden's National Chemicals Inspectorate told the meeting. The National Chemical Inspectorate conducts all the health and environmental chemicals research in Sweden.

Sweden's interpretation of the precautionary principle includes a substitution clause enacted in 1991, Wahlström said. It

reads: "Anyone handling or importing a chemical product must take such steps and otherwise observe such precautions as are needed to prevent or minimize harm to man or the environment. This includes avoiding chemical products for which less hazardous substitutes are available." The law also states that "a scientifically based suspicion of risk shall constitute sufficient grounds" for the government to take measures against a chemical. To avoid restrictions on a chemical, he said, the producer must show the suspicion is unfounded.

In the U.S., decision-making on the use of MMT (methylcyclopentadienylmanganese tricarbonyl) in gasoline would be greatly simplified if the precautionary principle could be used, according to Ted Schettler, cochair of the Human Health & Environment Project of the Physicians for Social Responsibility. In 1995, a U.S. federal court decision ruled that gasoline producers should be allowed to use MMT as an octane enhancer, but it is unclear whether any of them are actually using it.

However, MMT poses risks of potential neurological effects, in both adults and

children, Schettler said. Under current law, the only way MMT can be banned is if EPA can demonstrate conclusively that MMT in gasoline is unsafe, he explained. So the burden is on EPA to show a danger, rather than on the producer to demonstrate safety. "If gasoline producers choose to proceed, agency personnel will now need to conduct a laborious and expensive toxicity and exposure analysis to determine whether or not adding MMT to gasoline is a significant threat to public health," he said.

This analysis would be difficult, Schettler explained, because many complicated, unanswered questions remain about the toxicity and behavior of manganese in humans. Manganese is an essential trace element, but it is also toxic after excessive exposure. Inhaled manganese, some of which goes directly to the brain along the olfactory nerve, behaves differently from ingested manganese. Also, infants and young children have an immature blood-brain barrier, so their central nervous systems may be vulnerable to the blood-borne manganese. Several studies show that children with higher

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### Precautionary principle requires different questions

The differences between the standard approach to environmental policy and the approach stemming from the precautionary principle are sometimes subtle—matters of degree. They can most clearly be seen in the questions that are asked when trying to estimate the environmental or health risk of a substance, explains Joel A. Tickner, researcher in the Work Environment Program at the University of Massachusetts, Lowell. "Current decision-making approaches ask, 'How safe is safe? What level of risk is acceptable? How much contamination can a human or ecosystem assimilate without showing any obvious adverse effects?' The approach stemming from the precautionary principle asks a

different set of questions: 'How much contamination can be avoided while still maintaining necessary values? What are the alternatives to this product or activity that achieve the desired goal? Does society need this activity in the first place?'"

Policymakers using the precautionary principle ask these questions because they are taking steps to prevent risk before a cause-and-effect relationship between the product or activity and harm to the environment or health has been conclusively established. Often, too little is known about a product or process to compute how much humans or the environment can assimilate without damage.

levels of manganese in their hair, which indicate higher exposure, are more likely to have attention-deficit hyperactivity disorder, but a cause-and-effect relationship between manganese and ADHD has not been rigorously established.

Consequently, extensive tests would be required before the questions about manganese toxicity can be answered. However, if an "alternatives assessment" were performed, as could be required by the precautionary principle, manganese in gasoline would probably be banned, Schettler said, based on a lack of data to demonstrate safety, the availability of alternative octane enhancers, and a lack of public health or environmental advantages resulting from MMT use.

One way of implementing the precautionary principle would be to use "assurance bonds," said Robert Costanza, a professor of ecology in the University of Maryland's Center for Environmental Science in Solomons. A flexible environmental assurance bonding system—sort of an environmental deposit fund—"could shift the burden of proof to the polluter" and "provide strong and effective economic incentives for both environmental precaution and technological innovation," he said.

The European Chemical Industry Council (CEFIC) is the only major chemical industry association that has an official policy on the precautionary principle. Its views on how the principle

should be defined and implemented differ sharply from those voiced at Wingspread. Specifically, CEFIC's opinions directly conflict with the idea that a weight-of-evidence approach should be used when risk assessment is not feasible and with the notion that the precautionary principle should be codified in law.

In a position paper on its web site, the council says it supports the precautionary principle only as a "guiding principle" rather than as a code that could have a direct effect on laws. CEFIC would apply the precautionary principle only when a "sufficient body of evidence . . . establishes that serious and irreversible damage to health or the environment could be caused by the challenged activity or product."

Furthermore, CEFIC says, the precautionary principle may be used to dictate the substitution of one product or activity for another only if risk assessment and risk-benefit analyses are used to compare the original activity or product and the alternative proposal and if a less dangerous alternative is available on the market.

Despite these industrial concerns, Rafensperger believes "the Wingspread meeting will help move the precautionary principle beyond the rather remote realm of international treaties to local, state, and national activities." The principle has flourished in treaties in part because the Europeans have driven it, she said. "But we now have a chance to make it an active and vibrant idea guiding environmental decision-making in the U.S." ◀

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