REGULATION

BEING CAUTIOUS ABOUT THE PRECAUTIONARY PRINCIPLE

By Chauncey Starr

Precautionary behavior is a common daily event for most of us, an instinctive reaction to any sudden and unfamiliar intrusion. It serves a valuable protective purpose in two ways. First, it causes a quick retreat to the safety of the familiar; second, it provides time for a realistic friend-or-foe assessment of the event.

In its strictest sense, precaution in regulation is a simple concept—if the safety of anything new is uncertain or might have unknown future hazards, it should be prohibited. As applied by most regulatory agencies, this prohibition is tempered by the practical need to accept some level of risk, but you can see the concept at work in emission regulations imposed on electric utility operations—stack emissions, electromagnetic fields, water effluent, radiation, and so on.

Now, with some success, cities, nations, and world bodies are codifying the "precautionary principle" in environmental and social regulation. (See the sidebar, "Precaution Creeps In," page 60.) But the term itself has no intellectual content—it is merely a rhetorical device to avoid a thorough risk analysis, which weighs risks against benefits. The political reluctance to undertake a risk analysis arises from several of its qualities. First, its findings may suggest an unwanted political option—a regulator may be reluctant to have it disclosed. Second, it is a time-consuming task, especially if data search and detailed analysis is required. Third, it may reveal the conflict of policies and motivations behind alternative choices—regulators generally prefer that their decisions go unchallenged.

So, for reasons of political or status quo advocacy, governments conveniently use the umbrella of the "precautionary principle" to prohibit physical imports or competitive technologies. That has been obvious in the European Union's (EU's) attempt to halt the import of gene-spliced grain from the United States.

Though on the verge of being codified in Europe as official policy, the precautionary principle is being actively considered in policy circles of the Environmental Protection Agency (EPA).

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Risk Prohibition

In its extreme application, the precautionary principle dictates a total prohibition of a specified substance in a society. A "biosafety protocol" of the United Nations Convention on Biologic Diversity encouraged the EU to forbid the import of gene-spliced grains in any form. The ostensible explanation is that while there have been no health effects revealed by the use of such grains in other countries (notably in the United States), it has not yet been proven that the health of subsequent generations of users would not be impaired by latent effects from the gene-spliced grains in their food supply. Obviously, providing proof now of a future negative intergenerational finding is impractical. The environmental movement's promulgation of such fears has resulted in their

While almost all U.S. corn is genetically modified, Europe has banned its import along with other genetically modified produce.

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repetition by the Codex Alimentarius Commission, the guidebook on food standards. This so impressed the leaders of Zimbabwe that they refused for years the importation of genetically modified U.S. grain to relieve mass starvation—a barrier very recently removed. The European embargo is now a major case brought by the United States to the World Trade Organization (WTO) based on its apparent purpose of shielding European agriculture from competition.

The environmental movement has also been avidly seeking a similar worldwide prohibition of nuclear power. During its tenure, the Clinton administration succeeded in eliminating nuclear power from the Department of Energy (DOE) agenda of future power sources. The environmentalist's argument is the basic precautionary principle—that regardless of present benefits, unknown intergenerational harm may arise in the future from nuclear power and radiation applications.

Radiation has been demonstrated as particularly effective in killing bacteria such as salmonella and *E. coli* bacillus. Recently the U.S. Department of Agriculture has added raw red meat to its approved list of irradiated foods. The Center for Disease Control has estimated that 5,000-9,000 Americans die, and 33 million become ill every year from foodborne illnesses. After decades of indoctrination on the dangers of radiation, the public must now overcome this fear. Unfortunately, the benefits to society of the developments of gene-spliced food, nuclear power, and radiation are not deemed sufficient by environmentalists to override the hypothetical fear inherent in the precautionary principle.

EPA has modified the "safety by denial" philosophy of the precautionary principle to a less obtrusive "safety at all costs" rhetoric, but the target is the same. The agency assumes that if a substance requires regulation, then the public exposure should be reduced to its lowest possible level. This may be zero, as the precautionary principle would dictate, or at least the lowest achievable in practice. EPA usually makes a minimal concession to feasibility and economics. Thus if direct data show no observable health effects below a threshold exposure, EPA will arbitrarily set a regulatory target lower by a factor of 10 or 100 or more. Such is the situation with powerplant emissions.

We should recognize that Congressional legislation directed EPA to regulate without regard to cost. In practice the only restraint on the agency is the public awareness and political response to potential costly consequences of excessive regulation. An awkward compromise usually results from the pressure of public opinion and political negotiation. Automobile exhaust criteria are an example of such negotiations. The result is a practical accommodation but with a less than optimal use of national expenditures for public health.

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Risk Analysis and Regulatory Targets

Because electric utility systems are point sources of many byproduct emissions, they today represent prime targets for regulatory attention. In the early 20th century, powerplant smokestacks symbolized a vibrant economy, and regulations were few. The added costs of early regulations were a modest part of the approved rate structure, with public utility commissions assuming the public's willingness to pay. Over the years, utilities have made the expenditures required by a steadily growing stream of regulations, albeit reluctantly. Regulations now have become a significant cost component. In the current era of free-market cost competition among all energy sources, the public health, environmental, and social values of such regulations need careful evaluation by the industry and regulators. Though the industry has a social responsibility to contribute to a clean environment, the added costs of doing so is becoming a sizable national economic burden. The feedback from such costs results in a hidden public health penalty, and they should not be accepted lightly, either by the industry or the public.

Such is the essence of the problems faced when decisionmakers seek quantitative guidance from a risk analysis (that is, a benefit/cost/risk spectrum). Risk analysis is a professional expansion of the gambler's "pay-out" betting criterion. It is much more complex due to the many interacting "pay-outs" and "costs" that enter public policy decisions. Most interesting for us is the EPA process for setting environmental criteria in the United States. This process depends for its database on epidemiological findings and the consensus of interpretations by scientists. Both have large components of judgment and bias. There usually is no dispute about regulation when practical exposure to a pollutant or risk has a visibly large public impact. In our population of hundreds of millions, large regional disease clusters or spikes become clearly visible to epidemiologists, and once causation is verified, these become part of the accepted database for assessing regulation.

It is the extrapolation of observed high-level exposure effects to levels below an easily detectable or measurable range that creates the regulatory arguments. Below this observable threshold, regulators usually make the "safe" assumption that high-level effects have an extrapolated risk to zero exposure and therefore should be regulated to a zero target.

This precautionary principle of "zero tolerance" is attractive as it caters to the public's instinctive dislike for involuntary exposure to health risk of any size. Neither the public nor the media that inform it commonly understand the famous toxicology admonition of Paracelsus—the dose makes the poison. In fact, dema-

goguery and journalistic hype get more public attention than in-depth analysis. In reality, the hypothetical extrapolations of exposures to zero would usually disappear into the massive indiscriminate "noise level" of the public's common low-level health complaints. Thus regulators strive for the next best—that is, targets as low as achievable and usually with small regard for implementation costs.

Social Costs

Electric utilities and other industries that face the task of pollutant removal to achieve a regulatory target are of course very concerned with the incremental costs to them. So should the public, as it is in the public interest to produce electricity at the lowest cost. Electricity is a basic survival need for everyone, including the U.S. poor, for whom it represents a large fraction of expenditures. Unnecessary energy costs are directly inflationary for our economy, as they are equivalent to a consumption tax on all consumers, raising the price of all goods. Further, increased energy costs reduce the nation's funds that might be available for investment in production and thus make the United States less competitive in international trade. Resulting unemployment amplifies the energy cost burden for the poor, which in turn creates the adverse consequences of impaired health, stroke, violence, and suicide.

The point is that the imposition of regulatory targets in excess of what is needed to meet reasonable environmental goals creates feedback interactions that adversely affect employment, public welfare, public health, and our national economic well-being. The key words are "reasonable environmental goals." There obviously should be an optimal societal balance. Both the industry and the regulators should seek it. It is therefore important to probe the validity of the analytical base used to set regulatory targets and to consider the potential role of electric utilities in negotiating them.

Easiest to understand is the role of epidemiology, which seeks cause-and-effect relationships in pockets of measurable disease among the public. For example, epidemiology is quite effective in finding neighborhood clusters of digestive attacks among the customers of one food source. However, the same number dispersed among our total population would probably not be reported. Thus, when studying very low-level cause/effects, the cluster designation becomes a statistical challenge. The classic "do-it-yourself" demonstration is to mix an equally large number of black and white balls, and then to spill them on a flat surface. This will show a somewhat random distribution with some clusters of common color. Such clusters are clearly not the result of a cause/effect connection. The real-life practical problem arises when a low-level disease cluster is detected near a possible

source (a powerplant, for example). Is it random or not? Then the epidemiologist seeks help from scientists who have experience with the pharmacology of the plant effluents to assist in source validation. Let's examine what science can do.

Unfortunately science is itself a probabilistic assembly of information. Science assumes that natural processes firmly follow internal laws, some we understand well, some partially, and most we only hypothecate at present. Credible science is revealed by repeated verification through predictive use in practical applications (principles of mechanics, for example). In any significant decision-making, the credibility of a "scientific" risk projection requires careful evaluation of its probabilistic status—and science does not guarantee infallibility. This is especially the case in public health-related medicine. We are reluctant to use people for experimental verification. Thus a preponderance of noninvasive and animal observations, rather than physiologic understanding, often replaces science. Medicine calls such empirical outcomes guides to "generally accepted practice." Unfortunately, correlation doesn't prove causation. In the absence of confirmation by the replication process of good science, causation always remains uncertain.

So regulators resort to a "scientific consensus" of experts, who have a historical background of analogs that might provide insight to a new specific case. Past experience, limited as it may be, always guides experts—the common phrase "if it looks like a duck and quacks like a duck, it's a duck" describes their strongest guidance. But it may not be correct, as has been recently shown with the new respiratory diseases. Also, professional advisors tend to avoid the possibility of blame for unpredictable outcomes, as it impairs their professional status. As a class, experts are therefore unconsciously biased toward precautionary positions—they want to be "better safe than sorry."

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Risk analysis thus becomes a probabilistic process, hampered by a precautionary bias. Professional risk takers, like the military, use the two-team approach: a "blue team" to study alternate paths to success, and a "red team" to seek the failure modes in each path. This provides a reasonably comprehensive risk perspective for evaluating military plans. Unlike the military, environmental regulators have a political directive to avoid risk, so we must recognize that their scientific advisors are judgmental and conservative, even if they are reputable scientists. The drive to "zero tolerance" is thus strengthened, constrained only by the strong opposition to the consequent costs from the industries impacted.

Astride the whole process is the empirical observation of public health "thresholds." Except in a few instances, a threshold is just under the lowest recorded public health cause/effect relationship—below that threshold is no physically measurable value in reducing exposure. There is a sizeable professional community that hypothesizes about this hidden range between "thresholds" and zero with alternative models and with theories for its existence. The common illustration is aspirin. At high dosages the drug is clearly a health risk, while it's a health aid at modest levels and now is approved for children at a half-dose and recommended to adults as a daily dose for reducing heart attacks. Aspirin clearly has a threshold below which it shifts from risk to health asset.

Whether aspirin is a guide for other

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Applying the precautionary principle to powerplant emissions affects the benefits of generating electricity.

A SCIENTIFIC SEA CHANGE

By Eric R. Blume

The precautionary principle is a powerful scientific and regulatory philosophy that has come slowly into use.

The German government in the 1970s, suspecting that acid rain was responsible for the deterioration of the nation's forests, took the precautionary measure of cutting sulfur dioxide emissions. It did so under the principle of *Vorsorge*, or "forecaring," and *Vorsorgenprinzip*—the precautionary principle—became a part of German environmental and health policy. The idea gained real traction at the UN Conference on Environment and Development in Rio de Janeiro in 1992. World leaders adopted Principle 15, which stated, "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."

In the 1992 Treaty of Maastricht, the European Union (EU) adopted the precautionary principle. It appeared in the UN Treaty on Biodiversity and the 2000 Cartagena Protocol on Biosafety. The Codex Alimentarius Commission, which sets worldwide standards for food (including the genetically modified variety), is a battleground between the EU and the United States, a fierce defender of risk analysis. The World Health Organization anticipates that the principle will be applied to electromagnetic fields, even though recent research points to little risk from EMF. The city of San Francisco recently adopted a resolution to apply the principle in health and environment decisions.

According to the European Commission, in a 2000 memo directing the application of the principle, if there is "reasonable ground for concern" that a substance might be harmful (even absent concrete evidence), then any experimentation should not proceed. The most serious effect of this is that the burden of proof is shifted to those who want to implement a new technology or substance. The argument is that harm to the public can often occur before science has time to prove a substance's harmlessness.

But critics point out that risk analysis allows for action, whereas too much precaution can stymie progress and innovation. In "Science, Risk, and the Price of Precaution," an article from spiked.com, author Sandy Starr lists several historic scientific achievements that would not have been possible had the precautionary principle informed them. Among them: digitalis, poisonous in large quantities but helpful for people with heart disease; open heart surgery itself; the contraceptive Pill (and, according to Carl Djerassi, father of the Pill, "the precautionary principle is also the principal reason we have no such Pill for men"); antibiotics, as well as any type of vaccination; and electrification, light bulbs, alternating current, steam power, and nuclear power.

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high-level exposure hazards such as radiation, electromagnetic fields, and so on is not significant for regulatory purposes. What is important is whether a regulatory target should be set at an observable "threshold." The economic significance may be very high, as removal of low levels of pollutants is usually much more costly than the gross removal of high levels. Regulators have generally refused to accept the reality of thresholds, asserting that the "safe" assumption is the continuum of health effects to zero exposure, even if they are hidden. This is a no-man's land of philosophic warfare. If the social target is the use of national resources to achieve the highest measurable public health, then funds spent to go below evident threshold levels are obviously wasted; and they can actually impair public health and the national economy.

A comprehensive risk analysis provides a process for evaluating the many factors relevant to regulatory targets. In such a process, all the public benefits, costs, and health risks are disclosed, estimated, and quantitatively weighed in concert. The key is the recognition that it is desirable for regulations to establish a pragmatic social optimum. We have a successful example in the decades long history of the closely regulated nuclear power field, where risk evaluations have been continuously negotiated with the professional staff of the Nuclear Regulatory Commission (NRC). Nuclear utilities may groan about the detailed oversight, but as a proponent of safe nuclear power, I like the result. The nuclear utilities have recognized the need for public confidence in their operation, and NRC has recognized the social values of low cost electricity. Because of its birth in World War II nuclear weapons technology, nuclear power has had to overcome the political urge to apply the "precautionary principle" as a barrier to its growth. Half a century later, the risk analysis task is a routine burden. The success of the NRC model for nuclear plants establishes a template for electric utilities to promote risk analysis as a joint approach for negotiations on all environmental targets.

Avoid the Tentacles

Utilities should recognize that the social decisionmaking tensions created by the public desire for a clean environment versus the constraining public goal of low-cost electricity is a permanent field of negotiation. Regulators and environmentalists represent one side of the negotiation. Utilities must capably represent their side. To participate, they must learn the tools and practice of risk analysis as a normal competency of their management and analysts. To support their view of the regulatory social optimum, they must publicly emphasize the social benefits of delivering low cost electricity. In contrast with the utilities' historical preference for avoiding the public limelight, these activities call for an aggressive public and institutional communication posture. Otherwise, the enveloping tentacles of the precautionary principle will continue to grow. ◆