The Precautionary Principle: Making Wise Decisions in an Uncertain World

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The Sunday *New York Times*, in May 2003, quoted John Graham of the Office of Information and Regulatory Affairs in the Bush administration, in a speech to European Union regulators, as follows:

> *The precautionary principle is an unjustified constraint on business and [the administration] does not even recognize the existence of the doctrine. We consider [the precautionary principle] to be a mythical concept, perhaps like a unicorn.*

Many think that the precautionary principle is used only to address biotechnology and agriculture. That's not the case. I will describe the history of the principle, focusing on scientific uncertainty—one of its elements—and describe some of the recent debates, especially with respect to trade.

Global Changes

We have caused major global change, some of which has serious implications, *e.g.*, the hole in the ozone layer and climate change as mentioned in some of the other presentations. Marine fisheries are collapsing and endocrine disruptors are present in wildlife and humans. I submit to you that the magnitude of human-induced global changes is unprecedented.

In a 1997 *Science*-magazine article, Peter Vitousek said that we've transformed the land and the sea and we've done it in myriad ways. We've altered the major biogeochemical cycles, *e.g.*, carbon, nitrogen, water. We've introduced synthetic chemicals across the globe—some of which may be found in the farthest corner of the Arctic. Also, we've added and removed species and genetically distinct populations via habitat alteration and loss, hunting, fishing and species invasion.

Consider the magnitude of these changes. Data from 1997 indicate that between a third and a half of the land surface has been transformed by human activity. Carbon dioxide concentration in the atmosphere has increased by about 30%. Since the beginning of the Industrial Revolution, more atmospheric

nitrogen has been fixed by humanity than by all natural terrestrial sources combined. Half of all accessible surface fresh water is used by humans. A quarter of the bird species on earth have been driven to extinction and two thirds of the major marine fisheries are fully exploited, over-exploited, or depleted. Data recently published in *Nature* indicate that these statistics, particularly on marine fisheries, are far worse than they were in 1997.

Need for the Precautionary Principle

Some trends in public environmental health are cause at least for more research and rethinking of regulatory policies, such as increases in autism, e.g. in California. The old arguments around environmental health were:

> *Oh come on, you environmentalists are always complaining about something. We're increasing life expectancy, infant mortality is going down,* etc.*, so what are you complaining about? We're all living longer. We are getting fatter, but, apart from that, we're really doing well.*

However, increased rates of some cancers, age-adjusted, are troubling, as are neuro-developmental diseases, including autism, reproductive disorders, *etc*. We have difficulty in assessing cumulative systems levels and interactive effects. Although we have evidence of global impacts, we have failed to predict outcomes.

What about future generations? Will we discount them indefinitely or start to factor in their needs and the long-term effects of our current actions? Silvio Funtowicz and Jerry Ravetz have stated that there are some situations where much uncertainty is coupled with far-reaching consequences. That matrix—high decision stakes and high uncertainty—falls into "post-normal" science. In fact, high stakes apply to many of our current choices.

We know that novel synthetic industrial chemicals contaminate the world's ecosystems, including our own bodies. The human food supply and those for other species are contaminated at levels of concern. Water is often contaminated at levels of concern. Look around, even at this continent, and consider again changing patterns of illness. Why has our 60-year history with chemicals caused so many surprises? Given those surprises, does it make sense to use the same kind of science to assess environmental and public-health effects of transgenic crops?

This is a wonderful quote from T.L. Hill:

> *It's a truism that humans have, and will always use, tools. Just as obvious is that technology, the use of tools, occurs in a social, political, cultural and economic context and it's never neutral. Tools are always shaped by their use, by the people or institutions which control their production and distribution, and by a culture which validates, circumscribes or discourages their creation and/or use.*

And we have heard overtones of that debate at this meeting. What kinds of cultural mechanisms are being used to validate or discourage the creation and use of biotechnology? Do we have a right to say no to a technology, and who are "we"? Are there wise ways to say yes to a technology? Can we increase our skill in predicting the consequences of a technology, and how do we understand the cultural, social and political differences that exist in other countries with regard to biotechnology?

The bigger the technological solution, the greater the chance of extensive, unforeseen side-effects. Clearly, scale matters. The greater the rapidity of human-induced change the more likely it is to destabilize the complex systems of nature. As stated by Aldo Leopold, speed also matters.

What is the precautionary principle? The 1998 Wingspread Statement on the precautionary principle (http://www.gdrc.org/u-gov/precaution-3.html) was as follows:

> *Where an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.*

At the 1972 United Nations Conference on the Human Environment, held in Stockholm, sustainable development was elevated to a global ethic. This was the first paring of the moral principles of social justice and environmental responsibility—themes that have played out in this discussion in terms of the development of biotechnology to ease hunger and how we think about environmental responsibility. The 1987 Brundtland Report, *Our Common Future*, stated that poverty is a cause and effect of environmental degradation. Present policies encourage environmental deterioration and deepen economic and social disparities. This led to the 1992 United Nations Conference on Environment and Development, from which came the statement of the precautionary principle and two derivative treaties, the Persistent Organic Pollutants (POPs) Treaty and the Convention on Biological Diversity, which led to the Biosafety Protocol. The POPs treaty and the Biosafety Protocol were the first treaties to incorporate what we now understand as the precautionary principle: 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.

The Europeans who developed the precautionary principle in the late 1960s and 1970s thought of it as an ethical directive. It was a philosophical guide, and that's why it was put into treaty preambles. It comes from a German word that literally means "for caring." It's a literal word that doesn't exist in English, translated by Conrad von Moltke while explaining a matter of German air-pollution law to the British.

The concept of it being an ethical directive in some ways is foreign to people in the United States. When I organized the Wingspread Conference, I thought if we could get it out of the realm of ethics and make it a *regulatory* tool, everything would be fine. We'd give it some teeth. But, I didn't understand that the precautionary principle is a tool that uses epistemology—How do we know? What do we know?—philosophy that deals with scientific uncertainty. But it also has an ethical dimension, as pointed out to me by the head of Cancer Prevention at the National Cancer Institute, Doug Weed, a philosopher as well as an MD. He said it was the first time he'd heard of a decision rule that actually coupled ethics with epistemology.

After 20 years as an environmentalist, dealing with ethics made me nervous. We're not expected to do that here in the United States, and I wanted to ensure that it was a strong regulatory device. It's a risk-management device rather than risk assessment. We do the risk assessment, and then decide if we need the precautionary principle. But that gets us into trouble. It's a poor way of doing business. After a technology is developed, it may be rejected by the regulatory process after many millions of dollars have been spent.

The precautionary principle needs to be an overarching ethic guiding everything from the research agenda to the judicial elements, using science in new ways to examine and to predict. It sets a public-interest research agenda to help guide technologies rather than to be used only as a regulatory device.

Sometimes it is said, "We can't possibly use the precautionary principle because we can't define it. It's too mushy. It's too soft." Nonsense. The precautionary principle always contains the same three elements. It always has plausible threats of harm. It always has lack of scientific certainty. And it always has precautionary action to prevent harm—not to manage it, to prevent it, which is the difference in philosophy. That's part of the philosophical backdrop. In the United States we subscribe to the philosophy that says we can measure risk, we can manage risk, and the earth has an infinite capacity to fix our mistakes, whereas the precautionary principle says let's use science as a predictive and preventative tool.

Harm

The precautionary principle addresses potential harm in environmental and public-health matters, especially in the Biosafety Protocol, in which it was first expanded into public health. It is being used also to address cultural and social harms. The International Society for Ethnobiology put the precautionary principle into its code of ethics to guide the scientific use of cultural and social knowledge to prevent harm to foreign cultures.

Not all types of harm are applicable. Harms that have been written into treaties are serious, cumulative, and irreversible. On the other hand, if a harm is easily avoidable, it makes sense to avoid it.

Lack of Scientific Certainty

Scientific uncertainty is a complex concept. Usually uncertainty with regard to the precautionary principle is in terms of cause and/or magnitude. Consider autism, for example, the causes of which we don't fully understand. My environmental and public-health colleagues often settle on one issue, e.g., mercury in vaccines. Well, it might. It might not. How do we address cause and effect and then how do we address magnitude? Uncertainty comes in as many flavors as ice cream, and we have indeterminacy, and we have ignorance. Uncertainty can be resolved with more data. We can get a better model. We can figure it out. Indeterminacy refers to the complexity of systems. And ignorance refers to what I don't know and what maybe nobody knows; there are some things that you know that I don't know, and there are some things that none of us in this room knows. So for some of these, we can get more data and should get more data to reduce uncertainty. Sometimes we have very complex systems and sometimes we just haven't asked the right questions. And the issue of the right question comes up over and over again in biotechnology.

I want to consider causation briefly. In the 1700s, Hume said that we don't perceive or see causes, we observe consequences and we infer causes. How do we know something causes a disease? Koch's postulates for infectious disease was one of the first sets of ideas that helped map out thinking about causation in Bradford Hill's criteria. In Koch's postulates, the organism must be present in every case, must be isolated from the diseased host, and grown in pure culture. The disease must be reproduced and the organism must be recoverable from the experimentally infected host. However, we've used Koch's postulates in non-infectious contexts, *i.e.*, old science for new problems, such as with endocrine disrupters, with which the postulates work less well. Certainly Hill's criteria work a little better, but they take a long time: consistency of findings, the strength of the association, the biological gradient, temporal sequence, biological plausibility, coherence with established facts, and specificity of association. Bradford Hill commented:

> *None of my criteria can bring indisputable evidence for or against a cause and effect hypothesis and none except for time sequence can be required as a* sine qua non. *All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge that we already have or to postpone the action that it appears to demand at a given time.*

Applying this to lung cancer, in 1945 we knew that incidences of lung cancer and cigarette smoking rise together. In 1950, we had a case-controlled study. In 1953, we knew tar causes cancer in mice. In 1954, we had follow-up studies showing an association between greater exposure and greater risk. Between 1954 and 1990, interesting things transpired in spite of the science. There were

lawsuits, and the tobacco companies declared to Congress that there was no proof that cigarette smoking causes cancer. At what point would you have taken action on cigarettes and tobacco? 1945? I don't know many people who would—not quite enough science. 1950? 1953? 1954? At what point do we come to a consensus within our democracy that evidence is sufficient? According to Hill, we already had enough information by 1954. Non-specificity is an issue that makes proof difficult to establish. Many diseases require multiple exposures, *e.g.*, smoking or allergenicity. Many diseases have multiple causes. There may be a long latent period between exposure and disease. Also, there may be windows of vulnerability, *i.e.* exposure is most hazardous when it occurs at a particular time. We know that at day 10 *in utero*, exposure to an organophosphate causes permanent hyperactivity in mice, but not on day 8 or day 12. Such windows of vulnerability can make causation difficult to establish.

Sometimes exposure is unavoidable, and there's no control population. Similarly genetically modified foods are ubiquitous in the food system. When an identified susceptible population is mixed in with the general population, then there's no identifiable endpoint.

Precautionary Action

Precautionary action is often viewed as cessation. I suggest that there's a much richer sense of precautionary action, and many different kinds. Precautionary action is anticipatory and preventive—unlike risk assessment—increasing rather than decreasing options. Factors must be monitored and reversed such as to increase the resilience, the health and the integrity of the system as a whole. Fred Kirschenmann criticized the interventionist approach where we deal with one part of the system at a time. How can we identify options that increase the resilience, the health and the integrity of the system as a whole, not just one part of it? By establishing goals, we have a means of evaluating options for meeting those goals.

Much has been written about the burden of proof lying with the proponents and not with the public. Chemicals policy in the United States provides an example. We have a "don't ask don't tell" system. Under the Toxic Substances Control Act, we don't test chemicals that were introduced before just a short while ago—all are "grandfathered" in. We wait until someone has been injured or there is enough evidence for court proceedings; still, the injured party bears the burden of proof. In some ways, it involves thinking about allocating responsibility, which comes from Donella Meadows's work on systems.

New technologies are launched largely without public consultation, which is a poor *modus operandi*. If we are to meet goals, we need to consider alternatives, looking for those that are least harmful, are reversible and those that increase the health and resilience of the whole system, and provide the most options. This approach was not dreamed up by environmental "wackos" or as a friend of mine in Washington says: "sane, reverent people." It is embedded in laws in

some form or another. The Department of Health and Human Services establishes health goals for a decade. The National Environmental Policy Act requires evaluation of alternatives when preparing environmental impact statements.

Decisions should be made through an open, informed and democratic process with all affected parties included, and not left to scientists. We must bring together the informed public mentioned by Charles Benbrook and by David Hoisington and Christopher Ngichabe. Since, the US regulatory system doesn't foster it, how do we involve all stakeholders in meaningful discussion? There is no good mechanism. Who speaks for whom is a large part of the discussion within biotechnology. Who speaks for people in Mexico or people in Kenya? Who is speaking for people in the United States? Many people would like to speak for others, but I believe that people should have the opportunity to speak for themselves.

Can we say yes to new technologies? Of course we can. We need the right yardstick for environmental predictions. In the past we have relied too much on data, and have lost sight of biological principles. *Homo sapiens* did not evolve in the presence of long-chain branching hydrocarbons. Rather than going back and testing every chemical, we should use biological principles and learn from evolutionary biology what nature does. In a book that I edited on the precautionary principle, Ted Schettler described the addition of manganese to infant formula because it's an essential micronutrient. Unfortunately it wasn't understood that manganese crosses the blood/brain barrier and high levels can be harmful. Although we didn't have good information on safety, we didn't consider the level of manganese in mother's breast milk. We didn't ask the right question: "What does nature do?"

We should consider instituting performance bonds, which are required, for example, in mining law. If you want to launch a new technology, put up the money. If the technology is found to be safe, you get the money back, otherwise, we get the money. The insurance companies could help establish such bonds. There has been discussion about posting bonds for the long-term performance of sites of decommissioned nuclear power plants. Similarly, in biotechnology, we need to set up means of monitoring and we need to establish early-warning systems.

Labeling

The pro-labeling argument is made usually in terms of consumers' right to choose—their right to information. I believe that the case for labeling is more important in terms of providing an epidemiological tool so public-health experts can track harm. Imagine you are an emergency-room physician with a patient showing a first-time allergic reaction and you want to know what caused it. If it was a genetically modified ingredient in a consumed food, how would you ever know it without labeling?

The following is a quote from James Maryansky at the Food and Drug Administration:

> *The possibility that bioengineered foods might have adverse long-term affects is an idea that keeps coming up.*

He said that we need to take another look at the science.

> *We haven't considered a monitoring program, per se. There's no endpoint we could look for. We think these foods are safe.*

It's impossible to monitor unless there's an identifiable health issue that can be traced. They've decided it's safe and are not looking for an endpoint. With no imaginable endpoint, we are in the same position as when chlorofluorocarbons were developed—CFCs that destroy the ozone layer. We knew that CFCs were stable and, without biological or geological principles for evaluation, assumed that they were safe. Although it wasn't foreseen, it doesn't mean that it wasn't foreseeable. So the question is: are some not-yet-foreseen endpoints foreseeable? Can we develop monitoring systems in the absence of known endpoints, and what early-warning systems can we create? We have actually achieved this with drugs. We have had many surprises with drugs pharmaceuticals and have developed a very different testing system for them. In the case of the diet drug phen-phen, an alert practitioner who examined a number of women noticed the occurrence of a heart-valve problem. By law, adverse drug reactions have to be reported, and a federal law specifically addresses vaccines. Although we don't necessarily know what adverse effects there might be with a new drug, a feedback route is in place that is not in place for biotechnology. Therefore, even in the absence of known endpoints could we expend scientific capital on developing monitoring and warning systems to detect results that at this point are not foreseen?

Most of us came into this room with a preconceived set of ideas. Ask yourself what information would be needed to change your opinion of agricultural biotechnology. Are there any events that would result in agreement to a total ban? And are there incremental actions that we could take in the event of other problems that would manifest themselves within the system? They're doing this at the US National Oceanic and Atmospheric Administration where they are studying fisheries; they agree on a step that they will take if they come up with certain science-based information.

We have different perspectives in the United States and Europe. In the Maastricht Treaty of the European Community, they adopted the precautionary principle. They put into place requirements for high-level protection and harmonization measures across Europe with which they are allowed to take provisional measures for non-economic, environmental reasons. Their policy on the environment directs the Community to take account of available scientific and technical data as well as environmental conditions in the various regions,

and then to appraise potential benefits resulting from action or lack of action. As already mentioned, the Biosafety Protocol actually uses the precautionary principle to address human health and biodiversity. It was a derivative treaty from the biodiversity convention. It's also mentioned in the preamble to the Protocol as an objective and in two operational articles.

Ethics and values are important in European decisions, whereas the United States prefers to make decisions on the basis of sound science, which generally means risk assessment. Another difference is that minority views on cutting-edge science have a place at the table in Europe; they see it as a component of the precautionary principle. Instead of dismissing a warning sign as a false positive, they take it seriously because it drives more science. In the United States, we want a very high level of scientific certainty before entertaining a conclusion. And we have a social contract that relies on post-market testing. We presume that if a company knows there's a problem it will do something about it.

The Current Trade Controversy and the Precautionary Principle

We've heard a lot both about African countries' refusal to accept aid and Europe's refusal to accept trade. Calestous Juma, at Harvard, former executive secretary of United Nations Convention on Biodiversity, said that we in the United States don't understand that, because so much of Africa was colonized, they are in a different position *vis-à-vis* the colonizer and want two things. Calestous suggested that that the former colonies want the benefits of technology. They don't want to be left behind, but at the same time they are cautious about being used as guinea pigs.

On 13 May, 2003, the USDA filed a WTO case against the European Union, calling their trade restrictions illegal and not science-based. The timing of that filing was interesting. At the time we announced that challenge, Colombia was soon to ratify the Biosafety Protocol, which happened a week later. We now have forty-nine parties to the Protocol, and fifty are needed for ratification. The assumption was that the fiftieth would come soon. So why file? There are mutually exclusive provisions about the relationship to trade treaties and I think that the United States looked at that and said that they don't want to have to adjudicate these exclusive provisions and they don't want to get involved with the Biosafety Protocol's conflicts. The precautionary principle would be a matter of hard international law for the first time, which would reinforce Europe's use of it. Moreover, the Protocol's nonparty provision encourages parties to it to encourage non-parties to comply. I think that the United States evaluated the legal implications and decided that it was too much of a hornet's nest. Is the United States afraid of a unicorn? Inquiring minds want to know.

There are four parts to the US challenge: consultation, a panel, the appeal, and then compliance. The United States will have to address a couple of

aspects, *e.g.*, whether an adequate risk assessment was undertaken, and whether other international standards apply. Burden of proof is a major part of the precautionary principle, and at the WTO there's actually a two-part process for the burden. The burden initially rests on the complaining party—in this case the United States and its allies—to bring a *prima facie* case of inconsistency with the sanitary and phytosanitary (SPS) agreements and once that *prima facie* case is made, the burden shifts to the responding party, in this case to Europe.

The role of science and uncertainty and the ability of countries to set their own health and safety standards are being contested. Al Gore wrote a letter around phthalates in children's toys and the precautionary principle that said that countries have a right to set their own health and safety standards. It's a matter of sovereignty, and I think that discussions about sovereignty will play out over and over with the precautionary principle. Again, we have different perspectives on the role of ethics. In sum, two worldviews are being contested. Is the unicorn a myth or a metaphor? A myth is a purely fictitious narrative. A metaphor is a figure of speech to suggest a likeness between two things—it's a comparison, with the same root as metamorphosis. Interestingly, the unicorn is part of folklore in many parts of the world. Asia has a legend. Some think that it comes from the African rhinoceros. It was mentioned by Aristotle as being in ancient Europe, *etc*. Its horn was a sovereign remedy against poison, and the unicorn could be tamed only by a pure and innocent person. It's a symbol of truth and justice. So, the precautionary principle: is it a twenty-first century remedy or an old European myth?