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IMPLICATIONS OF THE PRECAUTIONARY PRINCIPLE: IS IT A THREAT TO SCIENCE?

BERNARD D. GOLDSTEIN and RUSSELLYN S. CARRUTH

University of Pittsburgh Graduate School of Public Health
and University of Pittsburgh School of Law
Pittsburgh, PA, USA

Abstract. Scientific research is of proven value to protecting public health and the environment from current and future problems. We explore the extent to which the Precautionary Principle is a threat to this role for science and technology. Not surprisingly for a relatively simple yet still incompletely defined concept, supporters of the Precautionary Principle come from different viewpoints, including a viewpoint that is at least uneasy with the role of science, and particularly its use in risk assessment.

There are also aspects of the Precautionary Principle that inherently restrict obtaining and using science. The Hazardous Air Pollutant (HAP) provisions in the US Clean Air Act Amendments are an example of the Precautionary Principle, which both shifted the burden of proof so that the onus is now on showing a listed compound is harmless, and required maximum available control technology (MACT) instead of a primarily risk-based approach to pollution control. Since its passage in 1990 there has been a decrease in research funding for studies of HAPs. Other potential problems include that once MACT regulations are established, it may be difficult to develop new technological approaches that will further improve air pollution control; that by treating all regulated HAPs similarly, no distinction is made between those that provide a higher or lower risk; and that there is a perverse incentive to use less well studied agents that are not on the existing list. As acting on the Precautionary Principle inherently imposes significant costs for what is a potentially erroneous action, additional scientific study should be required to determine if the precautionary action was successful. If we are to maximize the value of the Precautionary Principle to public health and the environment, it is crucial that its impact not adversely affect the potent preventive role of science and technology.

Key words:
Precautionary Principle, Science and technology, Risk assessment, Hazardous air pollutants, Maximum available control technology

INTRODUCTION

The goal of this paper is to discuss the impact of the Precautionary Principle on scientific research. We will do so by describing the positive role of scientific research as a precautionary approach; the different forces driving the adoption of this as yet incompletely defined principle that are directly or indirectly opposed to scientific research; and the reasons why the thrust of the precautionary principle, if it is to fulfill expectations of it being a preventive force in public health and the environment, must actively seek to foster scientific research. We will also review the impact on scientific research of an example of the precautionary principle embodied in environmental legislation, that of the hazardous air pollutant provisions of the 1990 United States Clean Air Act Amendments.

As a result of this review, we express concern that insufficient attention is being placed on the potentially negative consequences of the Precautionary Principle on science and technology. We support the central concept of the Precautionary Principle, that we should err on the side of caution to protect public health and the environment. But we are concerned that the potential benefits of adhering

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Address reprint requests to Dr. B.D. Goldstein, Dean's Office, University of Pittsburgh Graduate School of Public Health, 130 DeSoto Street, Pittsburgh, PA 15261, USA (e-mail: bdgd@pitl.edu).

to any of the many definitions of the Precautionary Principle may be outweighed by the adverse impact of a simplistic approach to complex interrelated environmental and public health problems. The scientific community should actively confront the possible adverse implications of the Precautionary Principle to obtaining the knowledge base that is central to protecting public health and the environment.

THE ROLE PLAYED BY SCIENTIFIC RESEARCH IN ACHIEVING PRECAUTION AND PRIMARY PREVENTION

It is ironic that research activities which have contributed so centrally to the precautionary successes of the environmental movement are under threat from this same movement in the name of the Precautionary Principle. Chemical industries throughout the world continue to develop new chemicals to respond to human need, from medicinals to plastics, from fibres to solvents. The task that has faced our society has been to obtain the benefits conferred by our chemical age while avoiding or minimizing the risks to human health or the environment. One poorly understood fact is that there are nearly an infinite number of possible chemicals that can be developed. A usual approach in the chemical industry is to evaluate perhaps a dozen possible new chemicals for every one that is brought to the market. Along the way testing is performed to attempt to rule out adverse consequences, such as mutagenicity or persistence in the environment. The incentive not to develop such agents is at least economic, experience having taught the chemical industry that they can lose not only their investment but suffer severe regulatory and legal consequences, as well as loss of public support, as a result of marketing a chemical product for which toxicity has not been sufficiently ruled out.

The toxicity tests that potentially lead to abandoning the development of a chemical have required a whole range of new science, both basic and applied. The Ames test is an excellent example. It is based upon scientific advances that include an understanding of the role of mutagenesis in carcinogenesis; an understanding of microbial genetics; and an understanding of the role of metabolism in chemical carcinogenesis. Without scientific advances in these different disciplines, it would not have been possible to develop the Ames test. We can be certain that many chemicals that would have caused cancer have not been developed and released to the environment because of the availability of the Ames test. What we cannot do is reasonably estimate the number of cancers averted, or for that matter the protection provided by similar tests that weed out other chemicals with attributes that are potentially harmful to human health or the environment.

We do not claim that current pre-marketing testing approaches are perfect. But we see aspects of the Precautionary Principle as guiding us away from the further application of basic biological advances to developing testing procedures that lead to primary prevention. There are those who believe that human society will not benefit from any new chemicals, and for such individuals the Precautionary Principle works well if it is interpreted to stop our world at its present level of development. But if, as is likely, we will continue with chemical discovery, there remains a need for scientific research aimed at the development of preventive approaches to lessen the likelihood that new chemicals will cause adverse effects.

The precautionary value of research is also well illustrated by the history of removing lead from gasoline [1]. This began in the United States in a step wise fashion, each step accompanied by highly controversial battles about the cost and benefits of limiting gasoline lead levels. At the end of each of these battles, the regulatory agency, the US Environmental Protection Agency (EPA), lost interest in any further research on the subject of lead toxicity. This is understandable. They had regulated lead and needed their research resources to look at the next compound they were intending to regulate, a situation which is unchanged today. What produced the need for further regulation of lead was additional research funded by the US National Institute of Environmental Health Sciences and by the US Center for Disease Control and Prevention's Center for Environmental Health, neither of which are regulatory agencies. The combination of basic science and public health surveillance developed the compelling argument

that led to the complete removal of lead from American gasoline, a process now going on elsewhere in the world.

THE REASONS WHY THE PRECAUTIONARY PRINCIPLE HAS BECOME A POTENTIAL THREAT TO SCIENTIFIC RESEARCH

Described below are some of the reasons that the Precautionary Principle has developed into a threat to the future value of science to the protection of the environment. The list is both incomplete and overlapping, reflecting in part the lack of a clear definition of the Precautionary Principle, and its service as a wide umbrella under which many different groups can gather. For some of these definitions and some of these groups the resulting threat to research is indirect while for others it is overt. We emphasize that in our view it is not inevitable that the regulatory uses of the Precautionary Principle have an outcome that interferes with the precautionary value of science and technology.

Research is seen by supporters of the Precautionary Principle as being used by industry and government as a delaying tactic and as an excuse to avoid protecting the environment

The concern expressed by some advocates of the Precautionary Principle about research is understandable – those responsible for causing environmental pollution have often hidden behind the alleged need for more scientific research, or more review of existing research. Delaying tactics have included the search for scientific perfection when there was already more than enough information to make the case for action. This has led to the perception that the research enterprise is of value only for those who are opposed to environmental controls [2–4]. A recent European Community document has provided numerous insightful case studies in which delay in regulation led to adverse effects [5]. This of course is hindsight. Most importantly, it does not explore those situations where there were calls for banning a compound that turned out to provide societal benefit.

Risk assessment is seen as a technocratic approach that is antithetical to democracy and to the environment

Many supporters of the Precautionary Principle see it as a desired alternative to risk assessment which they attack as elitist and inherently anti-environment. For example, O'Brien [6] has stated: "Risk assessment obscures and removes the fundamental right to say no to unnecessary poisoning of one's body and environment". Others believe risk assessment is highly limited and readily subject to abuse [7].

Has risk assessment been misused? Certainly, but so has any scientific tool in the inherently confrontational approach fostered by the political or legal process. And it has been misused by environmentalists, by government, and by industry when the process suits them. The basic issue appears to be a misidentification of risk assessment as being responsible for risk management choices rather than simply a means to organize and analyze pertinent scientific information. There also appears to be some misunderstanding of the role of Risk Assessment Guidelines that govern the performance of risk assessments [8]. The development of these guidelines allows the incorporation of policy issues, including the degree of prudence, into the default assumptions. These generic guidelines can and should reflect the degree of precaution required to guide risk assessments.

It is traditional for any party in a dispute to question the facts presented by the other side, or the process used to organize and develop those facts. Risk assessment is primarily the latter. Contrary to the belief of some environmentalists who routinely attack risk assessment, industry has not had a free hand in how risk assessment is defined and used. As just one example, industry has persisted for more than two decades in attempting to move away from the linear one hit model for carcinogens. Despite enormous investment in lobbying activities, and a modicum of investment in science, the assumption that every molecule of a carcinogen has some risk of producing cancer continues to be the standard prudent default assumption used in risk assessment, at least in the United States.

Not every proponent of the Precautionary Principle believes that it is inherently antithetical to risk assessment.

To some, the Precautionary Principle can simply be translated as a part of risk assessment in the sense of calling for additional protective factors of ten or for more conservative default assumptions. To others, risk assessment and the Precautionary Principle are complementary, with the Precautionary Principle primarily a risk management tool involved with such issues as shifting the burden of proof to the polluter [9–11].

One of the strengths of risk assessment is that it provides an orderly way to determine research needs. A quantitative risk assessment can readily be converted into a sensitivity analysis leading to insight into what research would most likely narrow crucial uncertainties. In contrast, it is more difficult to use the Precautionary Principle as a means to focus on research needs.

Advocacy for the Precautionary Principle is in part an extension of deconstructionism and related nihilistic humanistic and social science doctrines

Some proponents of the Precautionary Principle associate it with deconstructionism and related nihilistic aspects of modern humanities and social science which have led to various theoretical constructs that belittle the value of science [12,13]. There is a reasonable debate as to whether this viewpoint is derived from novel theoretical insights, or from the antagonism of some academics to more classic scientific disciplines. It is true that scientists have values, and that there is nothing that is absolutely absolute, but such sentiments are also trite and trivial. What is certain to physical and biological scientists, and to the general public, is that actions have consequences, and that this is true for inactions as well. Further, the consequences of actions or inactions can be predicted, albeit with some degree of uncertainty.

The issue of the antagonism toward classic scientific thought of those involved in deconstructionism and postmodern science has been highlighted by the unwitting acceptance by the journal Social Text of an intentional parody of deconstructionism by Alan Sokal, a physicist [14]. Of note is that Sokal approaches the issue from the political left wing, stating that he wrote the article "to combat a currently fashionable postmodernist/poststructuralist/social-constructivist discourse – and more generally a penchant for subjectivism – which is... inimical to the values and future of the Left" [15]. Unfortunately, the response of the scientific community to Sokal's successful hoax is to feed our arrogance and to further blind us to the fact that the deconstructionist agenda has been highly successful, often under guises such as post-modern democracy. Those of us in science must recognize that it is the public who makes the decisions; but we also must forthrightly argue that those who believe that decision making on complex planetary issues can be done without scientific knowledge are in fact a threat to the planet.

The Precautionary Principle is easily manipulated to justify trade barriers on the pretext of environmental protection or public health

Economic interests, as exemplified by the European Community's tendency to use the Precautionary Principle as a means to justify otherwise unjustifiable trade barriers, represents another threat to science. That the Precautionary Principle has been used to justify trade barriers is unquestionable. This is not merely a trans-Atlantic issue. A recent example is the use of the Precautionary Principle to justify a more stringent EU aflatoxin standard, one that is lower than that recommended by the World Health Organization, the Food and Agriculture Organization or by other major countries. This protects southern European EU members from competition by African nations and has been estimated to cost these relatively destitute countries about $700 million a year at a benefit of less than one life saved per year in Europe. Majone [16] has pointed out that these African countries cannot readily switch their produce to non-EU states because their trade linkages are primarily with their former colonial masters. Further, in contrast to more developed areas like Latin America, they do not have the wherewithal to develop food processing plants to sell a finished product. The amount of funds that the EU would now generously provide in relief aid to the countries whose products they refuse to buy will more than amply pay for the scientific research needed to narrow down the

residual uncertainties concerning appropriate protective standards for aflatoxin.

The recent drought and resultant food shortages in sub-Saharan Africa also provides an example of the problems caused by the simple-minded application of the Precautionary Principle to a complex issue involving trade. Approximately 75% of the corn distributed in Zambia, one of the most affected nations, by the United Nations World Food Network has been donated by the United States. Based upon the Precautionary Principle and upon concern about losing any future export market to the EU, Zambia has ruled that this grain is not safe because it is partially genetically modified [17]. In August 2002 there were 14 000 metric tons of US corn in Zambian warehouses, with much more on the way. But only 7000 tons of non-US grain, approximately two weeks supply, were available for 2.5 million people in need. The Agricultural Minister of Zambia claimed that genetically modified grain was poisonous because it caused allergies, and the President of Zambia objected to the use of his people as "guinea pigs"[18]. This guinea pig claim had previously been asserted by environmental activists opposed to the distribution of donated US grain during a food shortage in India. Yet, of course, the grain is not at all different from that eaten by the average American, with no convincing evidence whatsoever of allergic reactions or any other adverse effects. The issue is not whether additional research is needed to ensure the safety of genetically modified products – of course additional information should be sought. But enough is already known to conclude that it is almost inconceivable for any such risks to exceed the benefits of avoiding the health and welfare consequences of malnutrition. In this case, the use of the Precautionary Principle in ways protective of European agricultural interests has clearly been harmful to public health. Fortunately, the issue appears to be increasingly recognized by the European Community, who appear now to have downplayed their concern with the use of US grain to relieve famine in Southern Africa.

To be effective in protecting health and the environment, the Precautionary Principle must also foster the role of scientific research

An obvious starting point in considering the value of scientific research to the Precautionary Principle is in noting that most formulations of this principle require some scientific information to even raise the question of the need for precautionary action. For example, the Rio Declaration begins with "Where there are threats of serious or irreversible damage...", which presumably means that there is some scientific information to lead to a concern [19].

It is not simply that more scientific research will lead to more information on which to take precautionary action. As a generalization, research that focuses on the hazard identification step of the risk assessment paradigm will be more effective in discovering problems worthy of precautionary action than will research focusing on dose-response issues for existing chemicals of concern.

There is a tautology about the precautionary approach that appears obvious but bears repeating. The more precautionary we are, the more likely we are to erroneously inflict major societal burdens [20,21]. The truth of this statement is inherent in two aspects of the Precautionary Principle. First, by definition, the Precautionary Principle is only invoked when there is scientific uncertainty. If we were reasonably certain, we would not need the Precautionary Principle as a rationale for action. Second, the precautionary action must have some significant adverse economic or social impact on some segment of society – if there were no such impact the action would be taken without resort to the Precautionary Principle as a justification. Therefore it seems reasonable to require that invoking a precautionary approach to reduce exposure to agents already present in the environment, such as endocrine disruptors, include as a necessary concomitant a research agenda designed to determine the effectiveness of the precautionary action. This is particularly important for agents that may be erroneously linked to an unwanted effect as the true cause of the effect might otherwise be overlooked. For example, imagine that endocrine disruptors were to be controlled based upon precautionary concern that they are responsible for the worldwide decline in amphibians, and that instead there was some other cause for this effect. Without research to evaluate whether amphibians had responded to the change in exposure to endo-

crine disruptors, there could well be further harmful delay in determining the true cause. Furthermore, studies done around the time of a precautionary action may provide the best opportunity to determine cause and effect relations. Assessing the effect of interventions is the closest we usually get in field studies to laboratory conditions in which all aspects of the experiment are controlled and exposure is intentionally varied. Obviously, it is difficult to measure an effect after the fact unless one has anticipated the need to do so, which means that the research must be in place at the time the precautionary action is being taken.

It is more difficult to develop a research approach to estimate the value of a precautionary action that stops something before it starts. In these cases the question to be posed is related to tradeoffs and second order issues. For certain actions of this nature, such as a chemical company choosing to develop a non-mutagenic agent rather than a mutagen, there seems to be little reason for concern. For others, such as the genetically-modified organisms issue, the potential value of genetically modified agricultural products requires a more thoughtful approach. Note that a major precautionary impact of the legitimate concern about persistent organic pollutants (POPs) has led to the development of scientific tests and of national and international legal processes that make the development of new POPs far less likely.

The Precautionary Principle provides a very powerful rationale for an increase in health and environmental surveillance [22]. Surveillance is a core but underutilized public health and environmental technique. It has three advantages in relation to the use of the Precautionary Principle: 1) it provides an early warning system capable of alerting us to the need for precautionary action; 2) it allows us to make judgements as to the likely severity of the threat (e.g., we arguably know the worst about the impact of persistent organic pollutants as their levels are for the most part decreasing in humans and in the general environment, but the worst case impact of global climate changes have not been seen and therefore are more of a concern); and 3) it provides a baseline for us to measure the extent and direction of impact of actions taken under the Precautionary Principle. What is needed is institution of surveillance programs using existing methodologies and, perhaps of greater importance, investment in the development of new indicators that accurately reflect the state of the environment and of human health.

THE 1990 US CLEAN AIR ACT AMENDMENTS ON HAZARDOUS AIR POLLUTANTS AS AN EXAMPLE OF THE POTENTIALLY ADVERSE IMPACT OF THE PRECAUTIONARY PRINCIPLE ON SCIENCE AND TECHNOLOGY

Any policy has its shortcomings. When adopting a new policy, such as the Precautionary Principle, it is crucial that we consider its weaknesses and adopt a plan to protect against these weaknesses. We have raised the question that a potential weakness of the Precautionary Principle is its lessening the preventive value provided by science and technology. In order to explore whether this is true, we have examined an example of a law that reflects the Precautionary Principle in action. We caution that this is one law only, and that it was adapted without the more mature consideration now given to actions under the Precautionary Principle - but we believe it is instructive.

In 1990 the law that controlled the way that hazardous air pollutants were regulated in the United States was radically changed [23]. The US Clean Air Act in essence recognizes two types of outdoor pollutants, those six pollutants for which there is clearcut evidence of harm at outdoor levels and for which ambient standards are set (National Ambient Air Quality Standards (NAAQS) – pollutants, e.g., particulates, ozone); and everything else lumped under the title of hazardous air pollutants (HAP). Before 1990, HAP regulation was a twostep process. First was the establishment by the US EPA that a compound was likely to be hazardous at ambient levels. Once this determination was made and survived an elaborate hearing process, the second step was to choose which emission sources of this pollutant were to be regulated using a variety of criteria including risk reduction and cost.

Impatience with this science and risk-based approach, which had led to the regulation of only a handful of pollutants (e.g., benzene, mercury), was a major driving force in

changing the approach to one that is fully consistent with the Precautionary Principle (Table 1). Sharply curtailing EPA's discretion, Congress listed more than 180 HAP compounds in the Act. With respect to these compounds, Congress shifted the burden of proof. Whereas before, EPA had to go through an elaborate process to prove a compound guilty before it could be regulated, now EPA must go through an elaborate process to prove a listed compound innocent before it can avoid regulation. Secondly, Congress required that maximum available control technology (MACT) be installed on all sources, regardless of extent of resulting exposure or toxicity. Risk assessment has been relegated to a residual risk provision that provides for additional action should MACT controls still leave a risk to the maximally exposed individual beyond a relatively stringent level. This shift of the burden of proof, requirement of MACT across the board, and downgrading of the importance of risk assessment clearly fall within the Precautionary Principle as does the use of a stringent risk criterion and of the maximally exposed individual rather than the population as the target of concern.

We can find no record that the Precautionary Principle was specifically mentioned in the contentious debate about the HAP provisions prior to the passage of the 1990 Clean Air Act Amendments, although it certainly would be a focus of deliberations if this same discussion were first occurring today. The dozen years since the passage of these amendments give us an opportunity to consider their impact in terms of science and risk and to at least speculate about the implications to science in general should all laws be promulgated on the basis of the Precautionary Principle.

A major argument in favor of the new approach to HAPs was that it would be faster, cheaper and better than the then existing risk-based approach. It is hard to see how it has been faster or cheaper. It has taken more than a decade for a greatly expanded EPA work force to complete its regulation. However, the key question is whether this new approach is better for the environment and for human health. Answering that question requires consideration not only of the benefits of the new approach, but also whether those benefits are outweighed by unanticipated losses to public health and the environment.

There is little question that the new approach should dramatically decrease the tonnage of many substantial contributors to total air pollution burden. For example, a substantial decrease should be achieved in the emissions of toluene and other alkyl benzenes beyond that required for the control of ozone precursors. But does reduced tonnage equal reduced toxicity? There is little reason to suspect that it will make any difference whatsoever to public health and the environment if background ambient urban toluene levels are decreased from about 2 ppb (a level already substantially lower than in most of the European Community) to 1 ppb. But perhaps there will be a public health and environmental advantage, as would be envisioned by the precautionary approach. This presumed benefit can be achieved only if there is not some unexpected loss to public health and the environment.

One casualty of this approach has been scientific research into the health effects of HAPs. EPA's budget for such studies, which focused to a large extent on cross-cutting methodologies to determine target organ toxicity, has decreased. Another problem presented by the use of MACT is the question of how will new technology capable of improved control of HAP emissions ever be developed? There have been two driving forces for pollution control: regulation and technical feasibility. There are many instances in which regulation has forced technology

Table 1. Control of hazardous air pollutants in the United States

	Before 1990	After 1990
Burden of proof	To list chemical, EPA must demonstrate that ambient levels of pollutant produce risk	To remove chemical from list, industry must demonstrate that chemical does not produce risk
Regulatory control for listed pollutant	Risk-based application of control technology	Maximum available control technology
Role of risk assessment	Primary	Secondary

development. There are many other instances in which the development of new advances in technology (for example, materials capable of improving baghouse filtration) have made better pollution control feasible. Once the MACT regulations are in place, there needs to be serious consideration as to the extent of any remaining impetus for investment and exploitation of new technology to further improve pollution control.

There are other potential problems in abandoning a risk-based approach. In essence, the new approach makes no initial distinction between those compounds for which there are no known adverse effects at ambient levels and those that have a risk-based concern. An equal MACT emphasis on toluene and on benzene, for example, makes little sense based upon what we know of the two compounds. The need for a residual risk approach, recognized in the 1990 Clean Air Act Amendments, argues against the Precautionary Principle being capable of fully replacing risk assessment. Of note is that for most of the more than 180 compounds on the list there is far less information than available for toluene and benzene. Without further research, which is unlikely now that the law is in place, it will be difficult to determine which of these compounds will require a residual risk approach. Perhaps more importantly in terms of the unknown threat of chemicals whose toxicity has not been fully explored, there is now an incentive for industry to shift away from compounds on the list to compounds in commerce that could do the same job but for which we know even less – or the compounds presumably would have been on the list. Although there are elements in the Clean Air Act amendments that are designed to combat such a shift, in essence the Precautionary Principle as enshrined in the HAPs amendments may be driving us away from a compound like toluene for which there is ample evidence of apparent lack of toxicity at ambient levels, to compounds for which there is little toxicological information and thus far more of a likelihood of unwanted public health and environmental consequences.

Another problem with the new approach to HAP regulation was revealed when EPA began to grapple with the provision of the Clean Air Act Amendments requiring cost-benefit analysis [24]. This has been achievable for NAAQS compounds for which there is an ample database concerning the public health and environmental benefits. But the large majority of HAP compounds included on Congress's list, particularly those that had not already been regulated, were compounds for which there is an inadequate scientific data base on which to perform a benefit analysis. Almost by definition, regulation under the Precautionary Principle precludes a standard economic cost-benefit analysis. If there were adequate information about benefits, we would not need to invoke the Precautionary Principle. This does not mean that precautionary actions are unwarranted, but rather that they can be antithetical to rational economic analysis. However, the traditional 16:1 benefit ratio between prevention and cure (an ounce vs. a pound) amply justifies precautionary action, as long as there are no second order effects that in the long term will cause as much or more harm than good [24]. To get the most public health and environmental benefit from the Precautionary Principle, we must ensure that it does not lead to loss of the highly effective precautionary value of scientific research.

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