THE PRECAUTIONARY PRINCIPLE IN ACTION

A HANDBOOK

First Edition

Written for the Science and Environmental Health Network

By
Joel Tickner – Lowell Center for Sustainable Production
Carolyn Raffensperger – Science and Environmental Health Network
and Nancy Myers

CONTENTS

I. INTRODUCTION

> "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically." *from the January 1998 Wingspread Statement on the Precautionary Principle*

For years, the environmental and public health movements have been struggling to find ways to protect health and the environment in the face of scientific uncertainty about cause and effect. The public has typically carried the burden of proving that a particular activity or substance is dangerous, while those undertaking potentially dangerous activities and the products of those activities are considered innocent until proven guilty. Chemicals, dangerous practices, and companies often seem to have more rights than citizens and the environment.

This burden of scientific proof has posed a monumental barrier in the campaign to protect health and the environment. Actions to prevent harm are usually taken only after significant proof of harm is established, at which point it may be too late. Hazards are generally addressed by industry and government agencies one at a time, in terms of a single pesticide or chemical, rather than as broader issues such as the need to promote organic agriculture and nontoxic products or to phase out whole classes of dangerous chemicals. When citizen groups base their calls for a stop to a particular activity on experience, observation, or anything less than stringent scientific proof, they are accused of being emotional and hysterical.

To overcome this barrier, advocates need a decision-making and action tool with ethical power and scientific rigor. The precautionary principle, which has become a critical aspect of environmental agreements and environmental activism throughout the world, offers the public and decision-makers a forceful, common-sense approach to environmental and public health problems. This Handbook describes how it can be used to make preventive decisions in the face of uncertainty and to drive actions that will protect public health and the environment.

This comprehensive presentation of ideas is new, yet precaution is a concept citizen activists have promoted for years. We, the authors, invite you to try these ideas out and write the next chapters on the precautionary principle with us.

We are at an exciting juncture in the history of the world. On the one hand, we are faced with unprecedented threats to human health and the life-sustaining environment. On the other hand, we have opportunities to fundamentally change the way things are done. We do not have to accept "business as usual." Precaution is a guiding principle we can use to stop environmental degradation.

II. HISTORY OF THE PRECAUTIONARY PRINCIPLE

One of the most important expressions of the precautionary principle internationally is the Rio Declaration from the 1992 United Nations Conference on Environment and Development, also known as Agenda 21. The declaration 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.

Because the United States signed and ratified the Rio Declaration, it is bound to use the precautionary principle. It is important for organizers to know that it is not a matter of whether the United States will abide by the precautionary principle, but how. Nevertheless, application of the principle is far more advanced in Europe and on the international level than it is in the United States.

The precautionary principle has its beginnings in the German principle of *Vorsorge*, or foresight. At the core of early conceptions of this principle was the belief that society should seek to avoid environmental damage by careful forward planning, blocking the flow of potentially harmful activities. The *Vorsorgeprinzip* developed in the early 1970s into a fundamental principle of German environmental law (balanced by principles of economic viability) and has been invoked to justify the implementation of vigorous policies to tackle acid rain, global warming, and North Sea pollution. It has also led to the development of a strong environmental industry in that country.

The precautionary principle has since flourished in international statements of policy; conventions dealing with high-stakes environmental concerns in which the science is uncertain; and national strategies for sustainable development. The principle was introduced in 1984 at the First International Conference on Protection of the North Sea. Following this conference, the principle was integrated into numerous international conventions and agreements, including the Bergen declaration on sustainable development, the Maastricht Treaty on the European Union, the Barcelona Convention, and the Global Climate Change Convention. (See Appendix) On a national level, Sweden and Denmark have made the precautionary principle and other principles, such as substitution for hazardous materials, guides to their environmental and public health policy.

In the United States, the precautionary principle is not expressly mentioned in laws or policies. However, some laws have a precautionary nature, and the principle underlay much of the early environmental legislation in this country:

The National Environmental Policy Act requires that any project receiving federal funding and which may pose serious harm to the environment undergo an environmental impact study, demonstrating that there are no safer alternatives.

The Clean Water Act established strict goals in order to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters."

The Occupational Safety and Health Act (OSHA) was designed to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions."

The OSHA draft Carcinogen Standard (which was never put into practice) required precautionary actions whenever a chemical used in the workplace was suspected of causing cancer in animals. Early court decisions gave the Environmental Protection Agency considerable freedom to take action to prevent harm even before considerable evidence of cause and effect was gathered.

More recently, *The Pollution Prevention Act* of 1990 set prevention as the highest priority in environmental programs in the country. In addition, the President's Council on Sustainable Development expressed support for the precautionary principle in the form of a core belief that "even in the face of scientific uncertainty, society should take reasonable actions to avert risks where the potential harm to human health or the environment is thought to be serious or irreparable." In 1996, the American Public Health Association passed a resolution (number 9606), "The Precautionary Principle and Chemical Exposure Standards for the Workplace," which recognized the need for implementing the precautionary approach, including the shifting of burdens of proof so that every chemical is considered potentially dangerous until the extent of its toxicity is sufficiently known, and the establishment of strict, preventive chemical exposure limits.

However, despite U.S. acceptance of the precautionary principle in international treaties and other statements, little work has been done to implement the principle. In some cases, especially those involving trade and proactive legislation in places like Europe, the U.S. government is actively lobbying against precautionary actions by other governments. This has happened most recently with regards to phthalates in children’s PVC toys, beef hormones, electronic take-back and genetically engineered foods. This lobbying threatens to undermine use of the precautionary principle in other countries, which will ultimately affect the pressure that other countries can exert on the U.S. to invoke the principle. Luckily, in the case of phthalates, Vice President Gore recently wrote a letter to U.S. trade representatives stating that European countries should be allowed to take precautionary actions to protect children's health without U.S. interference.

The first major effort in the United States to bring the precautionary principle to the level of day-to-day environmental and public health decision-making at the state or federal level was a January 1998 conference of activists, scholars, scientists, and lawyers at Wingspread, home of the Johnson Foundation in Racine, Wisconsin. Convened by the Science and Environmental Health Network (SEHN), participants discussed methods to implement the precautionary principle and barriers to that implementation.

The Wingspread definition of precaution (see Appendix) has three elements: threats of harm; scientific uncertainty; and preventive, precautionary action. The litmus test for knowing when to apply the precautionary principle is the combination of threat of harm and scientific uncertainty. Some would say the threatened harm must be serious or irreversible, but others point out that this does not allow for the cumulative effects of relatively small insults.

If there is certainty about cause and effect, as in the case of lead and children's health, then acting is no longer precautionary, although it might be preventive. In essence, the precautionary principle provides a rationale for taking action against a practice or substance in the absence of scientific certainty rather than continuing the suspect practice while it is under study, or without study.

Instead of asking what level of harm is acceptable, a precautionary approach asks: How much contamination can be avoided? What are the alternatives to this product or activity, and are they safer? Is this activity even necessary? The precautionary principle focuses on options and solutions rather than risk. It forces the initiator of an activity to address fundamental questions of how to behave in a more environmentally sensitive manner. The precautionary principle also serves as a "speed bump" to new technology, ensuring that decisions about new activities are made thoughtfully and in the light of potential consequences.

III. COMPONENTS OF PRECAUTION

An underlying theme of the principle is that decision-making in the face of extreme uncertainty and ignorance is a matter of policy and political considerations. Science can inform that decision but it is foolish to think that "independent" or "sound" science can resolve difficult issues over cause and effect. Thus, a decision for further study or not to do anything in the face of uncertainty is a policy decision not a scientific one just as as taking preventive action would be.

A precautionary approach to environmental and public health decision-making includes these specific components:

Taking precautionary action before scientific certainty of cause and effect. Most of the international treaties stating the precautionary principle incorporate it as a general duty on states to act under uncertainty. This provides a mechanism of accountability for preventing harm. General duties - obligations to act in a certain way even in the absence of specific laws - are not uncommon in the United States. For example, the Occupational Safety and Health Act demands that an employer "furnish each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical injury."

Setting goals. The precautionary principle encourages planning based on well-defined goals rather than on future scenarios and risk calculations that may be plagued by error and bias (see risk assessment discussion below). For example, Sweden has set the goal of phasing out persistent and bioaccumulative substances in products by the year 2007. The government is now involving a variety of stakeholders in determining how to reach that goal. Sometimes called "backcasting" in contrast to the more usual "forecasting" of an uncertain future, this type of planning creates fewer miscalculations and spurs innovative solutions.

Seeking out and evaluating alternatives. Rather than asking what level of contamination is safe or economically optimal, the precautionary approach asks how to reduce or eliminate the hazard and considers all possible means of achieving that goal, including forgoing the proposed activity. Needless to say, alternatives proposed to a potentially hazardous activity must be scrutinized as stringently as the activity itself.

Shifting burdens of proof. Proponents of an activity should prove that their activity will not cause undue harm to human health or ecosystems. Those who have the power, control, and resources to act and prevent harm should bear that responsibility. This responsibility has several components:

> *Financial responsibility.* Regulations alone are not likely to spur precautionary behavior on the part of governments or those who are proponents of a questionable activity. However, market incentives, such as requiring a bond for the worst possible consequences of an activity or liability for damages, will encourage companies to think about how to prevent impacts. Such assurance bonds are already used in construction projects as well as in Australia to minimize damage from development projects.
>
> *The duty to monitor, understand, investigate, inform, and act.* Under a precautionary decision-making scheme, those undertaking potentially harmful activities would be required to routinely monitor their impacts (with possible third party verification), inform the public and authorities when a potential impact is found, and act upon that knowledge. Ignorance and uncertainty are no longer excuses for postponing actions to prevent harm (see uncertainty discussion below).

Developing more democratic and thorough decision-making criteria and methods. The precautionary principle requires a new way of thinking about decisions and weighing scientific and other evidence in the face of uncertainty. This type of precautionary decision-flow, addressing both new and existing activities, is described in a later section. Because difficult questions of causality are in essence policy decisions, potentially impacted publics must be involved in the decision process. Thus, structures to better involve the public in decision-making are required under a precautionary approach.

IV. METHODS OF PRECAUTION

Preventive actions should be taken, when possible, at the design stage of a potentially hazardous activity to ensure their greatest impact. The precautionary principle does not fulfill its purpose unless preventive methods for carrying out precaution are implemented. Otherwise, risks may be shifted or the problem may persist, though to a lesser degree.

However, one can think of a spectrum of precautionary actions from weak (intensive studying of a problem) to strong (prohibiting or phasing out a specific activity). Numerous tools for carrying out precautionary policies have been used throughout the world:

Bans and phase-outs. A ban or phase-out could be considered the strongest precautionary action. At least 80 countries ban the production or use of a small number of highly toxic substances. The Nordic countries have particularly advanced the use of bans as a public health strategy. These countries see bans and phase-outs as the only way to eliminate the risk of injury or disease from a very toxic chemical or hazardous activity. Several chemicals, including cadmium and mercury, are now being phased out in Sweden. The International Joint Commission (see later discussion) recommended a phase-out of industrial chlorine chemistry in the Great Lakes region.

Clean production and pollution prevention. Clean production involves changes to production systems or products that reduce pollution at the source (in the production process or product development stage). Other clean-production activities address the dangers of products themselves, introducing sustainable product design, bio-based technologies, and the consideration of raw material and energy consumed in product creation, as well as questioning the fundamental need for products.

Alternatives assessment. Alternatives assessment is an accepted methodology as well as an underlying component of precaution. For example, the U.S. National Environmental Policy Act calls on the federal government to investigate alternatives (in an Environmental Impact Statement), including a no-action alternative, for all of its activities (or activities it funds) determined to have potential environmental impacts. Citizens have the right to appeal decisions if a full range of options is not considered. Several European countries have initiated such programs for all potential industrial polluters. Nicholas Ashford at the Massachusetts Institute of Technology has developed a structure for chemical accident prevention called Technology Options Assessment. Under this scheme, companies would be required to undertake comprehensive assessments of alternative primary prevention technologies and justify their decision if safer alternatives were not chosen.

Health-based occupational exposure limits. Over a period of several years, a group of occupational health experts in the United States has developed a list of occupational exposure limits based on the lowest exposure level at which health effects have been seen. These levels are proposed as new occupational exposure limits.

Reverse onus chemical listing. Proposals in Denmark and the U.S. have been put forward to drive the development of information on chemicals and their effects. In Denmark, one proposal would require a chemical to be considered the most toxic in its class if full information on its toxicity was not available. A U.S. proposal would require that all chemicals produced in high volume, for which basic toxicity information did not exist, would be added to the toxics-release inventory for emissions and waste reporting.

Organic agriculture. The U.S. Department of Agriculture is considering using the precautionary principle as a rule for deciding whether new technologies and substances may be permitted in organic agriculture. Although these decisions are now based on risk assessment upon evidence of "measurable degradation," organic agriculture lends itself to the precautionary approach. It is risk averse, premised on the principle of avoiding substances and practices that might cause harm rather than waiting for proof of harm.

Ecosystem management. Biodiversity issues are suited to the precautionary principle because their complexity and geographic scope increase scientific uncertainty, and because the results of errors can be devastating. Risk assessment and other tools have been unable to predict and prevent such disasters as the devastation of marine ecosystems and the collapse of fisheries. Ecosystem management, like epidemiology, calls for new approaches to the philosophy of science and new standards for human intervention. Applying the precautionary principle would suggest, for example, that interventions must be reversible and flexible. Any mistakes must be correctible.

Premarket or pre-activity testing requirements. The Federal Food and Drug Act requires that all new pharmaceuticals be tested for safety and efficacy before entering the market. This model could be applied to industrial chemicals and other activities.

V. EXAMPLES OF PRECAUTIONARY ACTION

The International Joint Commission

Perhaps the most noteworthy application of the precautionary principle in the United States has occurred in the Great Lakes Region. The Great Lakes have been threatened for years by the emission of persistent organic compounds into their waters. In the late 1970s, the United States and Canada signed the Great Lakes Water Quality Agreement (GLWQA) which establishes the goal of virtually eliminating discharges of persistent compounds from the Great Lakes. Under the GLWQA, the International Joint Commission (IJC), a 100-year-old bi-national body established to protect waters along the border, was designated to conduct research and issue statements on the quality of the lakes and threats to that quality.

In its Sixth Biennial Report on Great Lakes Water Quality (1992) the IJC noted the damage caused by persistent and bioaccumulative substances in the Great Lakes Basin and the critical need to address those. They also recognized that attempts to manage such chemicals, based on the notion of assimilative capacity in the environment, had failed miserably. The Commission issued a call to phase out all persistent toxic substances in the Great Lakes Ecosystem and stated:

> Such a strategy should recognize that all persistent toxic substances are dangerous to the environment, deleterious to the human condition, and can no longer be tolerated in the ecosystem, whether or not unassailable scientific proof of acute or chronic damage is universally accepted.

Gordon Durnil, who was appointed by President Bush to head the U.S. delegation to the Commission, recalled at the January 1998 Wingspread conference how the commission reached this conclusion: "When we commissioners asked scientists what they knew about the effects of pollutants on people and wildlife, they would say they knew nothing for sure. Finally we began asking them what they believed was happening, based on their vast experience and observations. What those scientists of diverse backgrounds said then convinced me that we knew enough about the effects of those discharges to try to eliminate them altogether."

Toxics use reduction in Massachusetts

The Massachusetts Toxics Use Reduction Act is a salient example of the principle of precautionary action. Passed in 1989, the Act requires that manufacturing firms using specific quantities of some 900 industrial chemicals undergo a biannual planning process to identify ways to reduce use of those chemicals. There are several aspects of Toxics Use Reduction that make it a good example of precautionary action:

Goal-setting. The Commonwealth established a goal of reducing toxic by-product (waste) by 50 percent.

Alternatives. Rather than instructing industrial facilities to identify the "safe" level of use, the Act considers any amount of use too much. Companies are required to understand why and how they use specific chemicals and to conduct comprehensive financial, technical, environmental, and occupational health and safety analysis of viable alternatives to ensure that the alternatives are indeed better.

Monitoring and reporting. Companies are required to measure their progress yearly at reducing their use of toxic chemicals. This information is available to the public.

Responsibility. While the burden is on the firm to identify alternatives and analyze their chemical impacts, Massachusetts provides support and incentives to ensure that progress is made in reducing toxic chemical use.

Firms are not required to undertake any particular option but in many cases the economic and environmental, health, and safety benefits provide enough justification for action. Costs associated with chemical purchases, tracking, and waste disposal are very high. From 1990 to 1995, companies in Massachusetts reduced their toxic chemical emissions by more than two-thirds, their total chemical waste by 30 percent, and their total use by 20 percent.The Act saved Massachusetts industry some $15 million, not including the public health and environmental benefits gained through the program.

VI. TRIGGERING PRECAUTION: A PROCESS FLOW

This section describes a process for applying the precautionary principle to a specific problem. It includes case studies of two types, one addressing a new or proposed activity, the other addressing an existing problem. The approaches are nearly identical, but with subtle differences. For new activities the emphasis will be on shifting the burden of proof to proponents of a potentially harmful activity. Proponents should not only demonstrate that the activity will not be harmful, but also that they have considered a wide range of alternatives, including forgoing the questionable activity. Of course, such analyses should also be independently verified. For existing activities the most useful tool is the heart of the precautionary principle: action before proof of harm, again, with the burden on the proponent.

This decision tree provides a consistent basis for advocates to define, examine, and identify alternatives to threats to health and the environment. Following these common-sense, rational steps in the decision-making process, some of which are described in business textbooks, leaves activists less open to charges of emotionalism. Instead of taking a simple opposition stance, advocates can lead a community toward rational and wise solutions.

The steps are simple: first characterize and understand the problem or potential threat; understand what is known and not known; identify alternatives to the activity or product; determine a course of action, and monitor. (If the impacts of a particular activity are known, then the actions taken are no longer precautionary; they are either preventive or control actions.)

Case study A, new product or activity: a proposal to spray aerially a new insecticide in your community.

Case study B, existing problem: a leaking landfill.

Step One: Identify the possible threat and characterize the problem

The purpose of this step is to gain a better understanding of what might happen should the activity continue and to ensure that you are asking the right questions about this activity. Poor solutions are often a result of badly defined problems. Identify both the immediate problem and any other global issues that might go along with this threat. Here are questions to ask:

Why is this a problem? Presumably it has the potential to threaten public health or the environment.

What is the potential spatial scale of the threat - local, statewide, regional, national, global?

What is the full range of potential impacts? To human health, ecosystems, or both? Will there be impacts to specific species or loss of biodiversity? Are the impacts to waterways, air, or soil? Do indirect impacts need to be considered (such as a product's lifecycle-production and disposal)?

Will some populations (human or ecosystems) be disproportionately affected?

What is the magnitude of possible impacts (intensity)? Is the extent of harm negligible, minimal, moderate, considerable, catastrophic?

What is the temporal scale of the threat? There are two issues to consider: 1) The time lapse between a threat and possible harm (immediate, near future, future, future generations). The further in the future harm might occur, the less likely that impacts can be predicted, the harder it will be to identify and halt a problem, and the more likely that future generations will be impacted. 2) Persistence of impacts (immediate, short term, mid term, long term, inter-generational).

How reversible is the threat? If the threat were to occur would it be easy to fix or last for generations? (easily/quickly reversed, difficult/expensive to reverse, irreversible, unknown)

A note about existing problems: Defining a problem at hand is less difficult than projecting problems from a future project. But the first questions are similar: Is the problem local pollution from a particular facility or broader lack of attention to pollution prevention or both? Is it caused by a government failure or a company's negligence? Is it a serious threat or just an eyesore?

A. In the aerial spraying case, the threat could be characterized as human and ecosystem exposure to pesticide drift, as well as impacts on non-target species. The spatial scale might be local, but if the pesticides are persistent or there are heavy winds, the impacts could be regional or even global. The magnitude and temporal scale would depend on the toxicity of the pesticide, as would reversibility.

B. In the landfill case, the problem is caused by a faulty liner and inadequate inspection by town officials. The problem is likely localized but if the leachate runs into surface water, it might be carried long distances. The problem could be short or long term, depending on what is leaking out of the landfill (e.g., heavy metals or solvents). The leaking may disproportionately impact certain populations living around the landfill.

Step Two: Identify what is known and what is not known about the threat.

The goal of this step is to gain a better picture of the uncertainty involved in understanding this threat. Scientists often focus on the what we know, but it is equally, and perhaps more, important to be clear about what we don't know. There are degrees and types of uncertainty, as the later discussion explains. Relevant questions:

Can the uncertainty be reduced by more study or data? If so, and if the threat is not great, a project with substantial benefits might be continued.

Are we dealing with something that is unknowableÑor about which we are totally ignorant? High uncertainty about possible harm is good reason not to go ahead with a project.

What is known about additive and synergistic effects from exposure to multiple stressors and cumulative effects from combined exposures to various stressors?

Do industry and government claims that an activity is safe mean only that it has not yet been proven dangerous?

You might want to make a chart listing what is known and what is not known about the threat to gain a better comparative picture and understand gaps in understanding.

A. In the case of the pesticide, you probably do not know the inert ingredients, which constitute the majority of the formulation. You probably do not know most human health effects other than neurotoxicity and carcinogenicity. You do not know about drift and volatilization. You do not know additive or cumulative effects to ecosystems or health. You do not know all the exposure routes (drinking water, showers, etc.) or how much exposure there will be. You do not know effects on beneficial insects and pollinators. You do have label information as well as information on wind direction and velocity on the day proposed for spraying. Perhaps there is also some monitoring data on drift.

B. In the case of the landfill you do not know what materials are in the landfill, as they come from multiple sources. You also do not know what reactions may occur between materials in the landfill. You have some information on the hydrology of the area but do not know whether drinking water will be affected or over what time course.

Step Three: Reframe the problem to describe what needs to be done

The goal of this step is to better understand what purpose the proposed activity serves. For example, a development provides housing, a solvent provides degreasing, a pesticide provides pest management, a factory provides jobs and a product for a specific service. The problem can then be reframed in terms of what needs to be achieved in order to more readily identify alternatives.

A. In the case of the pesticide, reframing the problem leads to the more important issue of managing pests rather than spraying pesticides.

B. An existing problem may or may not call for a reframing. In the landfill case, is it time for the community to reconsider how it disposes of waste?

Step Four: Assess alternatives.

Proposed and existing activities are addressed somewhat differently in this step.

Proposed activities: Integral to the precautionary principle is a comprehensive, systematic analysis of alternatives to threatening activities. This refocuses the questions to be considered by a regulator or company from how much risk is acceptable to whether there is a safer and cleaner way to undertake this activity. Assessing alternatives drives ingenuity and innovation. It is more difficult to dismiss proposals that not only name problems but set forth alternatives, or demand that they be considered. The "no action" alternative must be considered: perhaps an activity should not proceed because it poses too much of a threat and/or is not needed.

Existing activities: At this point you would develop and assess a range of alternative courses of action to deal with the problem. The options can be to study further, to completely stop the activity, prevent, control, mitigate, or remediate.

In either case, the assessment of alternatives is a multi-stage process.

First, you might brainstorm a wide range of alternatives, then screen out those options that seem impossible.

The next stage is to assess the alternatives to determine whether they are politically, technically, and economically feasible. Do not let conventional wisdom limit this assessment. Keep in mind that something that is not economically or technically feasible today may be feasible in the near future. And government agencies and firms rarely consider the "external" costs of threatening activities harm to health, loss of species, etc. which are often unquantifiable.These concerns must be incorporated in the assessment.

The last step of the alternatives assessment is to consider potential unintended consequences of the proposed alternatives. A common criticism of the precautionary principle is that its implementation will lead to more hazardous activities. This need not be true: alternatives to a threatening activity must be equally well examined.

A. In the case of the pesticide, alternatives might include not spraying at all, using integrated pest management techniques, spraying with a less toxic pesticide, or ground spraying to avoid drift.

B. In the case of the landfill, several alternatives exist. Further study could be conducted to better understand what is leaching and how it is affecting local groundwater. Another action would be to close the landfill but then the community would need to find alternative disposal methods, which may include incineration, the emissions from which present a substantial problem. Another option may be to cap sections of the landfill that are leaching.

Step Five: Determine the course of action.

Take all the information collected thus far and determine how much precaution should be takenÑ stopping the activity, demanding alternatives, or demanding modifications to reduce potential impacts. A useful way to do this is by convening a group of people to weigh the evidence, considering the information on the range and magnitude impacts, uncertainties, and alternatives coming from various sources. The weight of evidence would lead to a determination of the correct course of action.

> A. In the example of pesticide spraying, it might be determined that spraying is unnecessary because it is unclear what pests are being fought and the extent to which they might harm crops. The course of action would be to monitor pest damage and conduct localized interventions when needed.
>
> B. For the landfill, the course of action could be further study to identify the range of impacts, with independent review. This could be followed by a local choice of options, closing the landfill or controlling leachate.

Step Six: Monitor and follow up

No matter what action is taken, it is critical to monitor that activity over time to identify expected and unexpected results. Those undertaking the activity should bear the financial responsibility for such monitoring, but when possible this should be conducted by an independent source. The information gathered might warrant additional or different courses of action.

> In the pesticide example, if spraying proceeds, you might require health tests and alert doctors to health consequences.
>
> If parts of the landfill are capped, regular monitoring would ensure that leaching does not occur, or that prompt action will be taken if it does.

VII. DIOXIN: AN ARGUMENT FOR PRECAUTION

Dioxin is one of the most intensively studied substances ever, but we remain ignorant about the full range of its impacts. Growing evidence suggests that dioxin is harmful to humans and other living things, but absolute proof of harm has not been established. The dioxin assessment and reassessment process instigated by the U.S. Environmental Protection Agency in the early 1990s, is a seemingly endless attempt to reduce the uncertainties about the impacts of this chemical. But it will not stop exposure to dioxin. Instead, it is likely to lead to more debate about controlling sources of dioxin and about how much of the substance can be tolerated by humans and the ecosystem.

This case presents a classic example of why and how the precautionary principle should be applied. First, the argument for precaution:

Evidence of harm. Dioxin is extremely toxic in laboratory experiments, both acutely and chronically at very low doses. As a result of laboratory evidence and mechanistic evidence, the most toxic dioxin, TCDD, has been identified as carcinogenic to humans by the International Agency for Research on Cancer. Dioxin has been associated with various other effects as well, such as chloracne, and may be associated with endometriosis and other diseases. There is some evidence that adverse effects occur at very low levels, near current "background" levels.

Persistence and irreversible harm. The time and spatial scale of dioxin contamination is vast. Dioxin has been measured throughout the globe and its persistence, both in humans and the environment, means that future generations will be exposed to dioxin produced today. Harm caused by dioxin to humans and ecosystems is likely to be irreversible, or reversible only over decades.

Difficulty of control and cleanup. Because small quantities may be harmful, controlling dioxin emissions, especially from open sources such as burning, to the extent that would protect public health is virtually impossible and extremely costly. Thorough cleanup is also virtually impossible.

Scientific uncertainty. Because cancer, one result of dioxin exposure, can take years to manifest itself, it is often impossible to link exposure and disease. The connectivity of impacts, mixtures of dioxins with other persistent organic chemicals and other stressors, is also relatively unknown. For example, how might work-related stress combine with dioxin exposure to affect the immune system? There is some laboratory evidence of interactions but interactions are extremely difficult to prove.

Prevention is possible. There is general consensus that dioxin is mainly created by human activities. Many sources of dioxin can be reduced or eliminated in the short term through precautionary action.

Current measures are insufficient. While some data suggest that levels of dioxin have fallen, possibly because old incinerators have been shut down or retrofitted and pollution control and technologies have changed, the problem is not solved. Levels of dioxin may increase in the future, for example, as more PVC products are incinerated or burned in accidental fires.

A precautionary approach to dioxin would no doubt set a goal of zero exposure, which would probably mean zero emissions. But there are degrees of precaution.

A moderate precautionary approach would first look at reducing or eliminating the largest sources of dioxin, which we know to be municipal and medical waste incineration, as well as pulp and paper production, iron and steel production, hazardous waste incineration, and open burning. But this approach might mean that materials producing dioxin would be transferred elsewhere, perhaps to landfills where they might catch fire and burn without controls, or to Third World countries.

A stronger version of precaution, a materials approach, would attempt to address the main sources of chlorine, the ultimate source of dioxin. The focus would be on chlorinated pesticides and solvents, pulp and paper production, and polyvinyl chloride plastics. Phasing out PVCs, by far the largest users of chlorine, would no doubt greatly reduce dioxin emissions. But we would then have to ask what the alternatives are to PVCs, whether they are safer, and whether they involve chlorine. We would also have to ask whether chlorine now produced for PVCs would be channeled into other products.

Phasing out chlorine is the only way to virtually eliminate dioxin, especially in industrial processes and products. Otherwise, we will always be chasing sources, debating how much dioxin is safe, and attempting to measure the emissions from each source. More science is critical to precautionary action, to monitor and measure sources and exposure, to uncover possible new sources of exposure, to research alternatives to chlorine, and to make sure that these alternatives do not pose serious problems of their own. But this process should not forestall action to reduce and eliminate dioxin emissions and exposure. Precaution must be taken at once.

VIII. UNDERSTANDING UNCERTAINTY

In the open, dynamic environments in which humans live and operate, knowledge often has limits, and scientific certainty is difficult to attain. Uncertainty itself comes in many varieties, nonscientific as well as scientific. Some kinds of uncertainty can be addressed and reduced; others cannot. When we make judgments affecting the environment and public health, understanding what we do not know, and why, is as important as pinning down facts.

Uncertainties can be placed in the following categories:

Parameter uncertainty refers to missing or ambiguous information in specific informational components of an analysis. Parameter uncertainty can often be reduced by gathering more information or using better techniques to gather and analyze it. However, if it is due to variability, this may not be the case. In environmental releases, individuals not only receive various exposures; they also vary in their susceptibility to harm. Attempts to measure and control exposure to hazards may inadequately protect many in the population.

Model uncertainty refers to gaps in scientific theory or imprecision in the models used to bridge information gaps, for example, in a dose-response model. Models are constructed to explain current or past events or predict the future. They are only as good as the information used to build them which is necessarily incomplete when models refer to open and interdependent environmental systems. Models can be improved as they incorporate more, and more precise, information.

Systemic or epistemic uncertainty refers to the unknown effects of cumulative, multiple, and/or interactive exposures. Systemic uncertainty can be an important confounding factor in large-scale or long-term analyses.

Smokescreen uncertainty refers to the strategies of those who create risks and have a stake in concealing the effects of a specific substance or activity. They may refrain from studying a hazard, conceal knowledge of effects, or design studies to create uncertainty. Critics of regulation often use uncertainty to avoid it.

Politically induced uncertainty refers to deliberate ignorance on the part of agencies charged with protecting health and the environment. The agency may decide not to study a hazard, limit the scope of its analysis or alternatives to solve a problem, downplay uncertainty in its decisions, or hide uncertainty in quantitative models.

Indeterminacy means that the uncertainties involved are of such magnitude and variety that they may never be significantly reduced.

Ignorance has two faces: Positively, it is a humble admission that we don't know how much we don't know. Negatively, it is the practice of making decisions without considering uncertainties.

Example: Toxicity testing for industrial chemicals

Under the Toxic Substances Control Act, chemical manufacturers and importers are required to submit data related to the potential health effects of chemicals before manufacturing them. The Environmental Protection Agency can then require additional testing before that chemical reaches the market. Companies must also submit evidence of substantial risk if that becomes available once the substance is on the market.

As early as 1984, the National Academy of Sciences noted the overwhelming lack of data on the health effects of industrial chemicals. The Academy found that 78 percent of the chemicals in highest-volume commercial use did not have even "minimal" toxicity testing.

The situation has not improved some fourteen years later, as noted by the Environmental Defense Fund [1997] and the Environmental Protection Agency [1998]. For the 3,000 high-production-volume chemicals, those with over one million pounds in commerce, the studies noted the following: 93 percent lack some basic chemical screening data; 43 percent have no basic toxicity data; 51 percent of chemicals on the Toxic Release Inventory lack basic toxicity information; and a large percentage of available information is based only on acute toxicity.

Vice-President Al Gore has ordered industry to perform basic screening of these 3,000 chemicals, but this will not include data on human exposure, health effects, and risk. The EPA will not be bound to act on the information it receives.

Numerous forms and sources of uncertainty and ignorance exist in industrial chemical testing and the approval process:

Ignorance is manifest in the EPA practice of permitting chemicals to be used and released into the environment without knowing their full range of health effects.

Parameter uncertainty exists in the lack of data on human exposure and various results of toxicity, including how specific toxic chemicals affect developing fetuses and newborns.

The lack of data leads to *model uncertainty*.

Systemic uncertainty exists because science has only begun to study the interactions of toxic chemicals in the environment and their cumulative effects.

Industry's failure to conduct or report on testing and attempts to focus discussions on other factors (mechanisms of action of disease, diet and genetics, and "natural" carcinogens) represents a form of *smokescreen uncertainty*. For example, when the EPA offered temporary leniency to industry to submit notifications of substantial chemical risk, the agency received some 11,000 notifications in a short period.

Politically induced uncertainty occurs when government agencies do not enforce or require chemical testing, and when they determine to study one chemical rather than another.

Traditional research science attempts to gather nearly complete and perfectly supportive information before claiming a cause-and-effect relationship. Statistically, scientists want to be 95 percent sure that the results they have observed are not due to chance alone. This paradigm of science unfortunately has been carried over to looking at hazards to human health and the environment. Decision-makers' quest for 95 percent certainty is an attempt to avoid what are called Type I errors, taking action or regulating when a hazard does not exist in reality. By focusing on avoiding these types of errors, decision-makers increase the possibility of not taking action when there actually is harm, that is, of making what is called a Type II error.

Uncertainty can be a source of power to government agencies and industry. Uncertainty can be used to say that we do not know enough yet, and that taking action would be irrational or based on "junk science." These spokespersons seldom say, though, how much they know or do not know. Industry representatives will use terms like "safe" or "approved" when a product has not actually been tested, or when there is uncertainty.

Uncertainty can also be a weakness for a government agency faced with justifying to industry why action should be taken in the absence of absolute proof of harm. It is much easier for a government agency to cover up uncertainty with quantitative analyses that look objective and scientific on their surface than to face the wrath of industry. This coverup is also a way of deflecting public wrath. Knowledge is equated with scientific and technical knowledge. The knowledge that has been gained through tradition or life experience is discounted in favor of knowledge that can be quantified.

Currently, uncertainty is used as a reason not to take preventive action for human health and the environment. But we can use uncertainty as a reason to act, realizing that we may never know how a particular hazard affects humans or the environment. We need to consider what we know and how we know it, and the limits to knowing. Environmental and public health advocates have to ask difficult questions of industry and regulators to expose the depths of our ignorance. Once this lack of knowledge has been exposed, the notion of needlessly exposing humans and the environment to hazards without information on their effects seems irrational, and precaution seems logical.

IX. RISK ASSESSMENT OR THE PRECAUTIONARY PRINCIPLE?

During the 1970s, the decision-making tools of risk assessment and cost-benefit analysis were developed to bridge the gap between uncertain science and the political need for decision-making to limit harm. However, in their development, a great deal of faith was placed in the ability of science to model and predict harm in extremely complex ecological and human systems. Risk assessment, which was originally developed for mechanical problems such as bridge construction, in which the technical process and parameters are well-defined and can be analyzed, took on the role of predictor of extremely uncertain and highly variable events.

Risk assessment is viewed by government agencies and those in industry as the "sound science" approach to decision-making, in which decisions are made on the basis of what can be quantified, without considering what is unknown or cannot be measured. These are lumped into the category of uncertainty, as discussed earlier. Although few scientists will admit it, risk assessment and other "sound science" approaches to decision-making are highly reliant on policy and scientific assumptions, which are frequently unscientific or subjective.

There is a proper, if secondary, role for risk assessment in increasing our understanding of the complexities of environmental harm. But as traditionally practiced, risk assessment has often stood in the way of protecting human health and the environment. Here are some of the major assumptions and flaws of conventional risk assessment:

Risk assessment assumes "assimilative capacity," that is, that humans and the environment can render a certain amount of pollution harmless. Eliminating risk altogether is not a plausible outcome of risk assessment. Risk assessment is used to manage and reduce risks, not prevent them. This deters more fundamental efforts to institute clean production.

Risk assessment focuses on quantifying and analyzing problems rather than solving them. It asks how much pollution is safe or acceptable; which problems are we willing to live with; how should limited resources be directed? While these are valid questions, they bar more positive approaches: how do we prevent harmful exposures; move toward safer and cleaner alternatives; involve society in identifying, ranking, and implementing solutions?

Risk assessments are susceptible to model uncertainty. Current risk assessment is based on at least 50 different assumptions about exposure, dose-response, and extrapolation from animals to humans. All of these have subjective and arbitrary elements. As a result, the quantitative results of risk assessments are highly variable.

The European Union recognized the limitations to risk assessment assumptions in its European Benchmark exercise in hazard analysis. In the exercise, eleven European governments established teams of scientists and engineers to work on a problem about accidental releases of ammonia. The result of the exercise was eleven different risk estimates ranging from 1 in 400 to 1 in 10 million. The organizers concluded that "at any step of a risk analysis, many assumptions are introduced by the analyst and it must be recognized that the numerical results are strongly dependent on these assumptions [Contini, et al. 1991. Benchmark Exercise on Major Hazard Analysis. EUR 13386 EN Commission of the European Communities, Luxembourg].

At the same time, current risk assessment leaves out many variables, especially multiple exposures, sensitive populations, or results other than cancer. Risk assessment is geared toward setting single chemical standards and is incapable of analyzing the mixtures of chemicals found in many communities. It does not adequately take into account sensitive populations, such as the elderly, children, or those already suffering from environmentally induced disease. It rarely looks at effects other than cancer, although many environmental health problems involve respiratory disease, birth defects, and nervous system disorders. Risk assessment is designed to analyze linear response (more exposure leads to more harm) and is stymied if this is not the case. For example, emerging evidence about the ability of some synthetic substances to disrupt the hormone system in humans is showing that low doses rather than high doses may lead to these effects.

Risk assessment allows dangerous activities to continue under the guise of "acceptable risk." Risk assessment provides an air of quantitative, technical sophistication to inexact, assumption-laden, and politically driven science. It allows the continuation of activities that lead to greater pollution and degradation of health under the premise that it is either safe or acceptable to those who are exposed. It staves off regulation and action in the face of uncertainty and insufficient evidence.

Risk assessment is costly and time-consuming. A single risk assessment may take up to five person-years to complete. It ties up limited resources in trying to quantify and rank risks when the effects of exposures may already be obvious (see dioxin analysis above). Risk assessments take resources away from prevention-focused solutions.

Risk assessment is fundamentally undemocratic. Those exposed to harm are rarely asked whether exposure is acceptable to them, what biologist Sandra Steingraber labels a violation of fundamental human rights, or toxic trespass. Risk assessment traditionally does not include public perceptions, priorities, or needs, and while some efforts have been made to involve the public in risk-assessment processes, widespread public participation in either scientific analysis or decision-making is not a likely prospect in the coming years. No mechanisms for this exist. The risk-assessment process is most often confined to agency and industry scientists, consultants, and sometimes a high-tech environmental group. Public involvement in risk assessments has generally only legitimized a pernicious process.

Risk assessment puts responsibility in the wrong place. It assumes that society as a whole must deal with environmental harm, and assumes a scarcity of resources for this task. The contention that "society" does not have enough resources for all environmental protection activities diverts attention from those responsible for harm, those who created it, not those who have suffered from it. If scarcity is a factor, it would be wise to shift government resources from studying problems ad infinitum to identifying safer alternatives to potentially dangerous activities.

Risk assessment poses a false dichotomy between economic development and environmental protection. Regulatory agencies often attempt to tie the "scientific" process of risk assessment to cost-benefit analysis, linking science and economic policy in environmental decision-making. The agencies fail to consider, however, the question of who assumes the costs and who reaps the benefits. Moreover, the economic benefits of pollution prevention and toxics use reduction strategies have been clearly demonstrated. An important consideration is that the cost of under-regulating will typically be greater than over-regulating, when considering subsequent clean-up and health costs.

These criticisms aside, risk assessment can play a role in implementing the precautionary principle. Instead of using risk assessment to establish "safe" levels of exposure, levels that are fundamentally unknowable, it can be used to better understand the hazards of an activity and to compare options for prevention. It can also be used, in conjunction with democratic decision-making methods, to prioritize activities such as hazardous waste site cleanups and restoration activities. But the underlying basis of policy and decision-making must be precaution and prevention, rather than risk.

X. ANSWERING THE CRITICS

The precautionary principle is a new way of thinking about environmental and public health protection and long-term sustainability. It challenges us to make fundamental changes in the way we permit and restrict hazards. Some of these challenges will pose large threats to government agencies and polluters and are likely to lead to powerful resistance. It is important to anticipate critics of precaution and to know how to respond to their comments.

The precautionary principle is not based on sound science.

Sound science is a matter of definition. Conventional understanding of "sound science" emphasizes risk assessment and cost-benefit analysis. These are value-laden approaches, requiring numerous assumptions about how hazards occur, how people are exposed to them, and society's willingness to tolerate hazard. In fact, because of great uncertainties about cause and effect, all decisions about human health and the environment are value-laden and political.

The precautionary principle recognizes this, and proposes a shift in the basis for making these decisions. Precaution is based on the principle that we should not expose humans and the environment to hazards if it is unnecessary to do so.

Precaution is more thorough than risk assessment because it exposes uncertainty and admits the limitations of science. This is a "sounder" kind of science. Precaution does not call for less science, but more, to better understand how human activities affect our health and environment. But the need for better understanding must not prevent immediate action to protect ourselves and future generations.

This is emotional and irrational.

Because we are human, thinking about babies born with toxic substances in their bodies tugs at our emotions. Caring about future generations is an emotional impulse. But these emotions are not irrational; they are the basis for our survival. Precaution is a principle of justice, that no one should have to live with fear of harm to their health and environment. Decision-making about health is not value-neutral. It is political, emotional, and rational. Not taking precautions seems irrational.

We will go bankrupt. This will cost too much.

There is more reason to believe that precaution will increase prosperity in the long run, through improved health and cleaner industrial processes and products. The skyrocketing costs of environmental damage, health care from pollution, and pollution control and remediation are rarely included in estimates undertaken when precautionary action is advocated. Despite initial outcries about precautionary demands, industry has been able to learn and innovate to avoid hazards. In the area of pollution prevention, thousands of companies have saved millions of dollars by exercising precaution early, before proof of harm. These companies and governments that act similarly become leaders in their field when firmer proof of harm comes along.

In taking precaution, however, we should also plan ahead to mitigate immediate adverse economic impacts. Transition planning pulls together different sectors of society to ensure that precautionary action has as few adverse side-effects as possible. Precaution is practiced by setting societal goals, such as that children be born without toxic substances in their bodies, and then determining how best to achieve that goal.

What do you want to do, ban all chemicals? This will halt development and send us back to the Stone Age!

Precaution does not take the form of categorical denials and bans. It does redefine development not only to include economic well-being but also ecological well-being, freedom from disease and other hazards.

The idea of precaution is to progress more carefully than we have done before. It would encourage the exploration of alternatives, better, safer, cheaper ways to do things, and the development of cleaner products and technologies. Some technologies and developments may be brought onto the marketplace more slowly. Others may be phased out.

Those proposing potentially harmful activities would have to demonstrate their safety and necessity up front. On the other hand, there will be many incentives to create new technologies that will make it unnecessary to produce and use harmful substances and processes. With the right signals, we will be able to innovate to create development that takes less of a toll on our health and environment.

Naturally occurring substances and disasters harm many more people than do industrial activities.

We must deal with the hazards for which we are responsible and over which we have control. Those creating risk and benefiting from their activities also have an obligation not to cause harm. But an important reason for precaution is that we do not yet know, and may never know, the full extent of the harm caused by human activity. Some violent natural events, for example, may be a result of global warming, which in turn is linked to human activity.

We comply with regulations. We are already practicing precaution.

In some cases, to some extent, precaution is already being exercised. But we do not have laws covering each possible industrial hazard or chemical. Also, most environmental regulations, such as the Clean Air Act, the Clean Water Act, and the Superfund law, are aimed at controlling the amount of pollution released into the environment and cleaning up once contamination has occurred. They regulate toxic substances as they are emitted rather than limiting their use and production in the first place.

Most current regulations are based on the assumption that humans and ecosystems can absorb a certain amount of contamination without being harmed. There is extreme uncertainty about "safe" or "acceptable" levels, and we are now learning that in many cases we cannot identify those levels.

You can't prove anything is safe.

It is possible to demonstrate that there are safer alternatives to an activity.

You could say that every activity has some impact. Every chemical is toxic at some dose.

Almost all human/industrial activities will have some impact on ecosystems. The virtue of the precautionary principle is to continuously try to reduce our impacts rather than trying to identify a level of impact that is safe or acceptable.

XI. BIBLIOGRAPHY

Baender, Margo. 1991. Pesticides and Precaution: The Bamako Convention as a model for an international convention on pesticide regulation. *New York University Journal of International Law and Politics* 25:557-609.

Costanza, R and L. Cornwell. 1992. The 4P approach to dealing with scientific uncertainty. *Environment* 34: 12-20,42.

Deville, A and R. Harding. 1997. *Applying the Precautionary Principle*. Annandale: The Federation Press.

Dovers, S. and J. Hadmer. 1995. Ignorance, the precautionary principle, and sustainability. *Ambio* 24: 92-96.

Freestone, D. and E. Hey, eds. *The Precautionary Principle and International Law.* Boston: Klewer Law International.

Hey, E. 1992. The precautionary principle in environmental law and policy: Institutionalizing precaution. *Georgetown International Law Review,* vol. 4, pp. 303-318.

M'Gonigle, R.M., et. al. 1994. Taking Uncertainty Seriously: From Permissive Regulation to Preventive Design in Environmental Decision making. *Osgoode Hall Law Journal* 32:99-169.

O'Riordan, T. and J. Cameron. 1996. *Interpreting the Precautionary Principle.* London: Earthscan Publishers.

Raffensperger, C. and J. Tickner, eds. 1999. *Protecting Public Health and the Environment: Implementing the Precautionary Principle.* Washington, DC: Island Press.

Van Dommelen, A, ed. 1996. *Coping with Deliberate Release: the Limits of Risk Assessment*. Tilburg: International Centre for Human and Public Affairs.

Wynne, B. 1993. Uncertainty and environmental learning. In Jackson, T., ed., *Clean Production Strategies*. Boca Raton: Lewis Publishers.

XII. APPENDIX

Wingspread Statement on the Precautionary Principle
January 1998

The release and use of toxic substances, the exploitation of resources, and physical alterations of the environment have had substantial unintended consequences affecting human health and the environment. Some of these concerns are high rates of learning deficiencies, asthma, cancer, birth defects and species extinctions; along with global climate change, stratospheric ozone depletion and worldwide contamination with toxic substances and nuclear materials.

We believe existing environmental regulations and other decisions, particularly those based on risk assessment, have failed to protect adequately human health and the environment, the larger system of which humans are but a part.

We believe there is compelling evidence that damage to humans and the worldwide environment is of such magnitude and seriousness that new principles for conducting human activities are necessary.

While we realize that human activities may involve hazards, people must proceed more carefully than has been the case in recent history. Corporations, government entities, organizations, communities, scientists and other individuals must adopt a precautionary approach to all human endeavors.

Therefore, it is necessary to implement the Precautionary Principle: When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.

In this context the proponent of an activity, rather than the public, should bear the burden of proof.

The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.

Wingspread Participants:

(Affiliations are noted for identification purposes only.)

Dr. Nicholas Ashford, Massachusetts Institute of Technology
Katherine Barrett, University of British Columbia
Anita Bernstein, Chicago-Kent College of Law
Dr. Robert Costanza, University of Maryland
Pat Costner, Greenpeace
Dr. Carl Cranor, University of California, Riverside
Dr. Peter deFur, Virginia Commonwealth University
Gordon Durnil, attorney
Dr. Kenneth Geiser, Toxics Use Reduction Institute, University of Mass., Lowell
Dr. Andrew Jordan, Centre for Social and Economic Research on the Global Environment, University Of East Anglia, United Kingdom
Andrew King, United Steelworkers of America, Canadian Office, Toronto, Canada

Dr. Frederick Kirschenmann, farmer
Stephen Lester, Center for Health, Environment and Justice
Sue Maret, Union Institute
Dr. Michael M'Gonigle, University of Victoria, British Columbia, Canada
Dr. Peter Montague, Environmental Research Foundation
Dr. John Peterson Myers, W. Alton Jones Foundation
Dr. Mary O'Brien, environmental consultant
Dr. David Ozonoff, Boston University
Carolyn Raffensperger, Science and Environmental Health Network
Hon. Pamela Resor, Massachusetts House of Representatives
Florence Robinson, Louisiana Environmental Network
Dr. Ted Schettler, Physicians for Social Responsibility
Ted Smith, Silicon Valley Toxics Coalition
Dr. Klaus-Richard Sperling, Alfred-Wegener-Institut, Hamburg, Germany
Dr. Sandra Steingraber, author
Diane Takvorian, Environmental Health Coalition
Joel Tickner, University of Mass., Lowell
Dr. Konrad von Moltke, Dartmouth College
Dr. Bo Wahlstrom, KEMI (National Chemical Inspectorate), Sweden
Jackie Warledo, Indigenous Environmental Network

Language from the Massachusetts Precautionary Principle Act

Commonwealth of Massachusetts......House Bill No. 3140, 1997

An Act to establish the Principle of Precautionary Action as the guideline for developing environmental policy and quality standards for the Commonwealth

Be it enacted by the Senate and House of Representatives in General Court assembles, and by the authority of the same, as follows:

The precautionary principle shall be applied to all policy and regulatory decisions of the administration in order to prevent threats of serious or irreversible damage to the environment. The precautionary principle shall be applied when there are reasonable grounds for concern that a procedure or development may contribute to the degradation of the air, land and water of the Commonwealth. Lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent costly environmental degradation. The precautionary principle, by virtue of which preventive measures are to be taken when there are reasonable grounds for concern that substances or energy introduced, directly or indirectly, into the environment may bring about hazards to human health, harm living resources and ecosystems, damage amenities or interfere with other legitimate uses even when there is no conclusive evidence of a causal relationship between the inputs and the effects. All state entities and contracting parties shall take all necessary steps to ensure the effective implementation of the precautionary principle to environmental protection and to this end they shall:

a) encourage prevention of pollution at source, by the application of clean production methods, including raw materials selection, product substitution and clean product technologies and processes and waste minimalization throughout society;

b) evaluate the environmental and economic consequences of alternative methods, including long term consequences;

c) encourage and use as fully as possible scientific and socioeconomic research in order to achieve an improved understanding on which to base long-term policy options.

Uses of the Precautionary Principle in International Treaties and Agreements

Ozone Layer Protocol

Parties to this protocol . . . determined to protect the ozone layer by taking precautionary measures to control equitably total global emissions of substances that deplete it, with the ultimate objective of their elimination on the basis of developments in scientific knowledge, taking into account technical and economic considerations. . . . Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, 26 ILM 1541

Second North Sea Declaration

In order to protect the North Sea from possibly damaging effects of the most dangerous substances...a precautionary approach is addressed which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence. Ministerial Declaration Calling for Reduction of Pollution, Nov. 25, 1987, 27 ILM 835.

United Nations Environment Programme

Recommends that all Governments adopt "the principle of precautionary action" as the basis of their policy with regard to the prevention and elimination of marine pollution. Report of the Governing Council on the Work of its Fifteenth Session, United Nations Environment Programme, UN GAOR, 44th Sess. Supp No 25, 12th mtg at 153, UN DOC A44/25 (1989).

Nordic Council's Conference

And taking into account....the need for an effective precautionary approach, with that important principle intended to safeguard the marine ecosystem by, among other things, eliminating and preventing pollution emissions where there is reason to believe that damage or harmful effects are likely to be caused, even where there is inadequate or inconclusive scientific evidence to prove a causal link between emissions and effects. Nordic Council's International Conference on Pollution of the Seas: Final Document Agreed to Oct. 18, 1989, in Nordic Action Plan on Pollution of the Seas, 99 app. V (1990)

PARCOM Recommendation 89/1 - 22 June, 1989

The Contracting Parties to the Paris Convention for the Prevention of Marine Pollution from Land-Based Sources:

Accept the principle of safeguarding the marine ecosystem of the Paris Convention area by reducing at source polluting emissions of substances that are persistent, toxic, and liable to bioaccumulate by the use of the best available technology and other appropriate measures. This applies especially when there is reason to assume that certain damage or harmful effects on the living resources of the sea are likely to be caused by such substances, even where there is no scientific evidence to prove a causal link between emissions and effects (the principle of precautionary action).

Third North Sea Conference

The participants...will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic, and liable to bioaccumulate even where there is no scientific evidence to prove a causal link between emissions and effects Final Declaration of the Third International Conference on Protection of the North Sea, Mar. 7-8, 1990. 1 YB Int'l Envtl Law 658, 662-73 (1990).

Bergen Declaration on Sustainable Development

In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent, and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation. Bergen Ministerial Declaration on Sustainable Development in the ECE Region. UN Doc. A/CONF.151/PC/10 (1990), 1 YB Intl Envtl Law 429, 4312 (1990)

Second World Climate Conference

In order to achieve sustainable development in all countries and to meet the needs of present and future generations, precautionary measures to meet the climate challenge must anticipate, prevent, attack or minimize the causes of, and mitigate the adverse consequences of, environmental degradation that might result from climate change. Where there are threats of serious of irreversible damage, lack of full scientific certainty should not be used as a reasons for postponing cost-effective measures to prevent such environmental degradation. The measure adopted should take into account different socioeconomic contexts. Ministerial Declaration of the Second World Climate Conference (1990). 1 YB Intl Envtl Law 473, 475 (1990)

Bamako Convention on Transboundary Hazardous Waste into Africa

Each Party shall strive to adopt and implement the preventive, precautionary approach to pollution problems which entails, inter alia, preventing the release into the environment of substances which may cause harm to humans or the environment without waiting for scientific proof regarding such harm. The Parties shall cooperate with each other in taking appropriate measures to implement the precautionary principle to pollution prevention through the application of clean production methods, rather than the pursuit of a permissible emissions approach based on assimilative capacity assumptions. Bamako Convention on Hazardous Wastes within Africa, Jan. 30, 1991, art. 4, 30 ILM 773.

OECD Council Recommendation

The Recommendation is accompanied by Guidance which is an integral part of the Recommendation. It lists some essential policy aspects including: the absence of complete information should not preclude precautionary action to mitigate the risk of significant harm to the environment. OECD Council Recommendation C(90)164 on Integrated Pollution Prevention and Control - January 1991

Maastricht Treaty on the European Union

Community policy on the environment...shall be based on the precautionary principle and on the principles that preventive actions should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. Treaty on the European Union, Sept. 21, 1994, 31 ILM 247, 285-86.

Helsinki Convention on the Protection and Use of Transboundary Watercourses and International Lakes

The precautionary principle, by virtue of which action to avoid the potential transboundary impact of the release of hazardous substances shall not be postponed on the ground that scientific research has not fully proved a causal link between those substances, on the one hand, and the potential transboundary impact, on the other hand. Convention on the Protection and Use of Transboundary Watercourses and International Lakes, Mar. 17, 1992, 31 ILM 1312.

The Rio Declaration on Environment and Development

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. Rio Declaration on Environment and Development, June 14, 1992, 31 ILM 874.

Climate Change Conference

The parties should take precautionary measures to anticipate, prevent, or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost. To achieve this, such policies and measures should take into account different socioeconomic contexts, be comprehensive, cover all relevant sources, sinks and reservoirs of greenhouse gases and adaptation, and comprise all economic sectors. Efforts to address climate change may be carried out cooperatively by interested parties. Framework Convention on Climate Change, May 9, 1992, 31 ILM 849.

UNCED Text on Ocean Protection

A precautionary and anticipatory rather than a reactive approach is necessary to prevent the degradation of the marine environment. This requires inter alia, the adoption of precautionary measures, environment impact assessments, clean production techniques, recycling, waste audits and minimization,, construction and/or improvement of sewage treatment facilities, quality management criteria for the proper handling of hazardous substances, and a comprehensive approach to damaging impacts from air, land, and water. Any management framework must include the improvement of coastal human settlements and the integrated management and development of coastal areas. UNCED Text on Protection of Oceans. UN GAOR, 4th Sess., UN Doct A/CONF.151/PC/100 Add. 21 (1991)

Energy Charter Treaty

In pursuit of sustainable development and taking into account its obligations under those international agreements concerning the environment to which it is a party, each Contracting Party shall strive to minimize in an economically efficient manner harmful Environmental Impact occurring either within or outside its Area from all operations within the Energy Cycle within its Area, taking proper account of safety. In doing so each Contracting Party shall act in a Cost-Effective manner. In its policies and actions each Contracting Party shall strive to take precautionary measures to prevent or minimize Environmental Degradation. The Contracting Parties agree that the polluter in the Areas of Contracting Parties, should, in principle, bear the cost of pollution, including transboundary pollution, with due regard to the public interest and without distorting investment in the Energy Cycle or International Trade. The Draft European Energy Charter Treaty Annex I, Sept 14, 1994, 27/94 CONF/104.

U.S. President's Council on Sustainable Development

There are certain beliefs that we as Council members share that underlie all of our agreements. We believe: (number 12) even in the face of scientific uncertainty, society should take reasonable actions to avert risks where the potential harm to human health or the environment is thought to be serious or irreparable. President's Council on Sustainable Development. Sustainable America: A New Consensus, 1996

XIV. CONTACT INFORMATION

Science and Environmental Health Network
Carolyn Raffensperger
E-mail address - craffensperger@compuserve.com
Mailing address - SEHN, Rt. 1 Box 73,
Windsor North Dakota, 58424
Phone/Fax - 701-763-6286

Lowell Center for Sustainable Production
Joel Tickner
E-mail address – Joel_Tickner@student.uml.edu
Mailing address – University of Massachusetts Lowell,
One University Ave.
Lowell, MA 01854
Phone – 978-934-2981
Fax – 978-452-5711

PANELIST BIOGRAHPIES

PETER MONTAGUE is co-founder and director of Environmental Research Foundation (E.R.F.) in Annapolis, Maryland. The purpose of E.R.F. is to offer community organizations information about environmental problems and the technologies and policies that might contribute to their solution. Mr. Montague edits E.R.F.'s weekly newsletter, *Rachel's Environment Health News*. *Rachel's* provides grass-roots community groups with technical information about human health and chemical contamination in an understandable form.

For eight years (1971-1979) Mr. Montague taught "Environmental Impact Analysis" and "Statistical Research Concepts and Methods" in the School of Architecture and Planning at University of New Mexico in Albuquerque where he was associate professor of planning. From 1980 to 1983 he was project administrator of the Hazardous Waste Research Program in the School of Engineering/Applied Science at Princeton University in Princeton, New Jersey. From 1983 to 1990 he was employed in the computer field as Manager of Distributed Computing in the Office of Computing and Information Technology at Princeton University. During 1991 he was employed by Greenpeace USA as a senior research analyst in the Toxics Reduction Campaign. Mr. Montague is a historian holding a Ph.D. in American Studies from University of New Mexico (1971). He is 62 years old.

DR. F. JAY MURRAY is a toxicologist who is president the environmental health consulting firm of Murray & Associates in San Jose, California. He has over 25 years of experience in toxicology, risk assessment, and environmental health and safety. Dr. Murray is a former member (1987-89) of the California Governor's Scientific Advisory Panel for the Safe Drinking Water and Toxic Enforcement Act of 1986 (better known as Proposition 65). He is a graduate of the University of Cincinnati College of Medicine (Ph.D. in toxicology), Stanford University Graduate School of Business, and Seton Hall University. Dr. Murray is board-certified by the American Board of Toxicology, a member of the Society of Toxicology, and an Assistant Clinical Professor at the University of California, San Francisco. He is the author of over 125 scientific publications and presentations. Dr. Murray spent most of his career in the pharmaceutical industry at Syntex Corporation (currently Roche Biosciences).

JIM DOUGLAS, graduate of Northern Arizona University, is licensed by the State of California to teach and certify drycleaners for California's mandatory certification program (ATCM). Jim Douglas began his drycleaning career with Swanson's Cleaners located in Sacramento, California in 1969. He was co-owner and served as president of the company from 1988 to 1998. He is a member of the California Air Resources Board's Task Force and is currently the Chairperson for the Legislative Environmental Committee for the California Cleaners Association. He has also been certified by the International Fabricare Institute as a CPD and a CED.
Jim has also been involved in testing Dow Chemical's TVS (Temporary Vapor Storage) System from the prototype beta level to the OEM version. In addition, he has worked with the Tokyo-based YAC Corporation in the development of the usage of ozoniated water as an alternative cleaning method for drycleaning.
Jim's plant, Prestige Cleaners and Ram Leathercare, located in Sacramento, is the alpha and beta test site for the GreenEarth Cleaning System

CAROLYN RAFFENSPERGER, MA, JD, is the executive director of the Science and Environmental Health Network, a consortium of environmental organizations dedicated to using science to protect public health and the environment. She has served on various committees for the US EPA and the National Research Council, and has given keynote speeches at venues as diverse as the White House, environmental justice conferences, and Harvard University.

Cumulative Impacts

RACHEL MORELLO-FROSH is an assistant professor at the Department of Community Health, School of Medicine and the Center for Environmental Studies at Brown University. Rachel completed her bachelor's degree in development economics, a master of public health degree in epidemiology and biostatistics, and her Ph.D. in environmental health sciences at the University of California, Berkeley. She teaches methods courses on environmental health, risk assessment, and policy, epidemiology, and a seminar on the science and political economy of environmental health and justice.

Rachel's research examines race and class determinants of the distribution of health risks associated with air pollution among diverse communities in the United States. Her current work focuses on: comparative risk assessment and environmental justice, developing models for community-based environmental health research, science and environmental health policy-making, children's environmental health, and the intersection between economic restructuring and community environmental health. Rachel is currently working on a research collaborative with colleagues in Southern California, on "Air Pollution, Toxics and Environmental Justice." She is also collaborating with scientists at US EPA on research examining children's health and ambient air toxics.

Rachel has published much of her work in public health, planning, and policy journals including, *Environmental Health Perspectives, Risk Analysis, International Journal of Health Services, Urban Affairs Review, Annals of the American Academy of Political and Social Sciences, and Environment and Planning C,* and *Environmental Research*.

ROBERT W. LUCAS, Lucas Advocates' principal, is a registered lobbyist and practicing attorney in the state of California. Mr. Lucas is a graduate of New York University with a Bachelor of Engineering degree and a Juris Doctor from McGeorge School of Law in 1984. Prior to launching Lucas Advocates, Mr. Lucas served eight years as staff in the California Legislature as the principal consultant to the Joint Legislative Audit Committee, the principal consultant to the Assembly Transportation Committee and consultant to the Subcommittee on Transit and to the Subcommittee on Air Quality.

Partial list of clients:

- California Council for Environmental and Economic Balance
- California Society of Professional Engineers
- Carrier Corporation/United Technologies
- Sikorsky Aircraft Corporation/United Technologies
- Tosco Corporation
- The Norac Company

- MCI Worldcom

WINONA VICTERY, Ph.D., D.A.B.T.,serves as a Science Policy Advisor in the Region 9 office of U.S. EPA. She received her Ph.D. in Physiology at the University of Michigan, completed postdoctoral work at the National Institute of Environmental Health Sciences, with research interests in toxicology of heavy metals. She joined U.S. EPA Office of Research and Development as a health scientist writing health assessments for air toxics. In 1990,she served as the ORD Regional Scientist in Region 9 and joined the regional office in 1992. She serves as a resource to the region in health risk assessment, children's health issues, and is a member of the Technical Working Group that prepared the draft Cumulative Risk Assessment Framework for U.S. EPA.

END

Environmental Justice Requires Precautionary Action

****

If corporations and governments had acted with precaution in the past, environmental injustices would not exist today.

****

Testimony February 28, 2003 before the
California Environmental Protection Agency
Advisory Committee on Environmental Justice

Peter Montague, Ph.D., Director
Environmental Research Foundation
P.O. Box 160
New Brunswick, NJ 08903
Telephone 732-828-9995
E-mail: peter@rachel.org
http://www.rachel.org .

Environmental Justice Requires Precautionary Action

****

If corporations and governments had acted with precaution in the past, environmental injustices would not exist today.

****

Peter Montague

Thank you for the opportunity to offer testimony on the precautionary principle and its relation to environmental justice in California. I am a historian and the director of the Environmental Research Foundation in New Brunswick, New Jersey. As the editor of *Rachel's Environment & Health News*, I have been writing about environmental justice since 1989 and about the precautionary principle since 1991. See http://www.rachel.org.

What is the Precautionary Principle?

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

In this context the proponent of an activity, rather than the public, should bear the burden of proof.

The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action. -- 1998 *Wingspread Statement on the Precautionary Principle*

The Essence of Precaution:

In all formulations of the precautionary principle, we find three elements:

1) When we have a reasonable suspicion of harm, and
2) scientific uncertainty about cause and effect, then

3) we have a duty to take action to prevent harm.

The precautionary principle does not tell us what kind of action to take when we suspect impending (or on-going) harm. But the Wingspread statement on precaution offers these suggestions for action:

1) Consider all reasonable alternatives;

2) Place the burden of assuring safety onto the person whose activities raised the suspicion of harm in the first place;

3) In making decisions, fully involve the people who will be affected.

I. Five Reasons Why Precautionary Action is Needed Now

Reason 1: We and Our Children are Endangered by Industrial Poisons

Precaution is needed now because...

As the *Los Angeles Times* reported Feb. 1, 2003, commenting on a new report from the Centers for Disease Control (available at http://www.cdc.gov/exposurereport/):

** The Centers for Disease Control tested a representative sample of Americans for the presence of industrial poisons in their bodies and found that all Americans are contaminated and that children are bearing the brunt of these toxic exposures;

** Researchers suspect that tiny amounts of some environmental chemicals in the womb or early childhood may permanently alter a child's intelligence, motor skills, memory, behavior, fertility, and immune response;

** For some industrial poisons, children carry proportionately more in their bodies than adults do -- including cancer-causing polycyclic aromatic hydrocarbons (PAHs, found in sources of combustion including auto exhausts), lead, cobalt, barium, and second-hand tobacco smoke.

** Mexican Americans are carrying three times more DDT residue than non-Latino whites or blacks, the study found. The higher exposure may reflect recent use of the pesticide in Mexico, or it may be that farm workers in the United States, mostly Mexican Americans, are being exposed to decades-old DDT that remains in soil. DDT is believed to cause cancer.

** Some medical experts suspect that environmental contaminants could be behind some neurological disorders, such as attention deficit disorder and Parkinson's disease and hormone-related disorders, such as endometriosis, breast cancer, testicular cancer and infertility.

** Most of the chemicals included in the CDC's report disrupt hormones in animal tests, some by mimicking estrogen or blocking testosterone, others by attacking brain development, the immune system or the thyroid.

Reason 2:
In Many Cases, Scientific Certainty May Not be Possible to Achieve

We can document that the environment and all living creatures (including humans) have become contaminated with industrial poisons. The people of California are constantly exposed to multiple sources of contamination, and **we know that it is the cumulative impact of these exposures that causes health effects**. We can also document that the prevalence of chronic human diseases is rising. Diseases that are increasing in incidence include autism, asthma, diabetes, childhood cancers, Lou Gehrig's disease, Parkinson's, and many adult cancers including cancers of the breast, brain, prostate, colon, rectum, esophagus, and bladder, among others.

Unfortunately, cause and effect relationships between industrial contamination and disease are difficult to establish when causes and outcomes are multiple, latency periods are long, timing of exposure is crucial, unexposed "control" populations do not exist, and complicating factors remain unidentified.[2] Science can sometimes clarify cause and effect relationships between one chemical and one disease under laboratory conditions. But in the real world, **cumulative impacts of contamination from multiple sources prevent science from establishing clear cause-and-effect relationships.**

Because of these realities, we are often faced with strong suspicion of harm combined with irreducible scientific uncertainty, so the only ethical road open to us is to take precautionary action to protect the environment and the health of plants, animals, and humans.

Reason 3:
Human Health and Environmental Integrity are Essential to Economic Vitality

The Bristol-Myers Squibb corporation has adopted the precautionary principle as a guide for its business decisions because,

"...We recognize that the integrity of natural systems -- land, water, air, and biodiversity -- is critical to both economic and environmental vitality. Scientific uncertainty alone should not preclude efforts to address serious environmental, health, and safety threats." See Appendix A.

Reason 4:
We All Have a Fundamental Human Right to a Clean Environment

Human Rights, Part 1

The State Constitution of California says,

"ARTICLE 1 DECLARATION OF RIGHTS

"SECTION 1. All people are by nature free and independent and have inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing, and protecting property, and pursuing and obtaining safety, happiness, and privacy."

In sum, the citizens of California have certain inalienable rights, including

a) The right to enjoy and defend life itself;
b) The right to protect property;
c) The right to obtain safety and happiness.

From this we can see that the citizens of California have a fundamental right to be protected from activities that might

** diminish, harm or extinguish life;
** harm or degrade property;
** interfere with, or extinguish, safety or happiness.

Human Rights, Part 2

But Californians are not alone in having these rights. All citizens of the world are now entitled to similar rights, according to the United Nations Commission on Human Rights (UNCHR).

In 2001 the UNCHR formally concluded that everyone has a right to live in a world free from toxic pollution and environmental degradation. (See Appendix B and Appendix C.)

Mr. Klaus Toepfer, Executive Director of the United Nations Environment Program, welcomed the historic move saying: "Many of the fundamental rights enshrined in the Universal Declaration of Human Rights have significant environmental dimensions". (The Universal Declaration of Human Rights, which the United States signed in 1948, is attached as Appendix B.)

"Environmental conditions clearly help to determine the extent to which people enjoy their basic rights to life, health, adequate food and housing, and traditional livelihood and culture. It is time to recognize that those who pollute or destroy the natural environment are not just committing a crime against nature, but are violating human rights as well", he said.

"Human rights cannot be secured in a degraded or polluted environment", said Mr. Toepfer. "The fundamental right to life is threatened by soil degradation and deforestation and by exposures to toxic chemicals, hazardous wastes and contaminated drinking water."

Human Rights, Part 3

Medical experiments without informed consent violate fundamental human rights.

For the past 50 years, the general population -- and especially minorities, low-income populations, and children -- have been subjected to chemical exposures without their informed consent. These populations have later been studied to discover the effects of the chemical exposures, revealing that these exposures have resulted in increased risk of cancer in children and adults, central nervous system disorders, immune dysfunction, birth defects, attention deficits, overly-aggressive behavior, and other serious medical and social problems. [2]

Given what we know now about many toxic chemicals, continued exposure of citizens constitutes a medical experiment on unsuspecting, or unwilling, subjects. Such experimentation is explicitly prohibited by the United Nations Covenant on Civil and Political Rights (http://www.unhchr.ch/html/menu3/b/a_ccpr.htm).

The underlying right is very clear: We all have the right to give (or withhold) our informed consent before allowing ourselves to be subjected to a toxic exposure.

Informed consent requires two things: (a) complete information about the nature of the hazard (including what is known, what is suspected, what is not known, and acknowledgement of what may never be known), and (b) a way for citizens to control the decisions that can protect their lives, their property, and their safety.

Reason 5: Rights Entail Responsibilities

We are all responsible for the consequences of our own actions.

This means looking before we leap.

It means an ounce of prevention is worth a pound of cure.

It means it's better to be safe than sorry.

It means that we should not impose risks on others that we would not impose on ourselves.

It means we should do unto others as we would have others do unto us.

It means that people (including individuals making corporate decisions) who impose hazards on others that they would not impose on themselves are not taking responsibility for their actions and are therefore forfeiting their moral right to participate in the relevant decisions.

It means that those who will live with the consequences of a dangerous activity have the right to choose whether they will participate in the activity or not. They can give or withhold their informed consent. This is only fair.

In sum, we all have a responsibility to take preventive action to avoid harm whenever there is reasonable suspicion of a problem, even if all cause-and-effect relationships have not been scientifically established.

II. Twelve Kinds of Precautionary Action We Can Take

a) We can set human health and environmental goals

The community has the right to establish the level of protection that it desires.[3, pg. 3]

Possible examples:

** For example, we could set community health goals for 10 years in the future, taking into consideration cumulative impacts. (For example, the people of Sweden have set a goal of eliminating industrial chemicals from breast milk before 2020. They did not set such a goal because they know with 100% certainty that industrial chemicals harm infant children -- they acted on suspicion of harm and they acted because they want to create a particular future. Science informed their decision, but common sense and community goals were at least as important as science in the decision.)

** For example, we could set the goal of eliminating disproportionate impacts on minorities and the poor, taking into consideration cumulative impacts.

** For example, we could set the goal of reducing children's exposure to arsenic within 5 years. (Arsenic is often found in wooden playground equipment and is known to cause cancer.)

(Naturally, the goals and deadlines I've listed above are merely examples. Communities and their public servants in government could develop their own goals in partnership.)

b) With goals in mind, we can design the steps to get there

Starting with a goal, work backward to steps that could be taken now, and next week, next month, next year, to achieve the goal.

In developing "next steps," involve the public fully in setting goals, examine all available alternatives, and put the burden of proof of safety on the polluters.

c) We can look for, and act upon, early warnings of trouble.

Examples:

(1) Increases in asthma, diabetes, obesity, attention deficit disorder, or poor school performance, for example, signal that something is amiss.

(2) Pay close attention to inequalities. Economic inequalities give rise to disproportionate impacts of deprivation and very negative public health consequences can be expected to follow -- disproportionate increases in heart disease, cancer, diabetes, nervous system disorders, etc. Therefore, tracking inequalities will reveal important public health problems and will indicate

preventive actions we could take. [There is a substantial body of scientific and medical literature supporting the point that inequalities give rise to disease; see, for example, Richard G. Wilkinson, *Unhealthy Societies; the Afflictions of Inequality* (New York: Routledge, 1996; ISBN 0-415-09235-3).]

(3) When early warnings come to light, take the time to examine the history that led to the present problem. Ask, How could we have identified and intervened in this problem earlier, to prevent harm sooner? Ask, are similar situations developing right now? For example, when we find a toxic dump, or a toxic air emission, we could immediately ask if similar toxic discharges are occurring elsewhere now and take steps to curb them.

d) We can examine all reasonable alternatives and select the least-damaging (or explain in detail why the least-damaging was rejected)

e) We can ask, "How will this choice affect the most vulnerable among us?"

f) We can ask, "Will this choice increase or decrease inequalities (of many kinds)?"

g) We can ask, "Will this choice increase or decrease cumulative impacts on the affected communities?"

h) We can ask, "Will this decision violate basic human rights?" See Appendix B and Appendix C.

i) In any evaluation of costs and benefits, we can make sure that the protection of health takes precedence over economic considerations. The Commission of the European Communities, expresses the point this way: "Examining costs and benefits entails comparing the overall cost to the Community of action and lack of action, in both the short and long term. This is not simply an economic cost-benefit analysis: its scope is much broader, and includes non-economic considerations, such as the efficacy of possible options and their acceptability to the public. In the conduct of such an examination, account should be taken of the general principle and the case law of the Court that the protection of health takes precedence over economic considerations." [3, pg. 5]

j) We can take direction from the affected people as we search for solutions. We can acknowledge that affected people are the experts in finding solutions for their communities' problems, and governments can devise practical and effective methods for learning from these experts. (Techniques for improving community participation have been described at http://www.rachel.org/library/admin/uploadedFiles/showFile.cfm?filename=Democracy_and_the_Precautionary_Principle_Draf.doc .)

k) We can place the burden of proof on the owner/advocate of whatever it was that initially raised suspicion of harm. He or she has the responsibility to produce thorough information to show that the initial suspicions are not justified, or that mitigating steps can and will be taken to eliminate the suspected harms.

l) We can monitor results and revisit decisions every few years. How are we doing? Have things changed so that we could now do better by making different choices?

Lastly, I would like to leave you with this one thought:

****

If corporations and governments had acted with precaution in the past, environmental injustices would not exist today.

Environmental justice requires precautionary action.

****

Thank you.

Notes

[1] Marla Cone, "Study of Toxins Says U.S. Children Are at Risk," *Los Angeles Times* Feb. 1, 2003. Available at: http://www.latimes.com/la-me-toxics1feb01,0,7776456.story . The subject of this news article is the CDC report available here: http://www.cdc.gov/exposurereport/ .

[2] For scientific and medical confirmation of the dangers of industrial poisons, see, for example, Michael McCally, editor*, Life Support: The Environment and Human Health* (Cambridge, Mass.: MIT Press, 1002; ISBN 0262632578).

[3] Commission of the European Communities, *Communication from the Commission on the Precautionary Principle* (Brussels, Commission of the European Community, Feb. 2, 2000). Available at: http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf .

APPENDIX A -- Bristol-Myers Squibb Statement on Precaution

[From: http://www.bms.com/sustainability/manage/data/polici.html]

Implementing the Precautionary Principle

...We recognize that the integrity of natural systems -- land, water, air, and biodiversity -- is critical to both economic and environmental vitality. Scientific uncertainty alone should not preclude efforts to address serious environmental, health, and safety threats.

Bristol-Myers Squibb takes a precautionary approach when there is potential harm to human health or the environment as demonstrated by the following examples.

Our Worldwide Medicines Group is implementing a Process Greenness Scorecard, an electronic tool that provides scientists and engineers with a relative score for the EHS [environmental health and safety] impacts of new and modified processes. The scorecard consists of 16 parameters, such as solvent listings, hazardous waste generation, number of isolated compounds, number of listed reagents, process hazards, and worker exposure issues that are each numerically rated. Every time the scorecard is used for a chemical process throughout its development, and also after commercialization, the chemist's or chemical engineer's goal is to improve process "greenness" by raising the score. The mandatory use of the scorecard is now incorporated into all Worldwide Medicines Group standard operating procedures for product and process development.

In addition, we are involved in funding scientific studies that promote better understanding of environmental, health, and safety impacts from our operations and products and potential solutions. For example, Bristol-Myers Squibb partners with the University Hospital, Freiburg, Germany, to identify and minimize concentrations of pharmaceuticals in the environment.

APPENDIX B - United Nations Press Release April 27, 2001

Living in a Pollution-Free World a Basic Human Right

From United Nations Environment Programme Friday, April 27, 2001

NAIROBI Everyone has the right to live in a world free from toxic pollution and environmental degradation, the United Nations Commission on Human Rights has concluded.

The decision, the first time the Commission has addressed the links between the environment and human rights, was made at its annual meeting, which ended today in Geneva.

Mary Robinson, the UN High Commissioner for Human Rights, and Klaus Toepfer, the Executive Director of the United Nations Environment Programme (UNEP), have been invited to organize an international seminar to explore how environmental and human rights principles can be strengthened.

Mr. Toepfer welcomed the historic move saying: "Many of the fundamental rights enshrined in the Universal Declaration of Human Rights have significant environmental dimensions".

"Environmental conditions clearly help to determine the extent to which people enjoy their basic rights to life, health, adequate food and housing, and traditional livelihood and culture. It is time to recognize that those who pollute or destroy the natural environment are not just committing a crime against nature, but are violating human rights as well", he said.

"Human rights cannot be secured in a degraded or polluted environment", said Mr. Toepfer. "The fundamental right to life is threatened by soil degradation and deforestation and by exposures to toxic chemicals, hazardous wastes and contaminated drinking water."

"For this reason, we believe that the successful implementation of international environmental treaties on biodiversity, climate change, desertification and chemicals can make a major contribution to protecting human rights. We would welcome the Commission's continued work on the environmental dimensions of human rights, including enforcement and compliance", he said.

The results of the seminar will be considered at the Commission's next session in March 2002 and will feed into the review of progress towards sustainable development that has been achieved since the 1992 Rio Earth Summit. This 10-year review will form the basis for the World Summit on Sustainable Development, to be convened in Johannesburg in September 2002.

Note to journalists: For more information, please contact: Tore Brevik, UNEP Spokesman/Director of Communications and Public Information, in Nairobi, tel: 254-2-623292, fax: 254-2-623927, e-mail: tore.brevik@unep.org; or Michael Williams, UNEP Information Officer, in Geneva, tel: 41-22-917-8242/8244/8196, fax: 41-22-797-3464, mobile: 41-79-409-1528, e-mail: michael.williams@unep.ch

UNEP News Release 2001/49

For more information, contact:

Jim Sniffen Information Officer United Nations Environment Programme 1-212-963-8210 sniffenj@un.org
Web site: http://www.unep.org

APPENDIX C - The Universal Declaration of Human Rights (1948)

From: http://www.un.org/Overview/rights.html

Universal Declaration of Human Rights

Adopted and proclaimed by General Assembly resolution 217 A (III) of 10 December 1948

On December 10, 1948 the General Assembly of the United Nations adopted and proclaimed the Universal Declaration of Human Rights the full text of which appears in the following pages. Following this historic act the Assembly called upon all Member countries to publicize the text of the Declaration and "to cause it to be disseminated, displayed, read and expounded principally in schools and other educational institutions, without distinction based on the political status of countries or territories."

PREAMBLE

Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world,

Whereas disregard and contempt for human rights have resulted in barbarous acts which have outraged the conscience of mankind, and the advent of a world in which human beings shall enjoy freedom of speech and belief and freedom from fear and want has been proclaimed as the highest aspiration of the common people,

Whereas it is essential, if man is not to be compelled to have recourse, as a last resort, to rebellion against tyranny and oppression, that human rights should be protected by the rule of law,

Whereas it is essential to promote the development of friendly relations between nations,

Whereas the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women and have determined to promote social progress and better standards of life in larger freedom,

Whereas Member States have pledged themselves to achieve, in co-operation with the United Nations, the promotion of universal respect for and observance of human rights and fundamental freedoms,

Whereas a common understanding of these rights and freedoms is of the greatest importance for the full realization of this pledge,

Now, Therefore THE GENERAL ASSEMBLY proclaims THIS UNIVERSAL DECLARATION OF HUMAN RIGHTS as a common standard of achievement for all peoples and all nations, to the end that every individual and every organ of society, keeping this Declaration constantly in mind, shall strive by teaching and education to promote respect for these rights and freedoms and by progressive measures, national and international, to secure their universal and effective recognition and observance, both among the peoples of Member States themselves and among the peoples of territories under their jurisdiction.

Article 1.

All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.

Article 2.

Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. Furthermore, no distinction shall be made on the basis of the political, jurisdictional or international status of the country or territory to which a person belongs, whether it be independent, trust, non-self-governing or under any other limitation of sovereignty.

Article 3.

Everyone has the right to life, liberty and security of person.

Article 4.

No one shall be held in slavery or servitude; slavery and the slave trade shall be prohibited in all their forms.

Article 5.

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.

Article 6.

Everyone has the right to recognition everywhere as a person before the law.

Article 7.

All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination.

Article 8.

Everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law.

Article 9.

No one shall be subjected to arbitrary arrest, detention or exile.

Article 10.

Everyone is entitled in full equality to a fair and public hearing by an independent and impartial tribunal, in the determination of his rights and obligations and of any criminal charge against him.

Article 11.

(1) Everyone charged with a penal offence has the right to be presumed innocent until proved guilty according to law in a public trial at which he has had all the guarantees necessary for his defence.

(2) No one shall be held guilty of any penal offence on account of any act or omission which did not constitute a penal offence, under national or international law, at the time when it was committed. Nor shall a heavier penalty be imposed than the one that was applicable at the time the penal offence was committed.

Article 12.

No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honor and reputation. Everyone has the right to the protection of the law against such interference or attacks.

Article 13.

(1) Everyone has the right to freedom of movement and residence within the borders of each state.

(2) Everyone has the right to leave any country, including his own, and to return to his country.

Article 14.

(1) Everyone has the right to seek and to enjoy in other countries asylum from persecution.

(2) This right may not be invoked in the case of prosecutions genuinely arising from non-political crimes or from acts contrary to the purposes and principles of the United Nations.

Article 15.

(1) Everyone has the right to a nationality.

(2) No one shall be arbitrarily deprived of his nationality nor denied the right to change his nationality.

Article 16.

(1) Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and to found a family. They are entitled to equal rights as to marriage, during marriage and at its dissolution.

(2) Marriage shall be entered into only with the free and full consent of the intending spouses.

(3) The family is the natural and fundamental group unit of society and is entitled to protection by society and the State.

Article 17.

(1) Everyone has the right to own property alone as well as in association with others.

(2) No one shall be arbitrarily deprived of his property.

Article 18.

Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance.

Article 19.

Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers.

Article 20.

(1) Everyone has the right to freedom of peaceful assembly and association.

(2) No one may be compelled to belong to an association.

Article 21.

(1) Everyone has the right to take part in the government of his country, directly or through freely chosen representatives.

(2) Everyone has the right of equal access to public service in his country.

(3) The will of the people shall be the basis of the authority of government; this will shall be expressed in periodic and genuine elections which shall be by universal and equal suffrage and shall be held by secret vote or by equivalent free voting procedures.

Article 22.

Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality.

Article 23.

(1) Everyone has the right to work, to free choice of employment, to just and favorable conditions of work and to protection against unemployment.

(2) Everyone, without any discrimination, has the right to equal pay for equal work.

(3) Everyone who works has the right to just and favorable remuneration ensuring for himself and his family an existence worthy of human dignity, and supplemented, if necessary, by other means of social protection.

(4) Everyone has the right to form and to join trade unions for the protection of his interests.

Article 24.

Everyone has the right to rest and leisure, including reasonable limitation of working hours and periodic holidays with pay.

Article 25.

(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

(2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.

Article 26.

(1) Everyone has the right to education. Education shall be free, at least in the elementary and fundamental stages. Elementary education shall be compulsory. Technical and professional education shall be made generally available and higher education shall be equally accessible to all on the basis of merit.

(2) Education shall be directed to the full development of the human personality and to the strengthening of respect for human rights and fundamental freedoms. It shall promote understanding, tolerance and friendship among all nations, racial or religious groups, and shall further the activities of the United Nations for the maintenance of peace. (3) Parents have a prior right to choose the kind of education that shall be given to their children.

Article 27.

(1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Article 28.

Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized.

Article 29.

(1) Everyone has duties to the community in which alone the free and full development of his personality is possible.

(2) In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society.

(3) These rights and freedoms may in no case be exercised contrary to the purposes and principles of the United Nations.

Article 30.

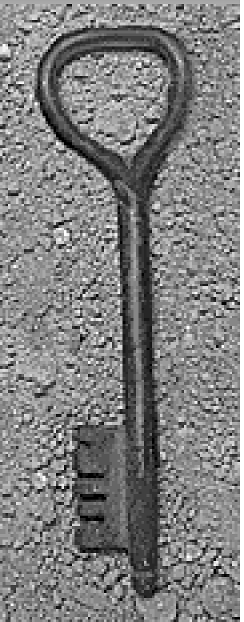
Nothing in this Declaration may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms set forth herein.

The Precautionary Principle: Its Use and Misuse

F. Jay Murray, Ph.D.

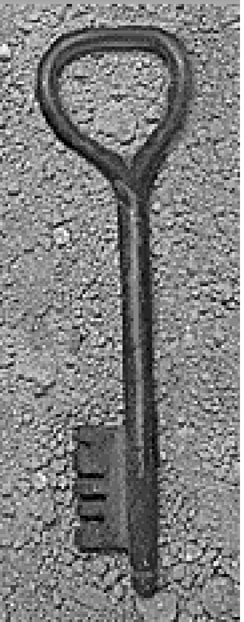
Presentation to the Cal/EPA Advisory Committee on Environmental Justice

February 18, 2003



Introduction

- Purpose: assessment of the precautionary principle
- Reviewed dozens of articles for and against
- Experience with California regulatory approach, risk assessment and standards
- Precautionary principle does not represent good public health policy

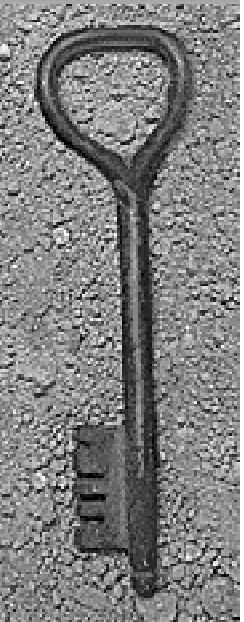


Topics of Discussion

- How could anybody object to the precautionary principle?
- Current regulatory approach, which uses risk assessment, is precautionary.
- Extreme precaution is harmful to public health and the environment.
- The precautionary principle is bad science and bad public policy.

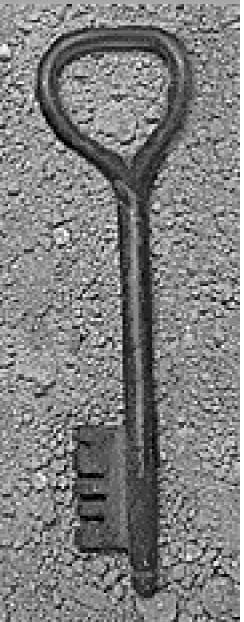
How could anybody object?

- Seems reasonable at first glance
- Reasonable precaution is essential.
- Important to understand what that term means to those who define and advocate it
- Important to examine the ramifications of the precautionary principle



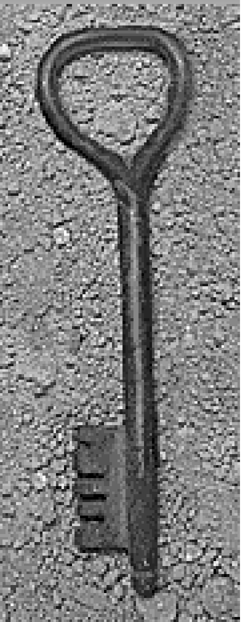
"Precaution is a necessary and useful concept, but it is also subjective and susceptible to abuse."

-- Dr. John Graham, Administrator, Office of Information and Regulatory Affairs (former Director of Harvard Center for Risk Analysis)



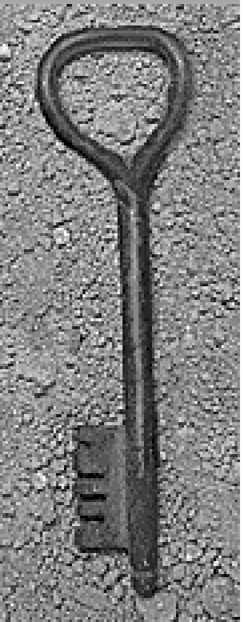
Key Elements of Precautionary Principle

- An extreme form of precaution
- Any risk is too much to tolerate
- The mere possibility of a risk is too great
- Rejects current regulatory approach
- Used to eliminate or regulate specific technologies (e.g., cell phones, pesticides, genetically modified crops, chlorine, pharmaceuticals, medical devices)



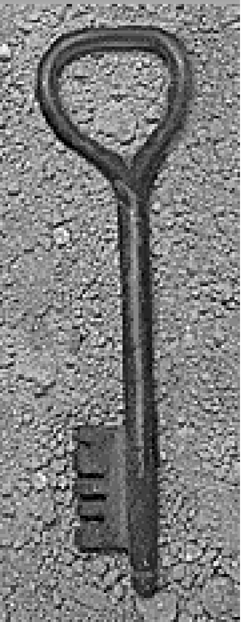
What's the harm?

- Focuses on theoretical, unproven risks
- Diverts attention from known, significant threats
- Does not consider risks of not accepting new technologies
- Turns a blind eye to the harm from lack of technological development
- Extreme precaution harms public health



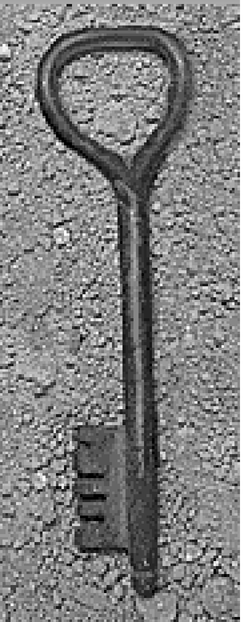
"The fatal flaw of the precautionary principle … is the unsupported presumption that an action aimed at public health protection cannot possibly have negative effects on public health."

-- Professor Frank Cross, U. of Texas

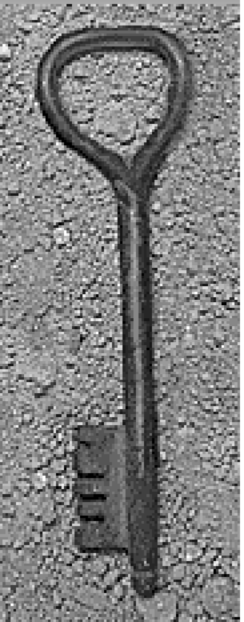


Unreasonable

- Requires an unreasonable degree of certainty and proof
- The absence of an effect can never be proved scientifically
- Whimsical claims don’t have to be proved
- Everything in life involves risk

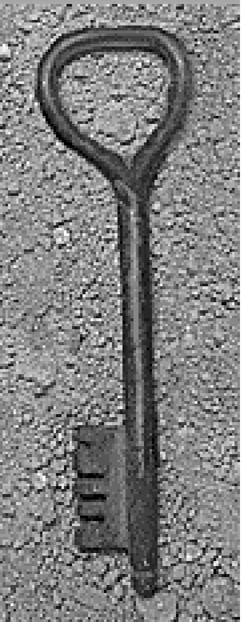


GRAPHIC



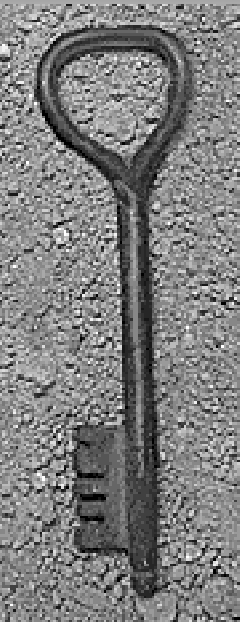
Reckless Rejection of Current Regulatory Approach

- Alleges failure of current regulatory approach
- Assumes regulators have not exercised adequate precaution
- Calls for replacement of current regulatory approach
- Claims “new principles for conducting human activities are necessary”



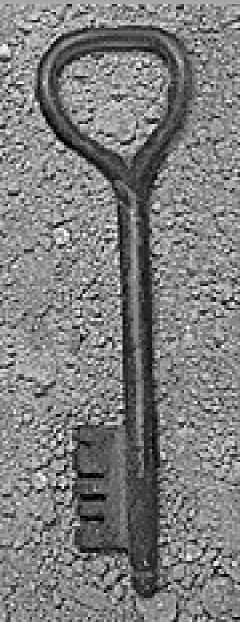
Current Regulatory Approach

- A science-based precautionary approach
- Risk assessment acknowledges what we know and don't know
- Openly deals with uncertainty
- Conservative assumptions err on side of safety
- Careful balancing of risks and benefits
- Not perfect, but excellent track record



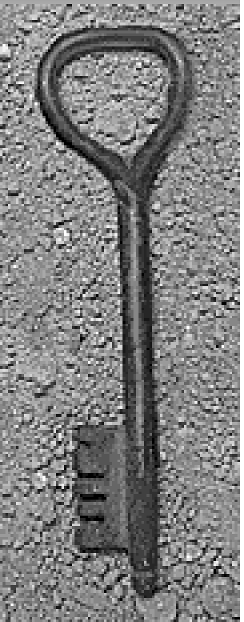
Case Study: Pharmaceuticals

- FDA balances risks and benefits
- Approval of an unsafe drug costs lives
- Too cautious costs lives too
- FDA does not embrace the precautionary principle
- Many valuable drugs would be lost, and human health would suffer
- Aspirin, antibiotics, anti-cancer drugs



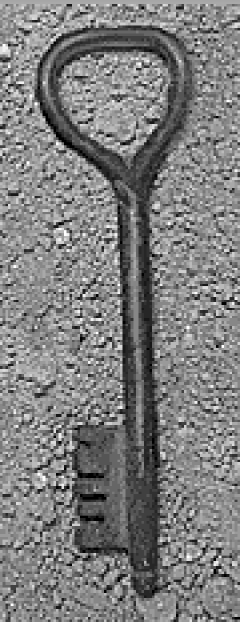
Current Regulatory Approach in California (CA)

- CA regulators exercise precaution
- CA relies heavily on science and risk assessment
- CA has some of the most stringent environmental and health standards in U.S.
- Independent review by RAAC
- We must be careful not to replace what works with something less effective in protecting public health



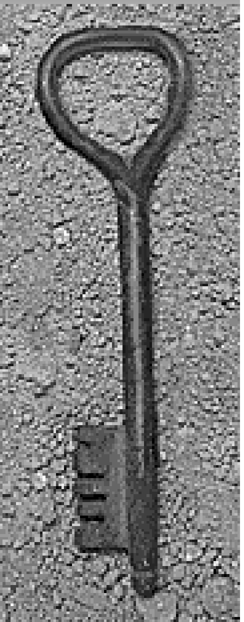
Benefits of Science and Technology

- Americans today are living longer and healthier lives than ever
- Life expectancy went from 47 years in 1900 to 77 years in 2000
- Examples of beneficial technology (water chlorination, antibiotics, vaccines)
- These advances were not without risk and uncertainty



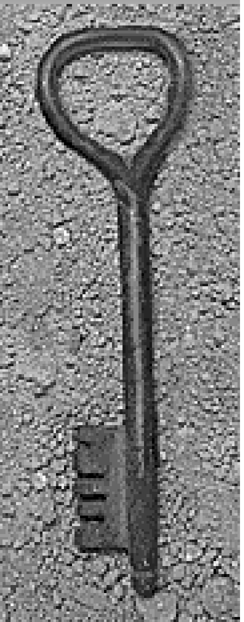
Anti-Innovation

- Stated intent is to slow the introduction of new technology
- California thrives on innovation and new technology
- The precautionary principle is the antithesis of what makes California great
- Too much attention on the risks of new technologies, while ignoring benefits
- A terrible idea, particularly for California



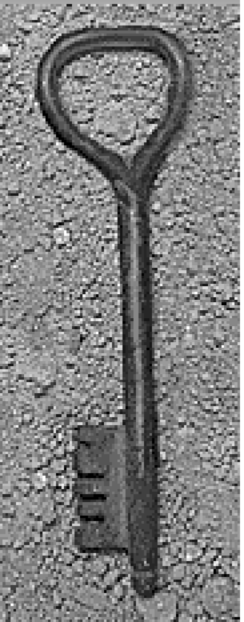
"Nothing will ever be attempted, if all possible objections must first be overcome."

-- Samuel Johnson



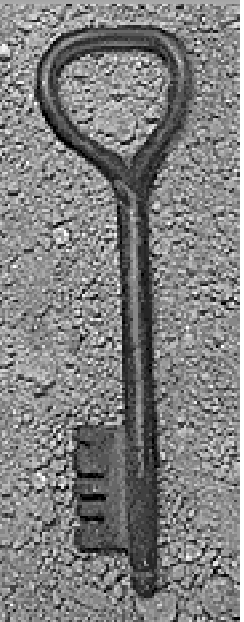
The Danger of Avoiding All Risk

- The precautionary principle applies the brakes, even when the risks are unknown
- The default position is to stand still, to accept things as they currently are
- It sacrifices the potential benefits of future discovery
- Accepting some level of risk can lead to far-reaching benefits for mankind



"The precautionary principle inflates the cost of research, inhibits new product development, wastes resources, restricts consumer choice, creates serious new risks and costs lives."

-- Henry I. Miller, M.D., Stanford U.



Conclusions

- Reasonable precaution is essential in balancing risks and benefits
- The current science-based precautionary approach has proved our best option
- The precautionary principle is an unproven and risky choice that will harm public health
- Exercise precaution in considering the precautionary principle

Science & Environmental Health Network

"The Precautionary Principle"

Silicone in Dry Cleaning

Jim Douglas
C.E.D., C.P.D.

February 18, 2003

Background

Swanson's Cleaners

- Central plant Arden way & Howe, 115 stores.
- Stoddard solvent (VOC, fp 102 F).
- Consumption 120,000 gallons / yr.
- Consumption 1984 on was 32,000 gallons / yr.
- Underground storage 65,000 gallons.
- Anticipation of elimination of underground tanks.

Background

- Testing of Dow's LS.
- Testing of Dupont's Valclene.
- Installed Perc operation in 1992.
- Testing of Dow's TVS System for Perc.
- Testing of Exxon's Df-2000 (VOC, fp 140 F).
- Decentralization of main plant 1998.

Background

- Swanson's moves to 4 plants.
- Prestige Cleaners is established as a separate company.
- Review of Alternative Cleaning Systems:

1. Evaluated CO_2 (Liquid Carbon Dioxide).

2. Evaluated 0_3 (Ozone).

3. Evaluated H_20 (Wet Cleaning).

Prestige Cleaners

- Alpha & Beta testing of silicone dry cleaning.
- Installed Prestige plant with 2 dry to dry Class III-A cleaning machines, 1 recovery drier.
- First plant in the world to use silicone for dry cleaning.
- Operated as a R & D site under CDA.
- SAQMD advised and assisted.

Prestige Cleaners

Results of operating with silicone

- 1. More efficient cleaning (classifications).
- 2. Savings in utilities (less loads).
- 3. Reduction in labor (easier finishing).
- 4. Reduction in waste removal (classification).

Prestige Cleaners

Effects of cleaning with silicone

- 1. Employee morale greatly improved.
- 2. No odors on garments or working area.
- 3. Environmental marketing message.
- 4. Access to retail sites not previously available.
- 5. Establish an exit strategy, no liabilities.

GREENEARTH® CLEANING

Joint Venture

- **GreenEarth Cleaning**: Industry experience & operational expertise.
- **General Electric**: R&D commitment & manufacturing prowess.
- **P&G**: Pioneer in detergency with silicones; outstanding consumer marketing.

What is GREENEARTH?

VOC Classification	**Non-VOC**
Flash Point	**77.7°C (170°F)**
Physical Form	Liquid
Color	Colorless
Odor	Odorless
Specific Gravity @ 25°C	0.950
Viscosity, @ 25°C (77°F)	4.0 CST
Freezing Point	-40°C (-40°F)
Boiling Point	210°C (410°F)
Refractive Index, 25°C (77°F)	1.395
Lower Flammability Index	0.70000 vol. % in air
Vapor Pressure @ 25°C (74°F)	0.1482
Surface Tension	17.42 dynes/cm @ 25°C

Affirmation Site Program

- 14 months of testing – no active selling.
- 29 sites on a global basis, primarily in the US.
- 17 states & D.C., Japan & U.K.
- 9 different machine manufacturers.
- >2 million pounds cleaned during program.

Affirmation Site Program

- Confirm alpha & beta test results.
- Various geographical environments.
- Wide variety of garments.
- Different equipment configurations.
- Variety of independent cleaners.

Affirmation Site Program

Independent Analysis

Filter Cartridges - Still Bottoms - Wastewater

SEVERN TRENT SERVICES Severn Trent Laboratories

Industrial Hygiene

CIH SERVICES

California Industrial Hygiene Services Inc.

Scope of Testing

Over 26,000 test measurements by independent agencies.

- Air samples.
- Wastewater samples.
- Still bottom samples.
- Cartridge filter samples.

Environmentally Friendly

Wastewater: Nonhazardous

Still Bottoms: Nonhazardous

Cartridge Filters: Nonhazardous

Environmental Features

RCRA	Non-regulated
CERCLA	Non-regulated
EPA	Non-toxic (oral, dermal, inhalation)
OSHA	Exceeds all standards
SNAP	Non-VOC (EPA program)

Five Criteria for Alternative Cleaning Process

1. Will not create or add to future contamination.
2. Has no known or expected health issues.
3. Has financially realistic capital costs.

Five Criteria for Alternative Cleaning Process

4. Has realistic/affordable labor and operating costs.
5. Will continue to clean garments and textiles currently being drycleaned by the industry.

IFI'S Evaluation of Cleaning Systems

Criteria	Perc	Petrol	DF2000	CO2	Green Earth	Rynex	Water
Contamination	1	3	3	5	5	3	5
Health Issues	1	3	3-5	5	5	3	5
Capital $	5	3-5	3-5	1-3	3-5	3	5
Labor/Oper $	5	5	5	1-5	5	3	5
Current Work	5	5	5	5	5	3	1
Does it Clean?	Yes	Yes	Yes	??	Yes	??	Yes
TOTAL	**17**	**19-21**	**19-23**	**15-23**	**23-25**	**15?**	**19**

Poor = 1   Average = 3   Excellent = 5

It's good for everybody

- It's good for the environment.
- It's good for clothes.
- It's good for our customers.
- It's good for our business.

The Precautionary Principle and Environmental Justice

California EPA
February 18, 2003

Carolyn Raffensperger

Science and Environmental Health Network

www.sehn.org

A Map of this talk

- Lessons learned (anthrax, shuttle, other disasters)
- How to Say “Yes”
- Where precaution is being used or considered in the U.S.
- Relationship of environmental justice to precaution
- Ideas about ways to move forward

What is the precautionary principle?

Wingspread Statement: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

Wingspread statement Jan., 1998

1. People have a duty to take anticipatory action to prevent harm.
2. The burden of proof lies with the proponents, not with the public.
3. Before using a new technology, process, or chemical or acting on warnings, people have an obligation to examine "a full range of alternatives."
4. Decisions applying the precautionary principle must be "open, informed, and democratic" and "must include affected parties."

Values underlying the precautionary principle

- "Forecaring"
- Prevention of harm
- Obligations to future generations
- An appreciation of and respect for the limits of science
- Obligation to make the ethical framework underlying decisions explicit
- Respect and Rationality
- Taking Responsibility for our actions

Precautionary principle and risk assessment

- Precautionary principle is overarching
- Precautionary principle and risk assessment begin at very different places
- Risk assessment/management attempt to quantify and manage risk
- The precautionary principle begins upstream; asks more fundamental questions; counsels prevention

Lessons learned

Prevention is wiser and less costly than repairing damage.

Lesson 2

Consider worst case scenarios carefully. Low probability, high risk events not only follow Murphy’s law, they follow statistical probability.

Lesson 3

Put certainty on a sliding scale rather than treating it as an absolute. If the potential harm is serious we need to take action even if we are less certain about the probability or magnitude of the harm.

Lesson 4

Foster the conditions that encourage foreseeability (openness, free-flowing information, protecting minority-view science, soliciting community observations). We failed to predict some problems like CFCs damaging the ozone layer, but that doesn't mean they were unforeseeable.

Lesson 5

Timing is everything. The higher the stakes, the more important it is to take precautionary action sooner rather than later. Speed up democracy. Slow down large scale deployment.

Lesson 6

Concentrating precious things (people) or harmful things (radioactive waste or hog manure in lagoons) increases the chances for major damage in the event of an unexpected problem. Scale determines whether a problem will be a minor disturbance or a catastrophe. Large scale activities will cause trouble some time, some place.

Lesson 7

Favor actions that keep options open.

Favor actions that allow for experimentation.

Favor actions that can be monitored and reversed if there are unintended consequences.

Lesson 8

When the science is uncertain, switch sciences: map relationships rather than measure things or move from toxicology to evolutionary biology, pharmacology and physiology. Rigid dependence on one discipline or scientific tool blinds us to the clues in other disciplines.

Lesson 9

Expand and protect information and wisdom. Adopt policies of openness rather than secrecy. Secrecy is the tool of tyrants.

Lesson 10

Connect the dots. Search for pattern. Emerging patterns provide new hypotheses and opportunities to avoid harm.

Regulatory Agencies: Implementing the precautionary principle

1) Establish a General Duty to act with precaution

2) Set goals

3) Establish a public interest research agenda, including cross-disciplinary approaches

4) Enhance information flows

5) Use the appropriate disciplines. Use multiple disciplines.

Implementing the precautionary principle (cont)

6) Shift the burden of responsibility/proof.

7) Create new torts. Specifically require pre-market testing.

8) Choose the least harmful alternative.

9) Engage in democratic decision-making processes.

Implementing the Precautionary Principle cont.

- 10) Take actions that are:
  - Anticipatory and preventive
  - Increase rather than decrease options
  - Can be monitored and reversed
  - Increase resilience, health, integrity of whole system
  - Enhance diversity (one size does not fit all)

Can we say “yes” using the precautionary principle?

1) Pre-market testing
2) Monitoring
3) Performance bonds
4) Alternatives assessment (Similar to an EIS under NEPA). Searching for alternatives drives technology innovation
5) Use biological principles when data is missing. (green chemistry, evolutionary biology)
6) Adaptive management/Bayesian approach

Using the precautionary principle:

- Chemicals
  - Pesticides
    - L.A Unified School Dist.
    - Park Dist. in Tx.
    - Canada
    - State proposed legislation: phase-out of 12 chemicals where alternatives exist
  - Other chemicals
    - Health Canada (DEHP in medical devices)
    - U.S. EPA's green chemistry program

Early Warning Systems

- State regulatory agency
- Business (Verizon)
- Federal alert practitioner statutes (adverse vaccine reactions)

Using the Precautionary Principle: Research Agenda

- Drugs in Water (Bristol Myers Squibb)
- State proposed legislation addressing novel technologies.
- California study on EMFs

Purchasing

- San Francisco
  - Seller has burden of responsibility to disclose information.
  - Search for best alternatives.

Observations

- Many U.S. businesses are ahead of U.S. regulatory agencies in using the precautionary principle.
- Many scientific disciplines are ahead of U.S. regulatory agencies in using the precautionary principle.

Relationship of the precautionary principle to environmental justice

- Both put ethics or values to the fore (justice and precaution)
- Justice implies fairness which is accomplished by shifting the burden of proof.
  - Who has the responsibility to provide information?
  - Who has to pay when damage occurs?
  - Who gets the benefit of the doubt when the science is uncertain?
- In U.S. law redressing injustice involves restitution, and prevention of future harm - the central tenet of the precautionary principle.
- Democratic involvement is central.

Environmental Justice

- How can we create the conditions for healthy communities, keeping in mind what we know and the uncertainties?
- How can we discuss and set goals?
- How can we systematically consider alternatives?
- What are the most respectful ways to foster democratic decision-making and participation?
- How are goals and alternatives reflected in the research agenda?
- How do we consider data? Role of Bayesian approach?
- How do we put the burden of proof / persuasion where it belongs?

"In a flying machine with more than 2.5 million parts, even a 99.9 percent reliability level would still leave 2,500 things to go wrong."

(Time magazine writer)

Why Addressing Cumulative Impact is Important for Environmental Justice

Testimony for the
California Environmental Protection Agency
Advisory Committee on Environmental Justice

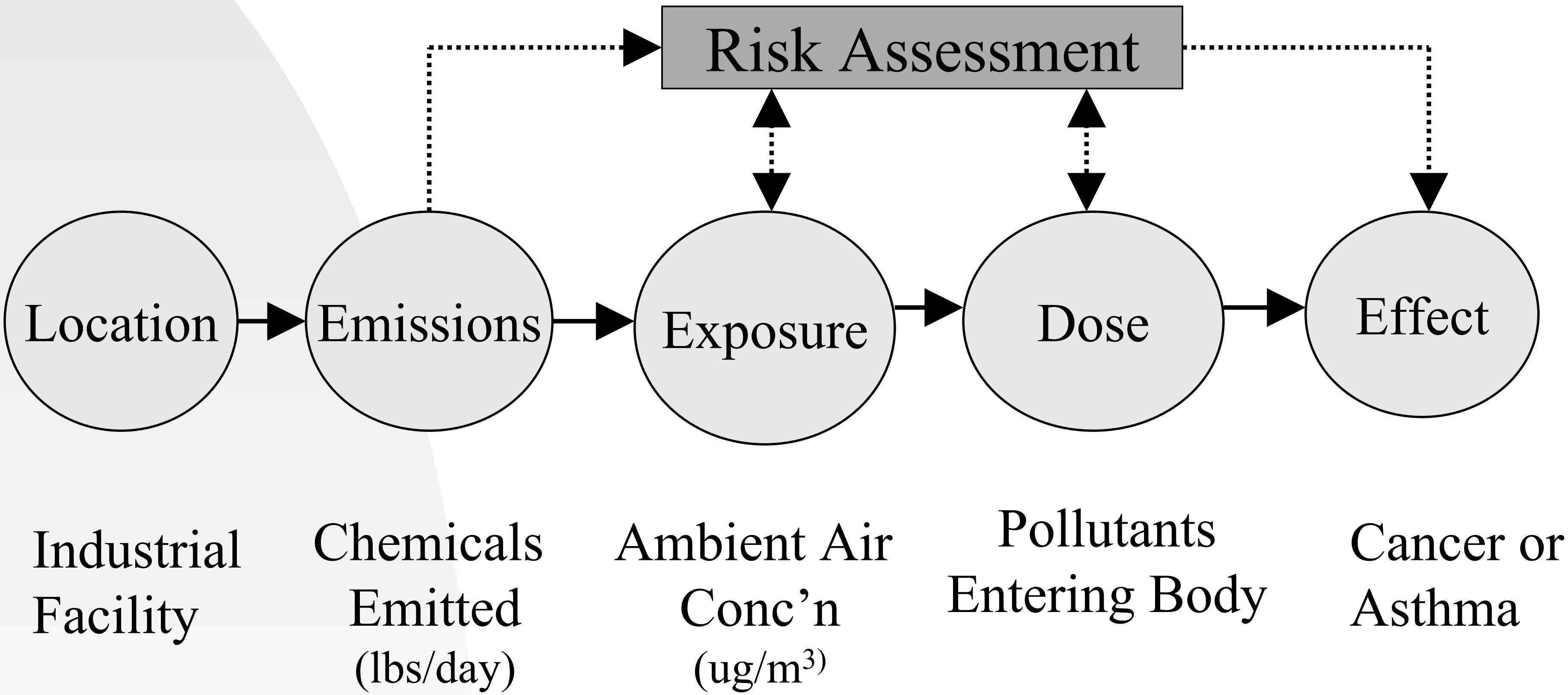
Rachel Morello-Frosch, Ph.D., M.P.H.
Department of Community Health, School of Medicine & Center for Environmental Studies
Brown University

February 18th 2003

Context – Why Cumulative Impact is an Environmental Justice Concern

- Preliminary research indicates that communities of color face a disparate impact of the location of environmental hazards.
- Little research has examined cumulative health impacts of environmental exposures comparatively across demographic groups.
- CDC's National Exposure Report indicates that children of color (Latinos and African Americans in particular) bear a disproportionate burden of exposures to certain harmful substances such as lead and pesticides.
- Data suggests a need for a more holistic regulatory approach to assessing exposure realities of diverse communities.

The Challenge of Linking Toxics to Adverse Health Outcomes



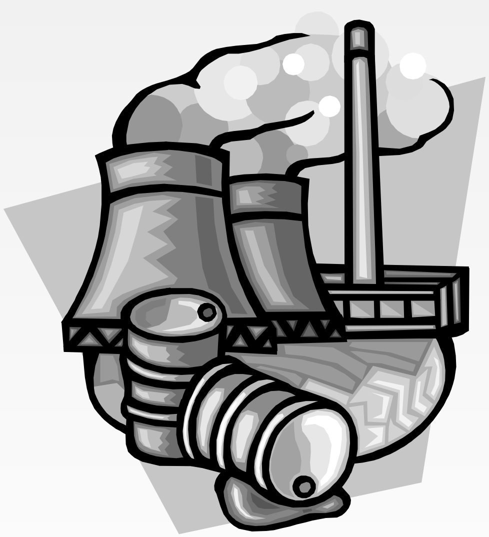
Previous Approaches to Examining Environmental Inequities Related to Air Pollution

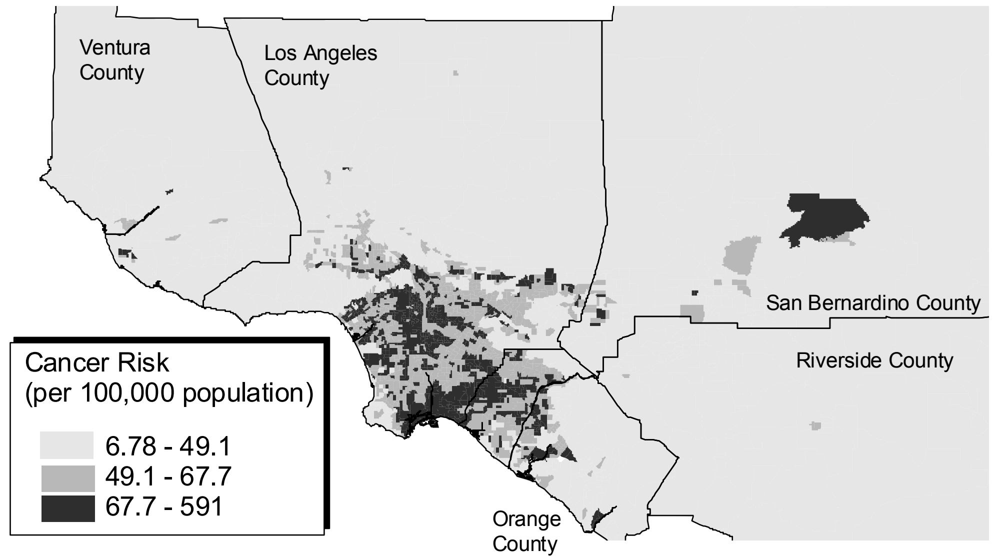
- Location of large industrial/waste disposal facilities
- Emissions loadings
  - Right-to-Know laws & Toxic Release Inventory make this possible
  - No information on potential health effects of mobile sources (e.g. cars)
- Distribution of ambient concentrations limited to a handful of pollutants
- Little research on the cumulative exposures faced by communities where they live, work and play
- Little known about potential impacts on community environmental health

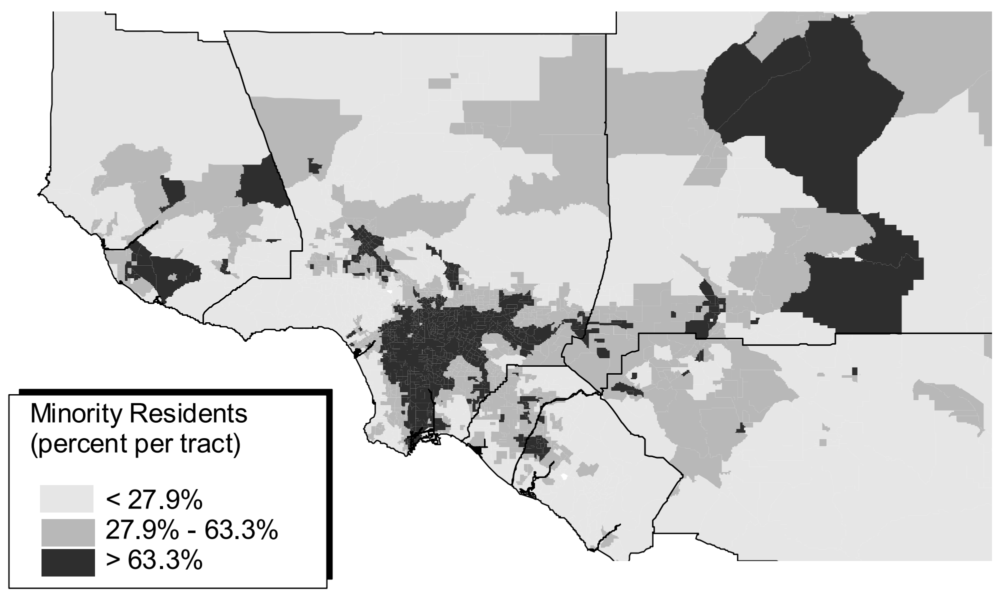
Environmental Justice & California's Riskscape: Methods

- US-EPA Cumulative Exposure Project models long-term annual average outdoor concentrations of 148 air toxics
- Model includes mobile and stationary emissions sources:
  - Manufacturing (point and area)
    - e.g.., refineries, small fabricators, chemical manufacturers
  - Non-Manufacturing (point and area)
    - e.g.., utilities, hospitals, dry cleaners, auto body shops
  - Mobile (onroad and offroad)
    - e.g.., cars, trucks, air craft, agricultural equipment
- Air toxics concentration estimates allocated to census tracts in Los Angeles.
- Cancer & respiratory risks estimated by combining concentration estimates with pollutant toxicity information

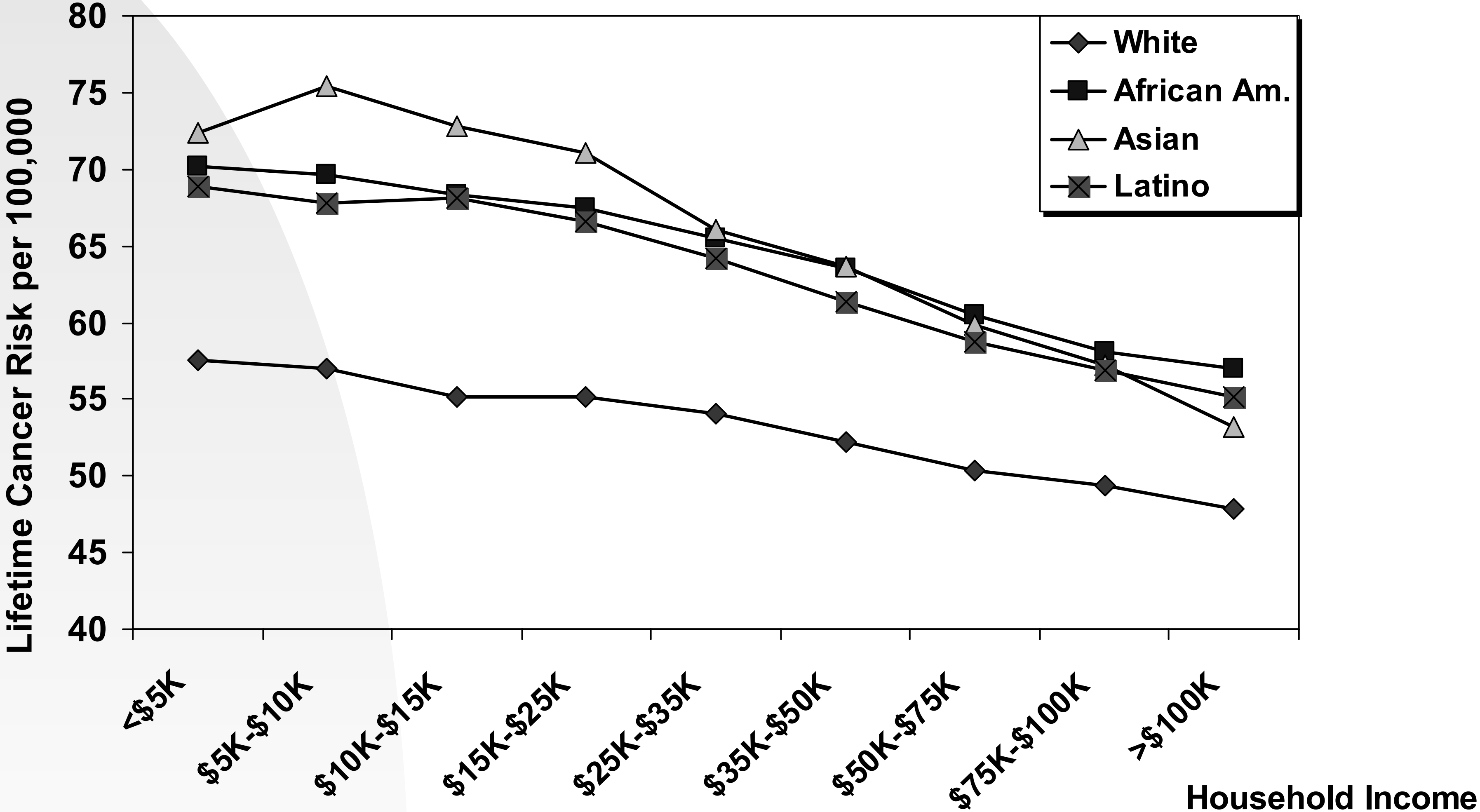
Cumulative Individual Lifetime Cancer Risk and Percent Minority Residents in Southern California



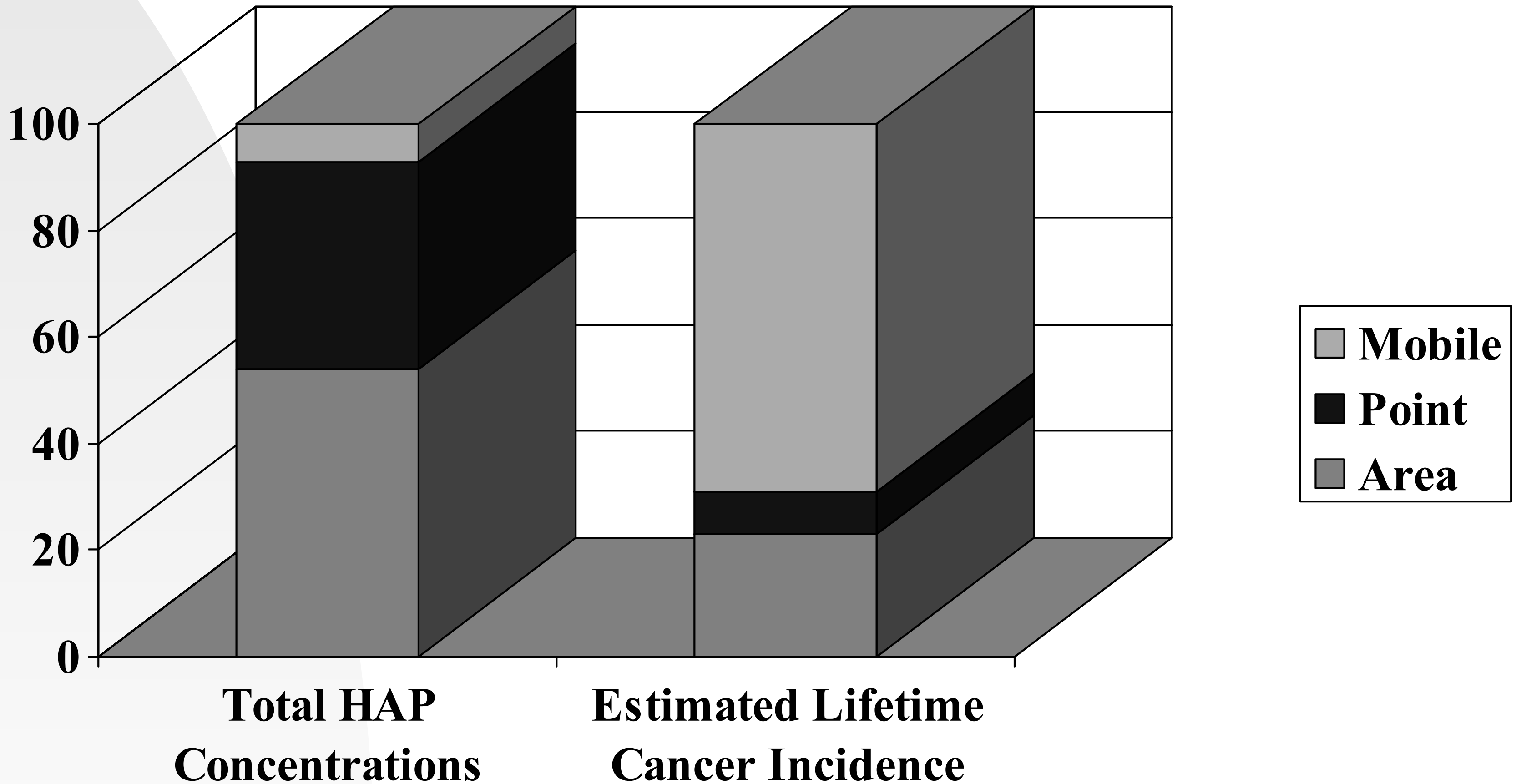




Estimated Lifetime Cancer Risks from Ambient Air Toxics Exposures by Race/Ethnicity & Income South Coast Air Basin



Emission Source Contributions to Air Toxics Concentrations and Estimated Lifetime Cancer Incidence in the South Coast Air Basin



Note: Mobile sources include onroad and offroad vehicles, area sources include small manufacturing and non-manufacturing facilities, and point sources include large manufacturing facilities such as TRI sources.

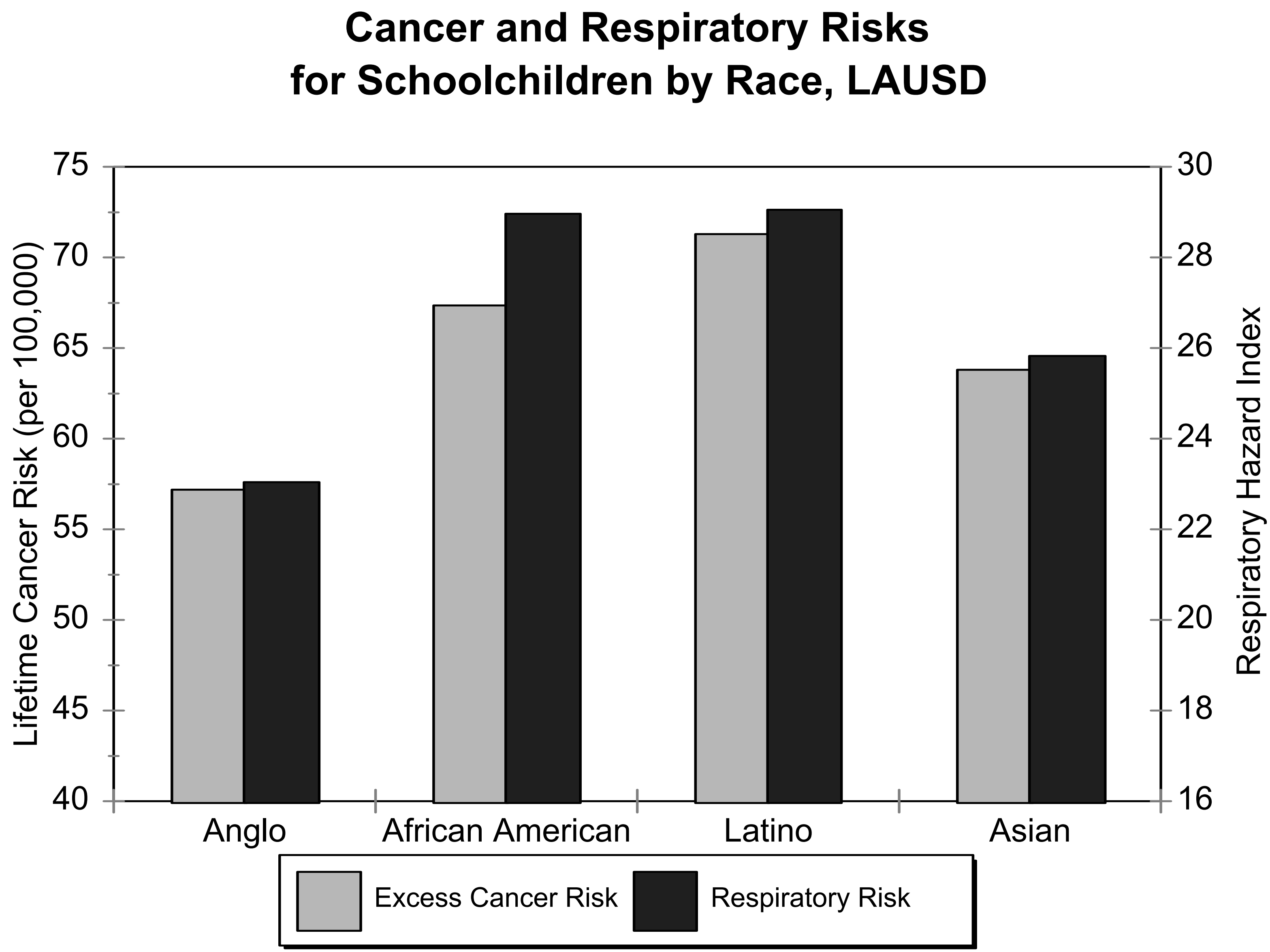
Children's Health, Environmental Justice & Cumulative Impact

- Children's health a priority in the regulatory and policy arenas
  - *President Clinton Exec. Order 13045 on Children's Health*
- Data indicate increased susceptibility of children to toxic exposures
  - *Differences in metabolism, exposure and absorption patterns*
- Studies indicate that children of color bear disparate burden of exposure to environmental hazards and their potentially adverse effects
- Paucity of information on cumulative health impacts of ambient air pollution among children while at school
  - *Issue often not examined through an environmental justice lens*
- Controversies over school siting in LA
  - *Educational opportunities and environmental justice concerns for students of color*
  - *LAUSD slated to build 80 schools over the next 5 years*

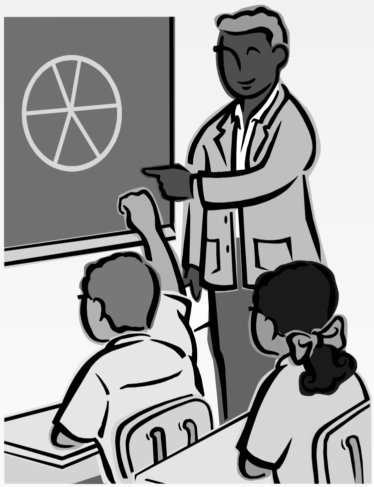
Methods

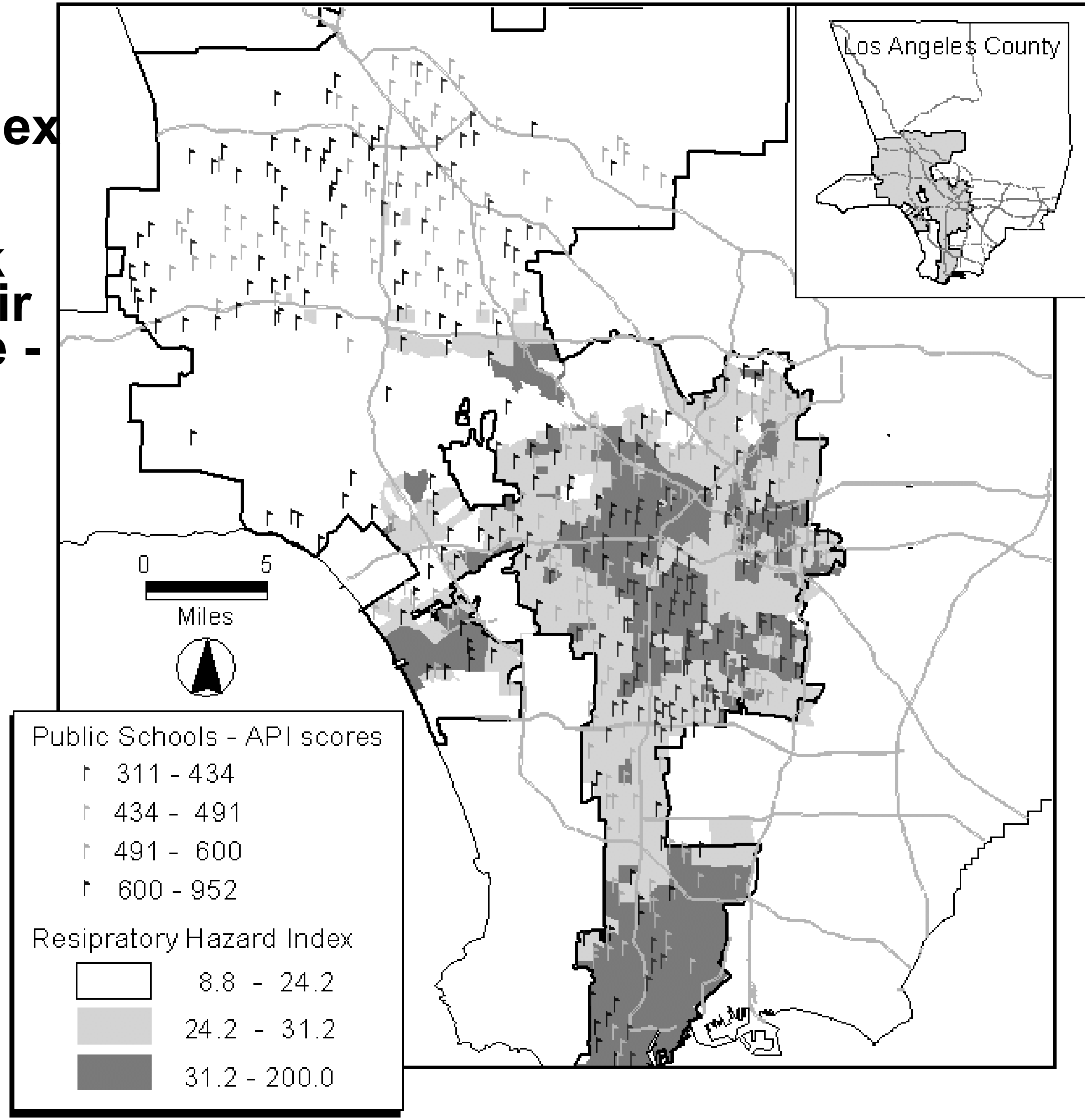
- Study examines distribution of ambient air toxics and associated health risks among demographic groups in LA Unified School District.
- Assesses the relationship between school performance and estimated respiratory risks
- Using GIS school locations matched with host census tracts containing demographic and economic information.
- Tract-level modeled ambient concentration data combined with relevant toxicity information from to estimate health risks

Racial Disparities in Environmental Risks Associated with Air Toxics Exposures Among Children



Public School Academic Performance Index and Estimated Cumulative Respiratory Risk From Ambient Air Toxics Exposure - LAUSD





Academic Performance Index (API) Score by Estimated Respiratory Risk Category Los Angeles Unified School District

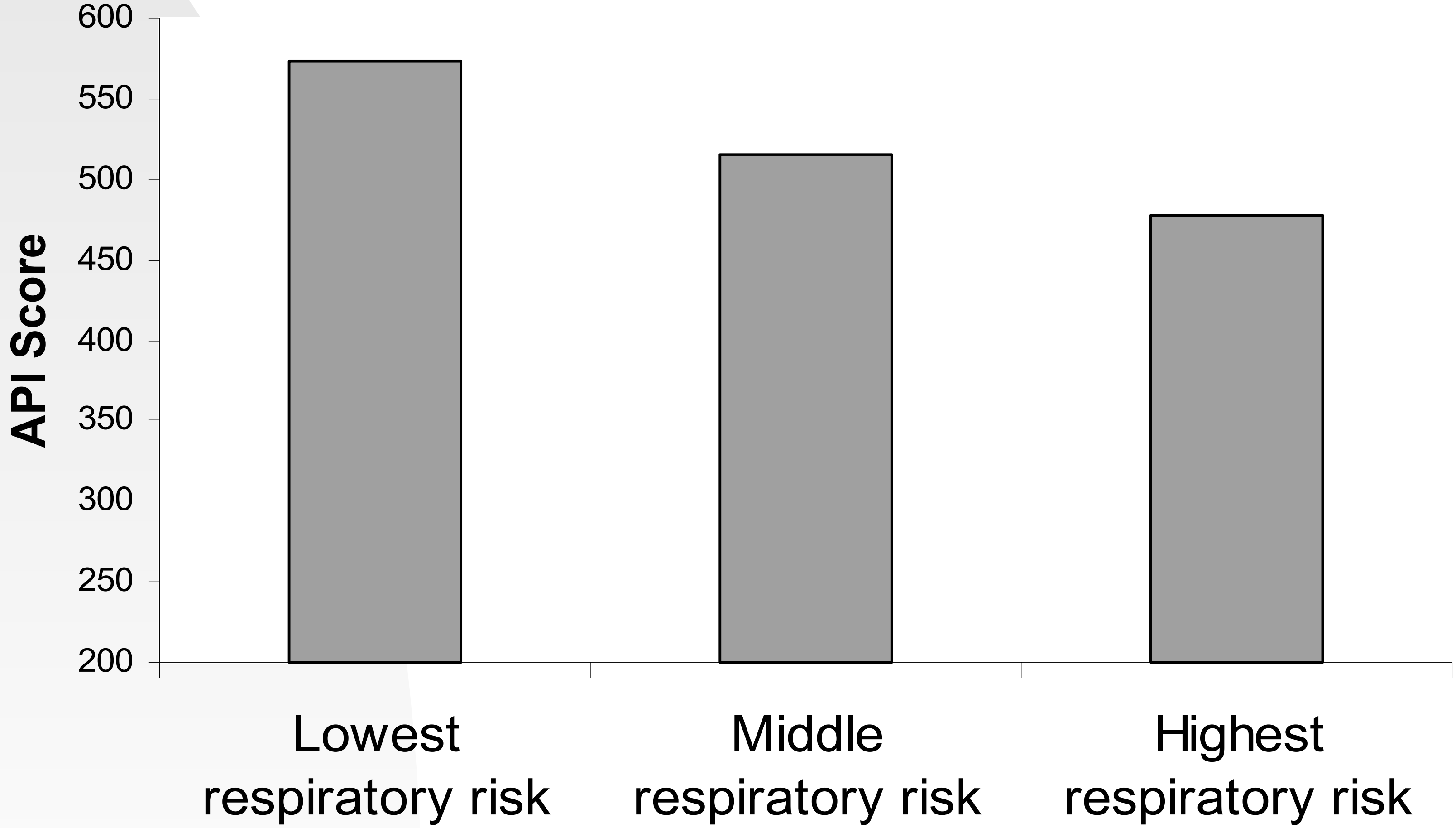


Table 2
Impact of Variables on School Performance Scores
Los Angeles Unified School District

Dependent variable: Academic Performance Index, 1999

Independent Variables	(a) **Direction of Effect**	**Stat. Sig.**	(b) **Direction of Effect**	**Stat. Sig.**
% children receiving free school lunches	(--)	***	(--)	***
% of emergency credentialed teachers	(--)	***	(--)	***
% of English learner students	(--)	***	(--)	***
Number of students in school	(--)	***	(--)	***
Mobility: % of students in school for first time	(--)	***	(--)	***
Average educational level of parents			+	***
Estimated ambient HAP respiratory risk	(--)	***	(--)	***
N	563		545	

*** highly significant (at the 1 % level)
** very significant (at the 5 % level)
ns not significant

Preliminary Results: Disparate Impact of Estimated Health Risks Associated with Ambient Air Toxics Across Demographic Groups

- Estimated cancer and non-cancer risks highest for communities of color, particularly Latino and African American students
- 80% of risk estimates from both studies are attributable to five pollutants (POM, benzene, chromium, butadiene, formaldehyde)
- Respiratory risks are associated with lower school-based API scores even after controlling for poverty, teacher quality, and other key factors
- Challenges for balancing educational needs with environmental health concerns of students of color

Considerations for Assessing Disparate Cumulative Impact

- Move beyond chemical-by-chemical and facility-by-facility analysis to address the exposure realities of diverse communities in California
- Cumulative Impact Assessment needs to incorporate various data sources and tools including:
  - Emissions data
  - Monitoring & modeled concentration data (e.g. CARB studies)
  - Risk Assessment (cancer & non-cancer)
- Don't put all the regulatory marbles into the risk assessment basket.
  - Risk assessment tools are useful, but remain imprecise and the lack of comprehensive toxicity data for non-cancer impacts remains a problem

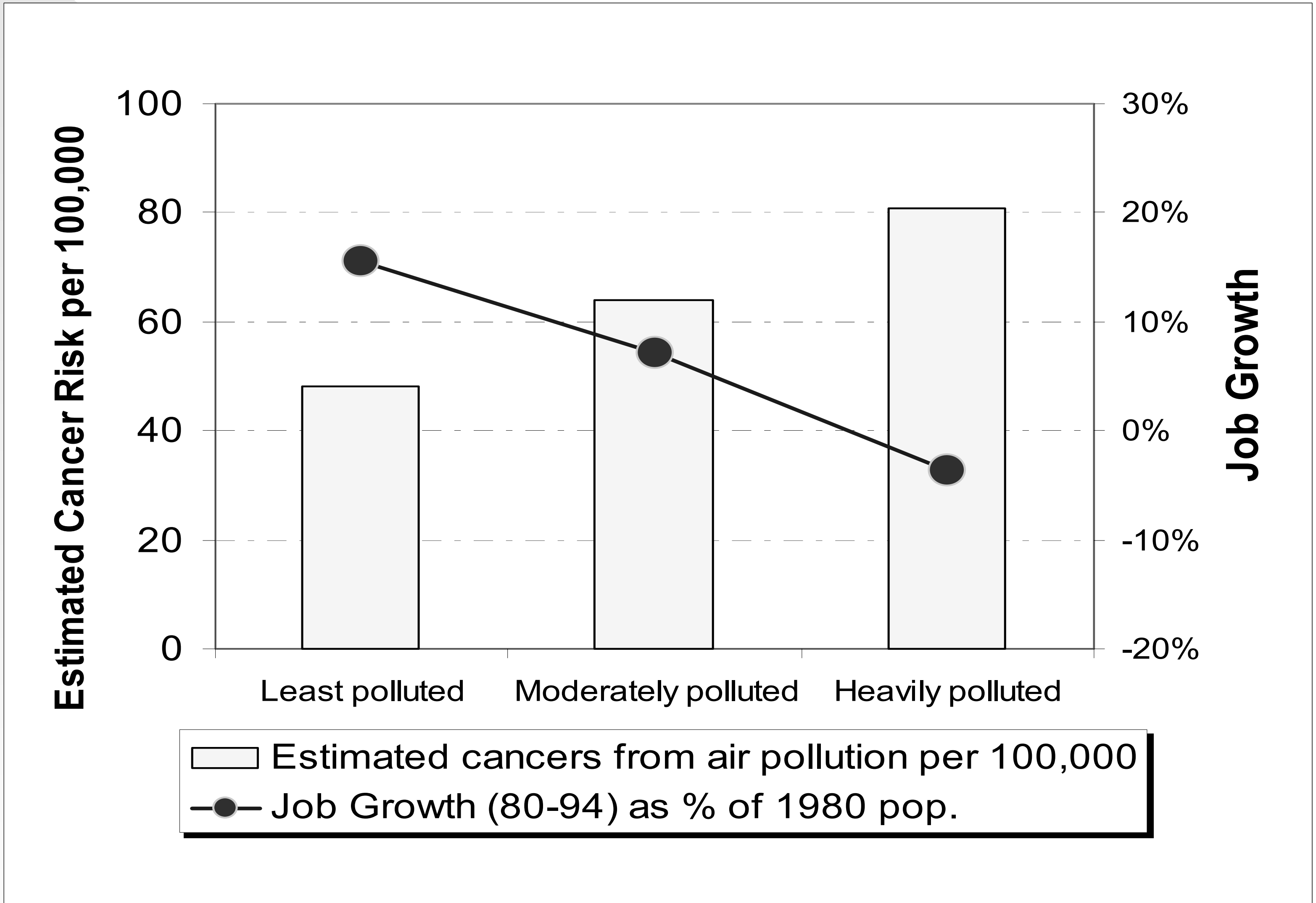
Considerations for Assessing Disparate Cumulative Impact

- Update emissions inventories and harmonize TRI estimates with state inventory estimates
- Results of local monitoring studies, such as Barrio Logan study, can be used to incorporate previously excluded emissions sources into emissions inventory.
  - Better emissions inventories will improve concentration estimates, exposure assessments and health risk assessments

Considerations for Assessing Disparate Cumulative Impact

- CARB EJ policies move in right direction
  - Challenge is developing tools for decision-making
- Air toxics modeling information needs a comparative analysis to examine potential disparities in risk burdens across demographic groups.
  - Demographic disparities should be analyzed at the neighborhood and regional levels
- Criteria pollutants:
  - Develop aggregate index of long-term exposures to examine locational differences in community exposures.
- Cross-media approaches could examine water, hazardous waste sites, risk of lead contamination and other indicators of cumulative impact
- Cal-EPA can play a leadership role in coordinating strategies to analyze cumulative impact across media.

Economics Versus Environmental Health: Is There a Trade-off in Los Angeles County?



Environmental Justice and Regional Inequality in Southern California: Implications for Future Research

Rachel Morello-Frosch,[1] Manuel Pastor Jr.,[2] Carlos Porras,[3] and James Sadd[4]

[1]College of Health and Human Services, San Francisco State University, Sat Francisco, California, USA; [2]Center for Justice, Tolerance and Community, University of California, Santa Cruz, California, USA; [3]Communities for a Better Environment, Huntington Park, California, USA; [4]Environmental Sciences, Occidental College, Los Angeles, California, USA

Environmental justice offers researchers new insights into the juncture of social inequality and public health and provides a framework for policy discussions on the impact of discrimination on the environmental health of diverse communities in the United States. Yet, causally linking the presence of potentially hazardous facilities or environmental pollution with adverse health effects is difficult, particularly in situations in which diverse populations are exposed to complex chemical mixtures. A community–academic research collaborative in southern California sought to address some of these methodological challenges by conducting environmental justice research that makes use of recent advances in air emissions inventories and air exposure modeling data. Results from several of our studies indicate that communities of color bear a disproportionate burden in the location of treatment, storage, and disposal facilities and Toxic Release Inventory facilities. Longitudinal analysis further suggests that facility siting in communities of color, not market-based "minority move-in," accounts for these disparities. The collaborative also investigated the health risk implications of outdoor air toxics exposures from mobile and stationary sources and found that race plays an explanatory role in predicting cancer risk distributions among populations in the region, even after controlling for other socioeconomic and demographic indicators. Although it is unclear whether study results from southern California can be meaningfully generalized to other regions in the United States, they do have implications for approaching future research in the realm of environmental justice. The authors propose a political economy and social inequality framework to guide future research that could better elucidate the origins of environmental inequality and reasons for its persistence. ***Key words*****: air toxics; cancer; environmental justice; risk; social inequality; treatment, storage, and disposal facilities.** ***Environ Health Perspect*** **110(suppl 2):149–154 (2002).**

http://ehpnet1.niehs.nih.gov/docs/2002/suppl-2/149-154morello-frosch/abstract.html

Environmental justice, with its emphasis on public health, social inequality, and environmental degradation, provides a framework for public policy debates about the impact of discrimination on the environmental health of diverse communities in the United States. Indeed, activists, academics, and some decision makers argue that biases within environmental policy making and the regulatory process, combined with discriminatory market forces, result in disproportionate exposures to hazardous pollution among the poor and communities of color. The environmental justice framework also raises the challenging question of whether disparities in exposures to environmental hazards may play an important, yet poorly understood, role in the complex and persistent patterns of disparate health status among the poor and people of color in the United States (*1–13*).

In seeking to redress disparities in exposures to toxics, communities organizing for environmental justice offer environmental health researchers new insights into the junctures of social inequality and public health on one hand, and the political and economic forces that lead to environmental inequality on the other. Emerging research on the broad question of environmental justice attempts to elucidate how socioeconomic and institutional forces create "riskscapes" in which overlapping pollution plumes, emitted by various sources into our air, soil, food, and water, pose a range of health risks to diverse communities, all of which in turn determine inequalities in community susceptibility to environmental hazards. The environmental justice movement has also sparked contentious debates among researchers, policy makers, activists, and industry as to whether environmental discrimination actually exists and why, or whether it is simply the result of other structural forces (*14–24*). These debates have fueled a surge of academic and scientific inquiry into the question of environmental inequality in the United States over the last two decades.

Research on race and class differences in exposures to toxics varies widely, ranging from anecdotal and descriptive studies to rigorous statistical modeling that quantifies the extent to which race and/or class explain disparities in environmental hazards among diverse communities. Although by no means unequivocal, much of the evidence points to a pattern of disproportionate exposures to toxics and associated health risks among communities of color and the poor, with racial differences sometimes persisting across economic strata (*25,26*).

Nevertheless, causally linking the presence of environmental pollution with potentially adverse health effects is an ongoing challenge in the environmental health field, particularly in situations in which populations are chronically exposed to complex chemical mixtures (*3*). With few exceptions, researchers examining environmental inequalities have limited their inquiries to evaluating differences in the location of pollution sources between population groups, while placing less emphasis on evaluating the distribution of exposures or, more important, potential health risks. Of special concern has been the need to move beyond chemical-by-chemical or facility-by-facility analysis toward a cumulative exposure approach that accounts for the exposure realities of diverse populations and incorporates concepts of race and class into assessments of community susceptibility to environmental pollutants (*27*).

We review the evolution of a 3-year environmental justice research initiative in southern California carried out through an academic and community-based collaborative. Our methodological approach entails a regional focus, starting with the premise of previous environmental research that examines the racial distribution of facility siting. We then expand upon this locational approach to look at issues more closely related to health, such as outdoor concentrations of air toxics and associated cancer risks, and then to answer the complex question of temporal trends.

This article is part of the monograph *Advancing Environmental Justice through Community-Based Participatory Research.*

Address correspondence to R. Morello-Frosch, Brown University, Box 1943, 135 Angell St., Providence, RI 02912 USA. Telephone: (401) 863-3449. Fax: (401) 863-3503. E-mail: rachel_morello-frosch@brown.edu

The authors thank the California Endowment, Liberty Hill Foundation, Occidental College, and the University of California, Santa Cruz, for providing the funding and logistical support for this research. Work on this project was also supported by the National Science Foundation and San Francisco State University research starter grant. All views in this article are those of the authors and do not necessarily reflect the perspectives of the sponsoring organizations.

Received 13 August 2001; accepted 6 February 2002.

Implications of the study results in southern California for policy making and developing a framework for future research are discussed in the conclusion.

Creating a Regional Collaborative for Environmental Health and Justice

In 1998, the authors, along with other community partners in southern California, formed an academic–community partnership to address environmental justice issues facing people of color and low-income communities in the Los Angeles Air Basin. (The lead author joined this community-academic collaborative in 1999.) In addition to training, organizing, and policy advocacy, a significant component of this collaborative supported research that would elucidate potential patterns of disproportionate exposures to environmental hazards among diverse communities in the region. Within the collaborative, potential research topics could be proposed by any partner—community or academic—and priorities and project development were decided in a way that was relevant to community organizing and environmental policy making. Although community partners had the most significant influence in the development of the collaborative research agenda, they prioritized basic environmental health research and risk assessment to address some of the persistent methodological challenges in the field of environmental justice research. We have worked toward this goal by making use of advances in air emissions inventories, such as the Toxic Release Inventory (TRI) and ambient air exposure modeling data (*28–30*). Until recently, there has been a paucity of research in which such environmental health and exposure information have been disaggregated by race and socioeconomic status (*31*).

We chose to focus our research efforts on southern California for several reasons: First, the region has a unique regulatory history in terms of its ongoing struggle to solve some of the worst air pollution problems in the country while still promoting economic growth. Second, southern California already comprises a majority of people of color and is rapidly becoming a bellwether of demographic and socioeconomic change for the state as well as the nation. Third, a regional focus in environmental justice research is crucial because industrial clusters, transportation planning, and economic development decisions are often regionally rooted. Thus, the equity question is how the social and environmental health effects of such industries are distributed within the regions that host them. Fourth, minority and low-income communities in the region have become increasingly concerned about whether they bear a disproportionate burden of exposures to air pollution and their associated environmental health risks. Thus, our collaborative is connected to community-based strategies for achieving environmental justice and rooted in a region where organizing on various environmental health issues is already happening. This also makes the results of our research directly relevant to ongoing policy efforts of the South Coast Air Quality Management District to address environmental inequality and to a new state legislative mandate, a law that directs California's Office of Planning and Research to coordinate the state's environmental justice initiatives with the federal government and across state agencies, including the California Environmental Protection Agency (*32*). Finally, the relevance of our work extends beyond southern California; understanding the patterns in this region may inform studies and policies elsewhere as local, state, and federal policy makers are compelled to consider the equity concerns of diverse communities impacted by environmental health risks from hazardous exposures.

In our research we sought to develop various indicators for assessing environmental inequalities: location of potentially hazardous stationary pollution sources such as TRI facilities and treatment, storage, and disposal facilities (TSDFs), and estimated cancer risks associated with outdoor air toxics exposures. We also sought to use the regulatory tools of risk assessment in a comparative framework to answer scientific and policy questions about what ambient concentrations of certain pollutants might in fact mean for distributions of potential health risks among diverse communities. In short, we wanted to address the ultimate question: Is there environmental inequality in southern California, and if so, who bears the burden? Our application of traditional regulatory risk assessment in a comparative framework provides a useful policy tool, particularly in situations in which epidemiologic data are not available and yet where time-sensitive decisions about disparate impact must be made, such as the judicial and administrative examination of Title VI complaints (42 U.S.C. §§ 2000d to 2000d-7) (*33–34*).

Evolution of Research Methodology and Results

Locational Studies

Following the lead of early watershed studies on environmental inequality (*25,35–37*), our first two studies in southern California examined the location of TSDFs in Los Angeles and TRI facilities in the entire region. The first study examining TSDFs found significant demographic differences between tracts with TSDFs versus tracts without (*38*). Those tracts hosting a TSDF or located within a 1-mile radius of a TSDF had significantly higher percentages of residents of color (particularly Latinos), lower per capita and household incomes, and a lower proportion of registered voters. Logistic regression results (Table 1) indicate that communities most impacted by TSDF location in Los Angeles County are working-class communities of color located in predominantly industrial areas. Following previous research (*38–40*), we found that the relationship between income and TSDF location is curvilinear, following an inverted U-shaped curve in which extremely poor tracts have fewer facilities because of less economic and industrial activity, whereas wealthier residents tend to live in tracts with fewer TSDFs, most likely because of their political power to resist pollution-generating activities. This result remained consistent even when the percentages of African American and Latino residents were evaluated as separate groupings (not shown).

Table 1. Logistic regression results for associaton between TSDF location and race/ethnicity, economic, and land use variables.

Independent variable	Parameter estimate (*t*-statistic)
Residents of color (%)	0.03 (6.32)***
Population density	0.00 (0.15)
Employment in manufacturing (%)	0.02 (2.22)**
Per capita income	0.03 (2.59)***
(Per capita income)^2	–0.00 (–2.45)***
Industrial land use (%)	0.03 (7.30)**

n = 1,636 tracts. R^2 = 0.17. ***p < 0.01. **p < 0.05.

Our second locational study broadened its regional scope by including the South Coast Air Quality Management District (which includes Ventura, Los Angeles, Orange, San Bernardino, and Riverside counties) and examining the distribution of facilities required to report air emissions to the TRI of the U.S. Environmental Protection Agency (U.S. EPA) (*40*). The study distinguished between all TRI facilities and those facilities releasing pollutants classified by the U.S. EPA as high priority for reduction and therefore included in the agency's 33/50 program. (The 33/50 program was designed to target 17 priority chemicals, most of them carcinogens, and set as its goal a 33% reduction in releases and transfers of these chemicals by 1992 and a 50% reduction by 1995 [using a 1988 baseline].) Study results indicated that compared with Anglo residents, Latinos have twice the likelihood of living in a tract with a TRI facility with 33/50 releases, followed closely by African Americans. Logistic regression

Table 2. Logistic regression results for associaton between TRI location and race/ethnicity, economic, and land use variables.

variable	Parameter estimate (*t*-statistic)	Independent
Residents of color (%)		0.01 (5.34)***
Population density		–0.00 (0.12)
Employment in manufacturing (%)		0.10 (15.1)***
Per capita income		0.03 (3.50)***
(Per capita income)^2		–0.00 (–3.91)***
Industrial land use (%)		0.05 (10.7)**

n = 2,567 tracts. R^2 = 0.17. ***p < 0.01; **p < 0.05.

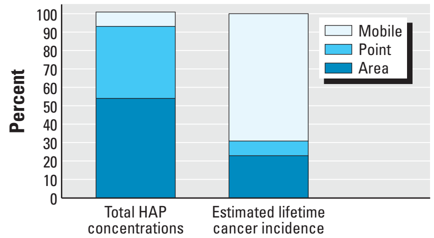


Figure 1. Emission source contributions to air toxics concentrations and estimated lifetime cancer incidence in the South Coast Air Basin. Mobile sources include onroad and offroad vehicles, area sources include small manufacturing and nonmanufacturing facilities, and point sources include large manufacturing facilities such as TRI sources.

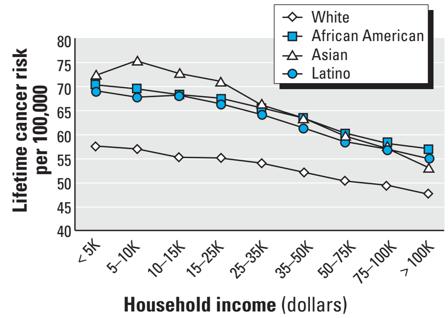


Figure 2. Estimated lifetime cancer risks from ambient air toxics exposures by race, ethnicity and income (South Coast Air Basin).

controlling for income, industrial land use, and population density found that the proportion of minority residents was significantly associated with proximity to a TRI facility (Table 2). A similar curvilinear relationship with income was also observed in this locational study.

Disparities in Outdoor Air Pollution Exposures and Estimated Cancer Risks

Although our preliminary studies focused on the location of potentially hazardous facilities, we sought to quantitatively assess the implications of outdoor air pollution exposures for potential disparities in estimated individual lifetime cancer risks among diverse communities (*27*). Making use of a recent modeling analysis undertaken by the U.S. EPA's Cumulative Exposure Project (*30,41–43*), our study combined estimated long-term annual average outdoor concentrations of 148 air toxics, or hazardous air pollutants (HAPs), listed under the 1990 Clean Air Act Amendments (*44*). We combined these data with demographic and land use information from the 1990 U.S. Census and the southern California Association of Governments. Our study examined a broader scope of air pollutants than previous environmental justice studies, incorporating outdoor HAP concentrations originating from mobile sources (e.g., cars), as well as pollutants from industrial manufacturing facilities, municipal waste combustors, small service industries, and other area emitters. By combining modeled concentration estimates with cancer toxicity information, we derived estimates of lifetime cancer risks and analyzed their distribution among populations in the region.

Estimated lifetime cancer risks associated with outdoor air toxics exposures in the South Coast Air Basin were found to be ubiquitously high, often exceeding the Clean Air Act Goal of one in one million by between one and three orders of magnitude. [In 1990, Congress established a health-based goal for the Clean Air Act: to reduce lifetime cancer risks from major sources of hazardous air pollutants to one in one million. The Act required that over time, U.S. EPA regulations for major sources should "provide an ample margin of safety to protect public health" (*45*).] Figure 1 presents source contributions to total air toxics concentrations and total estimated excess lifetime cancer incidence with the effects of background concentrations removed. Background concentrations are attributable to long-range transport, resuspension of historical emissions, and natural sources derived from measurements taken at clean air locations remote from known emissions sources (*30*).

Interestingly, area and point emissions account for over 90% of total estimated HAP concentrations, but mobile sources are the largest driver of estimated excess cancer incidence, accounting for 70% of the estimated excess cancer incidence associated with outdoor HAP concentrations from these three source categories. This difference is consistent with another exposure study conducted recently in southern California (*46*) and underscores the importance of distinguishing between exposures versus health risks when assessing emission source contributions to pollution problems. Although, on average, point sources do not appear to contribute substantially to modeled concentrations and predicted cancer risks, there are several tracts in the South Coast Basin where point source contributions to both concentration and risk estimates are dominant.

Figure 2 shows how the racial/ethnic disparities in estimated cancer risks persist across household income strata. The *y*-axis shows a population-weighted individual excess cancer risk estimate for each racial and economic category and the *x*-axis displays nine annual household income categories ranging from less than $5,000 to more than $100,000. As indicated in the figure legend, each line in the graph represents one of four racial/ethnic groups that include Anglos, African Americans, Asians, and Latinos. Asians, African Americans, and Latinos have the highest population cancer risk estimates, with risks nearly 50% higher than that for for Anglos. Although risk levels tend to decline for all groups as household income increases, the gap between residents of color and Anglos is fairly consistent across income strata. These preliminary results are likely to be influenced by demographic differences in where population groups reside. Whereas African Americans, Latinos, and Asians are concentrated mainly in the urban core where pollution levels and risks tend to be higher, Anglos are more dispersed, with significant numbers living in less-urban areas where risks are lower. Table 3 presents the multivariate regression models of the association between lifetime cancer risk and race/ethnicity, land use, and economic variables, including the percentage of home ownership, the percentage of industrial, commercial, and transportation land use, median housing value, median household income, and median household income squared. Model 1 uses the percentage of residents of color and model 2 shows a breakdown of the racial/ethnic groups. Multivariate regression results indicate that even after controlling for well-known causes of pollution such as population density, income, land use, and a proxy for assets (home ownership) (*47*), race was consistently shown to be positively associated with higher cancer risks. Note that median household income is entered as a quadratic variable. The curvilinear relationship between income and lifetime cancer risk is consistent with the locational studies, following the inverted U-shaped curve in which extremely poor tracts may have lower cancer risks due to low levels of economic and industrial activities, whereas wealthier residents tend to live in tracts with lower cancer risk levels.

Demographic Transition and the Siting of Environmental Hazards

Although these studies suggest that environmental hazards disparately impact communities of color in southern California, the cross-sectional nature of these results precludes the possibility of assessing the causal sequence of facility siting, that is, whether facilities were sited in communities of color or whether minority residents moved into neighborhoods after facility siting decreased property values and neighborhood desirability. Our subsequent study sought to examine this siting versus minority-move-in hypothesis, which entailed compiling longitudinal data on the siting and location of TSDFs from 1970 to 1990 (*23*). Preliminary results indicate that the proportion of minority residents living within a 1-mile radius of a TSDF increased from 9% in 1970 to over 20% in 1990, whereas the increase for White residents was less, from 5% to nearly 8%. Tracts receiving TSDFs between 1960 and 1990 had a higher proportion of residents of color, were poorer and more blue-collar, had lower initial home values and rents, and had significantly fewer homeowners. Moreover, multivariate analysis showed that there was little evidence of so-called minority move-in into areas where TSDFs had been previously sited.

Finally, we sought to examine whether neighborhoods that had undergone drastic demographic transitions in their ethnic and racial composition were more vulnerable to TSDF siting, possibly due to weak social and political networks that could undermine a community's capacity to influence siting decisions. A tract-level variable of ethnic churning was constructed to measure this phenomenon by taking the absolute sum of racial demographic change between 1970 and 1990. Figure 3 maps this ethnic-churning variable in Los Angeles overlaid onto the siting of TSDFs during the 1970s and 1980s. The apparent visual correlation between high demographic transition and TSDF siting was tested with simultaneous modeling using a two-stage least-squares regression. Results revealed that this type of demographic transition significantly predicted the siting of a TSDF even after controlling for economic and other demographic indicators (not shown). Thus, in historically or uniformly ethnic areas, siting seems less likely to occur than in locations where the proportion of residents of color is high but split and changing between African American and Latino groups.

Table 3. Regression results on associaton between cancer risks associated with air toxics and race/ethnicity, economic, and land use variables.

Independent variable	Model 1[a] parameter estimate (*t*-statistic)	Model 2[b] parameter estimate (*t*-statistic)
Residents of color (%)	0.17 (7.03)***	
Population density	0.18 (22.92)***	0.18 (22.67)***
Home ownership (%)	–0.02 (–0.46)	–0.02 (–0.56)
Median housing value	0.09 (5.08)***	0.08 (4.56)***
Median household income	0.26 (4.67)***	0.22 (4.10)***
(Median household income)^2	–0.0007 (–5.48)***	–0.0007 (–4.85)***
Transportation land use (%)	0.53 (6.19)***	0.53 (6.24)***
Industrial land use%	0.27 (5.57)***	0.28 (5.71)***
Commercial land use (%)	0.30 (6.34)***	0.29 (6.05)***
African American (%)		0.17 (5.40)***
Latino (%)		0.13 (4.79)***
Asian (%)		0.28 (5.75)***

***$p < 0.01$. [a]n = 2,495 tracts; R^2 = 0.41; F statistic = 188.3. [b]n = 2,495 tracts; R^2 = 0.41; F statistic = 155.4.

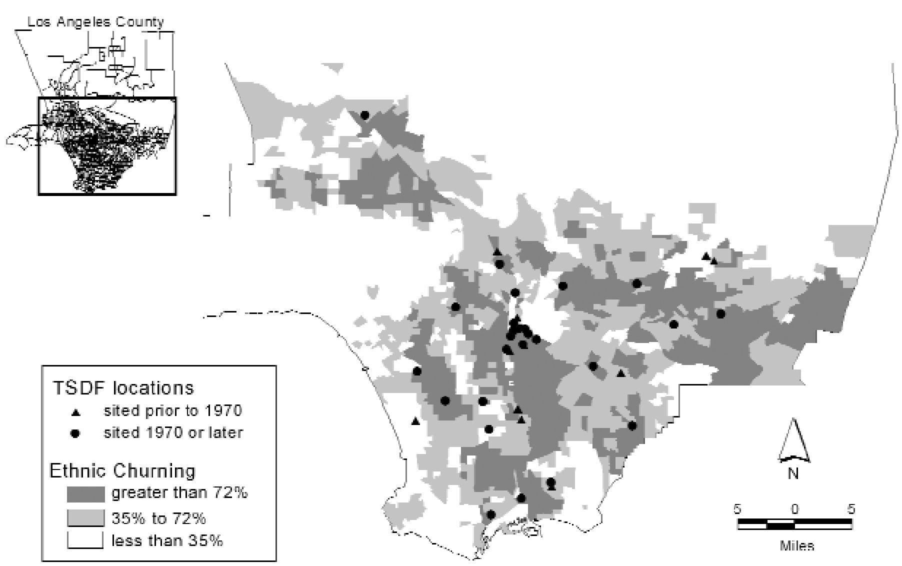


Figure 3. High capacity hazardous waste TSDFs and ethnic churning, 1970–1990, southern Los Angeles County, California. Data from 1970, 1980, and 1990 Census. Each category contains one-third of all Los Angeles County census tracts.

Policy Implications of Research Results

Our studies examining environmental inequality in southern California have consistently revealed a disproportionate burden borne by communities of color, particularly African Americans and Latinos, in the location of TRI and TSD facilities and lifetime cancer risks associated with outdoor air toxics exposures (*27,38,40*). A longitudinal study further suggests that the disproportionate location of TSD facilities in Los Angeles County has been the result of the siting of facilities predominantly in communities of color and not simply a market-induced move-in of poor residents of color to lower-rent areas already affected by environmental hazards (*23*). Moreover, communities undergoing rapid demographic transition seem more vulnerable to the placement of TSDFs. This measurement of ethnic churning merits further inquiry, as it may be a crude indicator of a community's capacity to mobilize social networks and politically resist or influence siting decisions.

Although three of our studies were locational, focusing on the siting of potentially hazardous facilities, we were also able to examine the health risk implications of outdoor air toxics exposures attributable to mobile and nonmobile sources. These latter results suggest that air toxics concentrations and their associated health risks originate mostly from smaller area and mobile sources, raising new challenges for policy makers and environmental justice advocates alike in terms of developing regulatory and pollution prevention strategies for these emission sources. Unlike large industrial and waste facilities that traditionally have been the focus of organizing, research, and regulatory attention, mobile and area sources are smaller, more widely dispersed, and diverse in terms of their emissions and production characteristics, making a uniform regulatory approach and community organizing strategy more difficult. Regulatory oversight of small manufacturing and service operations has been minimal because these facilities tend to be the most difficult to control from a technological perspective compared with large point sources that have been the focus of command and control efforts. Indeed, dispersed, small-scale production often turns industry into a moving target, as smaller firms avoid community scrutiny and regulatory responsibility for the social costs and environmental health impacts of production. Small factories are often undercapitalized, short-term operations that do not have the technology or know-how to safely produce, store, and transport toxic inputs and wastes (*48*). Finally, the proliferation of mobile sources may be eroding the previous gains made from stricter emissions standards. Thus, future emissions reduction efforts must better address mobile and area sources with a particular emphasis on how regional economic development, changing land use patterns, suburbanization, and the development of major transportation corridors impact pollution streams and the distribution of health risks among communities of color and the poor.

Equally important, these study results reinforce the need to take a more holistic approach to environmental equity research. As better data become available, future studies should move away from locational and pollutant-by-pollutant analysis and toward a cumulative exposure approach (across pollutants and emission sources) that better answers the question of what disparities in exposure mean for potential inequities in health risks. Of course, the use of risk assessment, even within an equity analysis framework, remains controversial among the public and policy makers alike (*49,50*). We sought to improve the use of risk assessment by using it comparatively to assess the distribution of cancer risk due to outdoor air toxic exposures among diverse communities.

Conclusion: A Framework for Future Research

Although risk assessment and statistical analysis can show how inequities in environmental health risks are spread among diverse communities, they shed little light on their origins or the reasons for their persistence. These larger questions necessarily lead us in a new direction in our research to address two overarching issues: *a*) using a social inequality framework (based on race, class and income) to facilitate the integration of knowledge from the fields of economics and sociology in a way that enables researchers to better understand the complex dynamics of environmental inequality (*51,52*); and *b*) examining the political and economic forces that lead to environmental inequality, which requires consideration of how institutional discrimination (such as occupational and residential segregation) interacts with larger structural forces, including disparities in patterns of economic and regional development. Figure 4 proposes such a social inequality framework that could be used to develop future research questions. Patterns of social inequality, segregation, and lack of social capital [such as social networks, cohesion, and a community's ability to mobilize politically (*53–55*)] impact a community's capacity to influence or resist environmental policy-making and regulatory enforcement activities (*56*). Similarly, social inequality diminishes a community's ability to shape regional and economic development activities in systematic ways that would benefit (or at minimum not harm) its residents (*57*). The interaction of these institutional and structural processes ultimately places additional environmental stress on communities of color through the placement of potentially hazardous facilities, transportation corridors, and pollutant exposures through various media. Ultimately, the adverse effects of these intersecting processes can be assessed through specific public health outcomes.

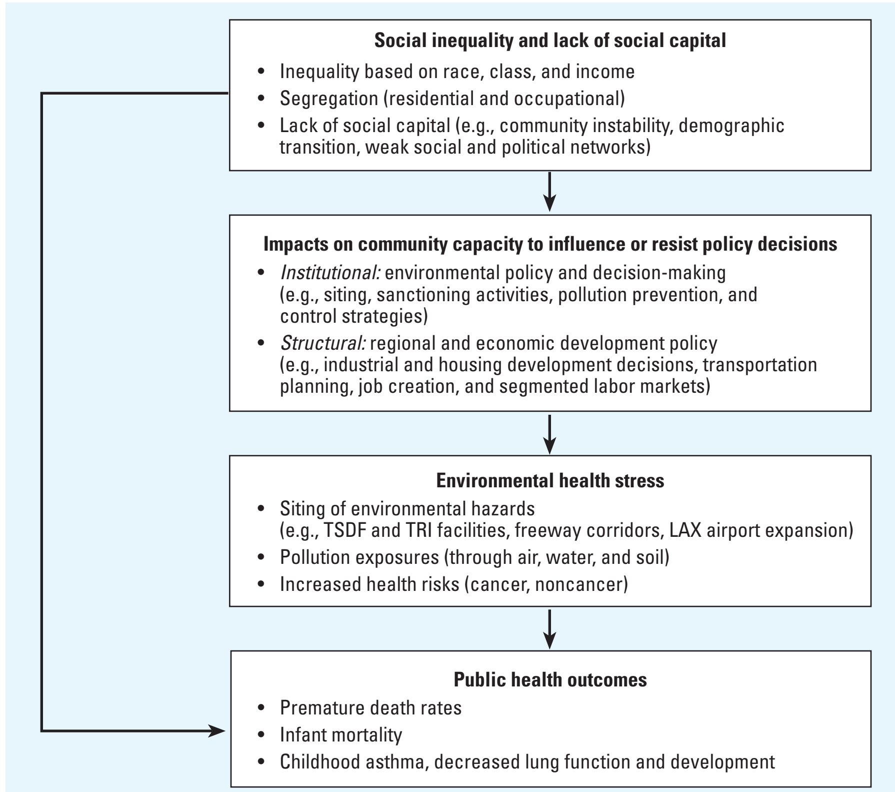


Figure 4. Political economy of environmental inequality.

Research examining the socioeconomic factors that create environmental inequalities can move policy discussions on environmental justice beyond simply tinkering with the regulatory process and toward addressing how social inequalities and discrimination directly and indirectly impact the environmental health of communities of color and the poor. Preliminary research in this area suggests that disparities in political power and residential segregation affect not only the net costs and benefits of environmentally degrading activities but also the overall magnitude of environmental degradation (e.g., air pollution) and health risks (e.g., individual estimated lifetime cancer risk) (*52,58*). Community participation is key to developing long-term regulatory, enforcement, and regional development initiatives that are politically and economically sustainable and that protect public health. The challenge for policy makers and researchers alike is to reorient future inquiry to examine how indicators of inequality and political empowerment can promote environmental protection and environmental justice for everyone.

References and Notes

1. Haan MN. Socio-Economic Position and Health: a Review. Berkeley, CA:California State Department of Public Health, 1985.
2. Haan M, Kaplan G, Camacho T. Poverty and health: prospective evidence from the Alameda County study. Am J Epidemiol 125:989–998 (1987).
3. Institute of Medicine. Toward Environmental Justice: Research, Education, and Health Policy Needs. Washington, DC:Institute of Medicine, 1999.
4. Lazarus RJ. Pursuing 'environmental justice': the distributional effects of environmental protection. Northwest U Law Rev 87:787–845 (1993).
5. Navarro V. Race or class versus race and class: mortality

differentials in the United States. Lancet 226:1238–1240 (1990).
6. Robinson JC. Racial inequality and the probability of occupational-related injury or illness. Milbank Q 62:567–590 (1984).
7. Robinson JC. Trends in racial inequality and exposure to work-related hazards. Milbank Q 65:404–419 (1987).
8. Syme S, Berkman L. Social class, susceptibility and sickness. Am J Epidemiol 104:1–8 (1976).
9. DHHS. Age-adjusted Death Rates for Selected Causes of Death, According to Sex and Race: United States, Selected Years, 1950-87. Washington, DC:U.S. Department of Health and Human Services, 1990.
10. Kubzansky L, Berkman L, Glass T, Seeman T. Is educational attainment associated with shared determinants of health in the elderly? Findings from the MacArthur Studies of Successful Aging. Psychosom Med 60:578–585 (1998).
11. Krieger N, Rowley D, Herman A, Avery B, Phillips M. Racism, sexism, and social class: implications for studies of health, disease, and well-being. Am J Prev Med 9:82–122 (1993).
12. Kawachi I, Marmot M. Commentary: what can we learn from studies of occupational class and cardiovascular disease? Am J Epidemiol 148:160–163 (1998).
13. Ecob R, Davey Smith G. Income and health: what is the nature of the relationship? Soc Sci Med 48:693–705 (1999).
14. Anderson G. Human Exposure to Atmospheric Concentrations of Selected Chemicals, Vol 1. NTIS PB84-102540. Research Triangle Park, NC:U.S. Environmental Protection Agency, 1983.
15. Anderton DL, Anderson AB, Oakes JM, Fraser MR. Environmental equity: the demographics of dumping. Demography 31:229–248 (1994).
16. Anderton DL, Anderson AB, Rossi RH, Oakes JM, Fraser MR, Weber EW, Calabrese EJ. Hazardous waste facilities: environmental equity issues in metropolitan areas. Eval Rev 18:123–140 (1994).
17. Been V. Unpopular neighbors: are dumps and landfills sited equitably? Resources Spring:16–19 (1994).
18. Bullard R. Confronting Environmental Racism: Voices from the Grassroots. Boston:South End Press, 1993.
19. Bullard R. Unequal Protection: Environmental Justice and Communities of Color. San Francisco:Sierra Club Books, 1994.
20. Pulido L. A critical review of the methodology of environmental racism research. Antipode 28:142–159 (1996).
21. Bowen WM, Salling MJ, Haynes KE, Cyran EJ. Toward environmental justice: spatial equity in Ohio and Cleveland. Ann Assoc Am Geog 85:641–663 (1995).
22. Bowen WM. Comments on 'Every Breath You Take...': The demographics of toxic air releases in Southern California. Econ Dev Q 13:124–134 (1999).
23. Pastor M, Sadd J, Hipp J. Which came first? Toxic facilities, minority move-in, and environmental justice. J Urban Aff 23:1–21 (2001).
24. Foreman C. The Promise and Peril of Environmental Justice. Washington, DC:Brookings Institution, 1998.
25. Mohai P, Bryant B. Environmental racism: reviewing the evidence. In: Race and the Incidence of Environmental Hazards: A Time for Discourse (Bryant B, Mohai P, eds). Boulder, CO:Westview, 1992;164–175.
26. Szasz A, Meuser M. Environmental inequalities: Literature review and proposals for new directions in research and theory. Curr Sociol 45:99–120 (1997).
27. Morello-Frosch R, Pastor M, Sadd J. Environmental justice and southern California's 'riskscape': the distribution of air toxics exposures and health risks among diverse communities. Urban Aff Rev 36:551–578 (2001).
28. U.S. EPA. Toxic Release Inventory 1987-1990. CD-ROM. Washington, DC:U.S. Environmental Protection Agency, 1991.
29. Rosenbaum A, Ligocki M, Wei Y. Modeling Cumulative Outdoor Concentrations of Hazardous Air Pollutants. Revised Final Report. San Rafael, CA:Systems Applications International, Inc., 1999. Available: *http://www.epa.gov/CumulativeExposure/resource/resource.htm* [accessed 12 May 2000].
30. Rosenbaum A, Axelrad DA, Woodruff TJ, Wei Y, Ligocki MP, Cohen JP. National estimates of outdoor air toxics concentrations. J Air Waste Manage Assoc 49:1138–1152 (1999).
31. U.S. EPA. Environmental Equity: Reducing Risk for all Communities. Washington, DC:U.S. Environmental Protection Agency, 1992.
32. California Senate Bill 115. Environmental Justice 1999. Government Code § 6504.12 and Public Resource Code §§ 7200-7201.
33. Civil Rights Act of 1964. Title VII. 42 U.S.C. §§ 2000d to 2000d7.
34. U.S. EPA. Interim Guidance for Investigating Title VI Complaints Challenging Permits. Available: *http://es.epa.gov/oeca/oej/titlevi.pdf* [accessed 23 June 2001]. Washington, DC:U.S. Environmental Protection Agency.
35. GAO. Siting of Hazardous Waste Landfills and Their Correlation with Racial and Economic Status of Surrounding Communities. Gaithersburg, MD:U.S. General Accounting Office, 1983.
36. United Church of Christ. A National Report on the Racial and Socio-Economic Characteristics of Communities with Hazardous Waste Sites. New York:United Church of Christ, 1987.
37. Bullard R. Solid waste sites and the black community. Sociol Inq 53:273–288 (1983).
38. Boer TJ, Pastor M, Sadd JL, Snyder LD. Is there environmental racism? The demographics of hazardous waste in Los Angeles County. Soc Sci Q 78:793–810 (1997).
39. Been V. Analyzing evidence of environmental justice. J Land Use Environ Law 11:1–37 (1995).
40. Sadd JL, Pastor M, Boer T, Snyder LD. 'Every breath you take...': The demographics of toxic air releases in Southern California. Econ Dev Q 13:107–123 (1999).
41. Caldwell JC, Woodruff TJ, Morello-Frosch R, Axelrad DA. Application of health information to hazardous air pollutants modeled in EPA's Cumulative Exposure Project. Toxicol Ind Health 14:429–454 (1998).
42. Woodruff TJ, Axelrad DA, Caldwell J, Morello-Frosch R, Rosenbaum A. Public health implications of 1990 air toxics concentrations across the United States. Environ Health Perspect 106:245–251 (1998).
43. Morello-Frosch RA, Woodruff TJ, Axelrad DA, Caldwell JC. Air toxics and health risks in California: the public health implications of outdoor concentrations. Risk Anal 20:273–291 (2000).
44. Clean Air Act Amendments of 1990. § 112 Hazardous Air Pollutants.
45. Clean Air Act Amendents of 1990. § 112(f) Standard to Protect Health and the Environment.
46. SCAQMD. Multiple Air Toxics Exposure Study in the South Coast Air Basin— MATES-II. Diamond Bar, CA: South Coast Air Quality Management District, 1999.
47. Krieger N, Fee E. Social class: the missing link in US health data. Int J Health Serv 24:25–44 (1994).
48. Mazurek J. Making Microchips: Policy, Globalization and Economic Restructuring in the Semiconductor Industry. Cambridge, MA:MIT Press, 1999.
49. Kuehn RR. The environmental justice implications of quantitative risk assessment. Univ Illinois Law Rev 1996:103–172 (1996).
50. Latin H. Good science, bad regulation, and toxic risk assessment. Yale J Reg 5:89–148 (1988).
51. Muntaner C, Lynch J, Davey Smith G. Social capital and the third way in public health. Crit Public Health 10:107–124 (2000).
52. Boyce J, Klemer A, Templet P, Willis C. Power distribution, the environment, and public health: a state-level analysis. Ecol Econ 29:127–140 (1999).
53. Massey D. Spatial Divisions of Labor: Social Structures and the Geography of Production. New York:Methuen, 1984.
54. Massey D, Denton N. American Apartheid: Segregation and the Making of the Underclass. Cambridge, MA:Harvard University Press, 1993.
55. Massey D, Gross A. Migration, segregation, and the geographic concentration of poverty. Am Sociol Rev 59:425–445 (1994).
56. Hill R. Separate and unequal: governmental inequality in the metropolis. Am Pol Sci Rev 68:1557–1568 (1974).
57. Pulido L, Sidawi S, Vos R. An archeology of environmental racism in Los Angeles. Urban Geogr 17:419–439 (1996).
58. Morello-Frosch RA. Environmental Justice and California's "Riskscape": The Distribution of Air Toxics and Associated Cancer and Non-Cancer Health Risks Among Diverse Communities [PhD Thesis]. Berkeley CA:University of California, Berkeley, 1997.

Workshop Overview & Framework for Cumulative Risk Assessment

ORD/Regional Cumulative Risk Assessment Workshop

November 4, 2002

Workshop Overview

- Framework for Cumulative RA
- Planning, Scoping, Community Issues
- Approaches to Cumulative RA
- Risk Characterization (Putting it Together)
- Long Term Impacts of Cumulative RA?
- Research Recommendations

Framework Document

- What is it?
- History
- Features
- State of the Science
- Future plans

1. Framework vs. Guidelines

- Framework: General description of the topic. An **information document** laying out scope of the subject and how various parts fit together. (This document)
- Guidelines: Description of how it's done, including **boundaries** (e.g., limits of "good science") not to be exceeded. (Several years away)

Impacts vs. Risks

- **Impacts – harm or adverse effects**
- **Risks – *Probability* of harm or adverse impacts**

Framework Definitions

- **Cumulative Risk:** The combined risks from aggregate [multi-pathway, multi-source, multi-route, over time] exposures to multiple agents or stressors.
- **Cumulative risk assessment:** An analysis, characterization, and possible quantification of the combined risks to health or the environment from multiple agents or stressors.

Key Definition Points

- Multiple stressors or chemicals
- Combined risks
- Can be qualitative

Goal of Cumulative RA

- Using the commonly accepted definition of risk as "probability of harm", the goal of a cumulative risk assessment is:
  - To address and hopefully answer questions related to the probability of harm, to human health or the environment, from multiple stressors acting together.

When do we do a CRA?

- Cumulative risk assessment is a tool
- It is not appropriate for every task
- Cumulative risk assessments will be most useful in situations where questions need to be addressed concerning the impacts of multiple stressors acting together
- Currently, there are methods limitations

2. History

- Planning & Scoping memo 1997
- Framework started 1999
- 3 external peer involvement meetings 2001
- 2 consultations with EPA's Science Advisory Board 2000, 2001
- External peer review June, 2002
- Plan to publish Framework this year

Types of Issues

- Process issues: Extent of public participation, organization of Framework, etc.
- Technical/scientific issues: Feasibility of certain components, etc.
- Policy issues: Requirements, etc.

Cumulative Risk Assessment

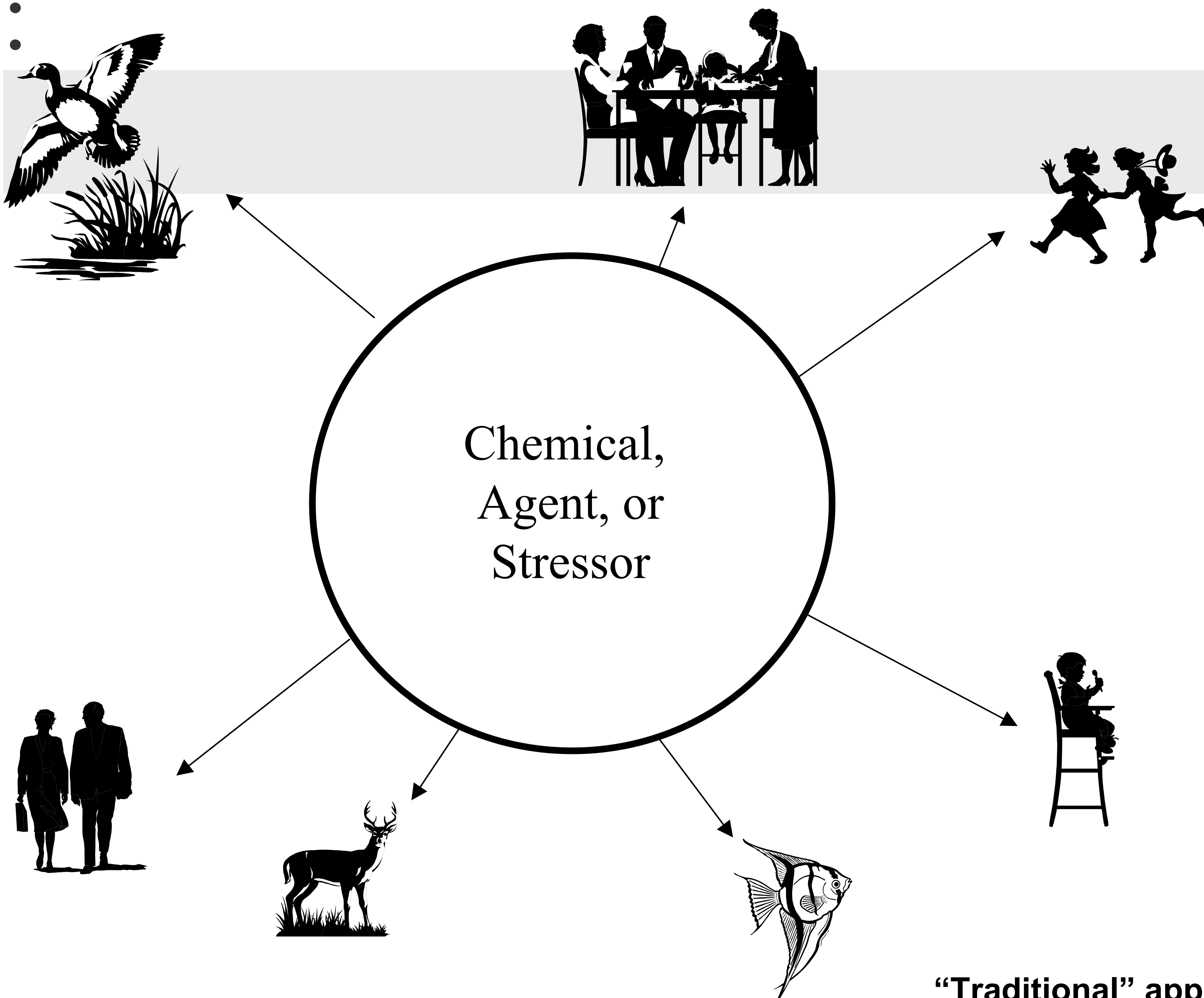
- “Traditional” Risk Assessment:
  - Where we’ve been
- Cumulative Risk Assessment (CRA):
  - Why change?

Some Policy Issues

- Interpreting the definition
- Value added (where/when done?)
- What Agency priority?
- Dealing with Stakeholder fairness
- Defining “acceptable risk”
- Types of stressors/risks included
- Legal issues

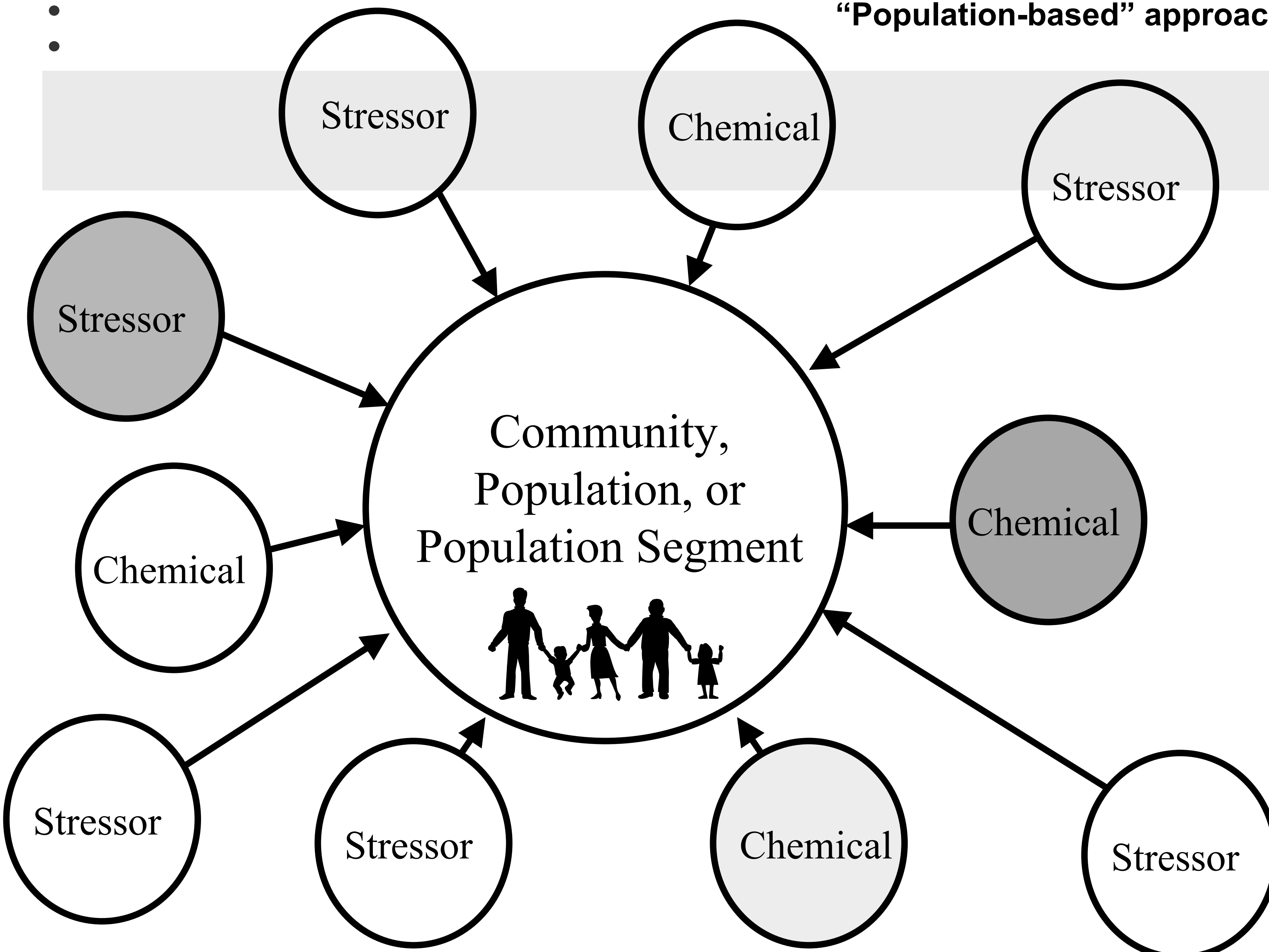
3. Features

- Multiple chemical/stressor
- Non-chemical stressors
- Population focus
- Stakeholder emphasis
- Vulnerability
- Human Health and Ecology
    - May have to assess parts together



“Traditional” approach

“Population-based” approach



3. Features

- Multiple chemical/stressor
- Non-chemical stressors
- Population focus
- Stakeholder emphasis
- Vulnerability
- Human Health and Ecology
    - May have to assess parts together

Vulnerability

- Susceptibility/Sensitivity
- Differential exposure
- Differential preparedness
- Differential ability to recover

- Question: How do these factors change risk?

3. Features

- Multiple chemical/stressor
- Non-chemical stressors
- Population focus
- Stakeholder emphasis
- Vulnerability
- Human Health and Ecology
  - May have to assess parts together

4. State of the Science

- What do we know about…
  - Adding risks across stressors?
  - Synergism & other interactions?
  - Vulnerability?
  - Non-chemical stressors?
  - Methods to do these assessments?
  - How all these factors change risk?

Combining Different Risks I

- Can (or even *should*) different types of risk be combined?
- Common metric approach
  - Must have "common denominator"

Common Denominators

- Combination toxicology/Combining risk
- Risk factor approach
- Biomarkers or biomonitoring
- Quality Adjusted Life Years (QALYs), Disability Adjusted Life Years (DALYs), Loss of Life Expectancy (LLEs) and other quasi-economic measures

Combining Different Risks II

- Index Approach
  - Keep different risks separate
  - Profiles
- Other: Probability of “Something Bad Happening”

Uncertainty

- Few good examples of uncertainty analysis for Cumulative Risk Assessments
- New GIS-based technology poses new challenges in uncertainty analysis
- What type of analysis would be useful to a decision-maker?

5. Future Plans

- Workshop Report/Research Recommendations to ORD
- Framework published late 2002/early 2003
- Case studies developed 2002-2003
- Issue papers on specific topics 2003
- Work with National Environmental Justice Advisory Committee on Spring 2004 meeting
- Guidelines development *starts* 2003-4

Letters to the Editor

The Bogus 'Precautionary Principle'

Biotechnology, or gene-splicing, applied to agriculture and food production faces more subtle obstacles than those discussed in your Feb. 21 editorial "No Green Peace." These are mainly related to the so-called "precautionary principle," which might be stated, in the Journal's words, as "for fear that something evil may possibly arise, do nothing." and which is being widely applied to biotechnology.

This principle (which is not one at all) focuses on the possibility that technologies could pose unique, extreme or unmanageable risks. What is missing is an acknowledgment that even when they introduce new risks, many technologies confer net benefits--that is, their use reduces many other, far more serious hazards. Consider the environmental movement's misguided crusade to rid society of all chlorinated compounds. By the late 1980s, activists were attempting to convince water authorities around the world of the possibility that carcinogenic byproducts of chlorination made drinking water a potential cancer risk. Peruvian officials caught in a budget crisis used this supposed threat as a justification to stop chlorinating much of their country's drinking water. That decision contributed to the acceleration appropriate spread of Latin America's 1991-96 cholera epidemic, which afflicted more than 1.3 million people and killed at least 11,000.

As it is being applied by the European Union and others to biotechnology, the pre cautionary principle provides no apparent evidentiary standards for "safety," and no procedural criteria for obtaining regulatory approval, no matter how much evidence has been accumulated- The precautionary principle allows overcautious, in competent, corrupt or politically' motivated regulators to require any amount and kind of testing they wish, arbitrarily withholding or deferring approvals indefinitely.

Dozens of scientific bodies have analyzed tile oversight appropriate for gene-spliced organisms with remarkable congruence in their conclusions: The newer molecular techniques for genetic improvement are an extension, or refinement, of earlier, far less precise ones; adding genes to plants does not make them less safe either to the environment or to eat; the risks associated with gene-spliced organisms are the same in kind as those associated with conventionally modified organisms; and regulation should be based upon the risk-related characteristics of' individual products, regardless of the techniques used in their development.

Nevertheless, most domestic and inter national regulators treat gene-spliced plants and micro-organisms in a discriminatory fashion, with the fact and degree of regulation determined solely by the production methods. For example, gene-spliced herbicide-tolerant crop plants such as soybeans and canola are subject to lengthy, hugely expensive mandatory testing and pre-market evaluation, while plants with virtually identical properties but developed with older, less precise genetic techniques are exempt from such requirements.

The application of the precautionary principle has. resulted in unscientific, discriminatory policies that inflate the costs of research, inhibit the development of new products, waste resources and re strict consumer choice. Other technologies are susceptible to a similar fate: European regulators are working feverishly to incorporate the bogus precautionary principle into various international health and safety standards and, most ominously. even into the World Trade Organization's rules.

Stanford, Calif.
HENRY I. MILLER

Hoover Institution

The Perils Of Precaution

Why Regulators' "Precautionary Principle"

Is Doing More Harm Than Good

By HENRY I. MILLER AND

GREGORY CONKO

ENVIRONMENTAL AND PUBLIC HEALTH activists have clashed with scholars and risk-analysis professionals for decades over the appropriate regulation of various risks, including those from consumer products and manufacturing processes. Underlying the controversies about various specific issues – such as chlorinated water, pesticides, gene-spliced foods, and hormones in beef – has been a fundamental, almost philosophical question: How should regulators, acting as society's surrogate, approach risk in the absence of certainty about the likelihood or magnitude of potential harm?

Proponents of a more risk-averse approach have advocated a "precautionary principle" to reduce risks and make our lives safer. There is no widely accepted definition of the principle, but in its most common formulation, governments should implement regulatory measures to prevent or restrict actions that raise even conjectural threats of harm to human health or the environment, even though there may be incomplete scientific evidence as to the potential significance of these dangers. Use of the precautionary principle is sometimes represented as "erring on the side of safety," or "better safe than sorry" – the idea being that the failure to regulate risky activities sufficiently could result in severe harm to human health or the environment, and

Henry I. Miller, M.D. (miller@hoover.stanford.edu) is a fellow at the Hoover Institution and the author of Policy Controversy in Biotechnology: An Insider's View. *Gregory Conko (conko@cei.org) is director of food safety policy at the Competitive Enterprise Institute.*

that "overregulation" causes little or no harm. Brandishing the precaution ary principle, environmental groups have prevailed upon governments in recent decades to assail the chemical industry and, more recently, the food industry.

Potential risks should, of course, be taken into consideration before pro ceeding with any new activity or product, whether it is the siring of a power plant or the introduction of a new drug into the pharmacy. But the precautionary principle focuses solely on the *possibility* that technologies could pose unique, extreme, or unmanageable risks, even after considerable testing has already been conducted. What is missing from precautionary calculus is an acknowledgment that even when technologies introduce new risks, most confer net benefits – that is, their use reduces many other, often far more serious, hazards. Examples include blood transfusions, MRJ scans, and auto mobile air bags, all of which offer immense benefits and only minimal risk.

Several subjective factors can cloud thinking about risks and influence how nonexperts view them. Studies of risk perception have shown that people tend to overestimate risks that are unfamiliar, hard to understand, invisible, involuntary, and/or potentially catastrophic – and vice versa. Thus, they overestimate invisible "threats" such as electromagnetic radiation and trace amounts of pesticides in foods, which inspire uncertainty and fear sometimes verging on superstition. Conversely, they tend to underestimate risks the nature of which they consider to be clear and comprehensible, such as using a chain saw or riding a motorcycle.

These distorted perceptions complicate the regulation of risk, for if democracy must eventually take public opinion into account, good government must also discount heuristic errors or prejudices. Edmund Burke emphasized government's pivotal role in making such judgments: "Your Representative owes you, not only his industry, but his judgment; *and* he betrays, instead of serving you, if he sacrifices it to your opinion." Government leaders should *lead;* or putting it another way, government officials should make decisions that are rational and in the public interest even if they are unpopular at the time. This is especially true if, as is the case for most federal and state regulators, they are granted what amounts to lifetime job tenure in order to shield them from political manipulation or retaliation. Yet in too many cases, the precautionary principle has led regulators to abandon the careful balancing of risks *and* benefits – that is, to make decisions, in the name of precaution, that cost real lives due to forgone benefits.

The danger of precaution

DANGER IN the precautionary principle is that it distracts consumers and policymakers from known, significant threats to human health and diverts limited public health resources from those genuine and far greater risks. Consider, for example, the environmental movement's campaign to rid society of chlorinated compounds. By the late 1980s, environmental activists were attempting to convince water authorities around the world of the possibility that carcinogenic byproducts from chlorination of drinking water posed a potential cancer risk. Peruvian officials, caught in a budget crisis, used this supposed threat to public health as a justification to stop chlorinating much of the country's drinking water. That decision contributed to the acceleration and spread of Latin America's 1991-96 cholera epidemic, which afflicted more than 1.3 million people and killed at least 11,000.

Activists have since extended their antichlorine campaign to so-called "endocrine disrupters," or modulators, asserting that certain primarily man-made chemicals mimic or interfere with human hormones (especially estrogens) in the body and thereby cause a range of abnormalities and diseases related to the endocrine system.

A chemical administered at high doses may cause cancer in certain animals but not in humans.

The American Council on Science and Health has explored the endocrine disrupter hypothesis and found that while *high* doses of certain environmental contaminants produce toxic effects in laboratory test animals – in some cases involving the endocrine system – humans' actual exposure to these suspected endocrine modulators is many orders of magnitude lower. It is well documented that while a chemical administered at high doses may cause cancer in certain laboratory animals, it does not necessarily cause cancer in humans – both because of different susceptibilities and because humans are subjected to far lower exposures to synthetic environmental chemicals.

No consistent, convincing association has been demonstrated between real-world exposures to synthetic chemicals in the environment and increased cancer in hormonally sensitive human tissues, Moreover, humans are routinely exposed through their diet to many estrogenic substances (substances having an effect similar to that of the human hormone estrogen) found in many plants. Dietary exposures to these plant estrogens, or phytoestrogens, are far greater than exposures to supposed synthetic endocrine modulators, and no adverse health effects have been associated with the overwhelming majority of these dietary exposures.

Furthermore, there is currently a trend toward *lower* concentrations of many contaminants in air, water, and soil – including several that are suspected of being endocrine disrupters. Some of the key research findings that stimulated the endocrine disrupter hypothesis originally have been retracted or are not reproducible. The available human epidemiological data do not show any consistent, convincing evidence of negative health effects related to industrial chemicals that are suspected of disrupting the endocrine system.

In spite of that, activists and many government regulators continue to invoke the need for precautionary (over-) regulation of various products, and even outright bans.

Antichiorine campaigners more recently have turned their attacks to phthalates, liquid organic compounds added to certain plastics to make them softer. These soft plastics are used for important medical devices, particularly fluid containers, blood bags, tubing, and gloves; children's toys such as teething rings and rattles; and household and industrial items such as wire coating and flooring. Waving the banner of the precautionary principle, activists claim that phthalates *might* have numerous adverse health effects – even in the face of significant scientific evidence to the contrary. Governments have taken these unsupported claims seriously, and several for mal and informal bans have been implemented around the world. As a result, consumers have been denied product choices, and doctors and their patients deprived of life-saving tools.

In addition to the loss of beneficial products, there are more indirect and subtle perils of government overregulation established in the name of the precautionary principle. Money spent on implementing and complying with regulation (justified or not) exerts an "income effect" that reflects the correlation between wealth and health, an issue popularized by the late political scientist Aaron Wildavsky. It is no coincidence, he argued, that richer societies have lower mortality rates than poorer ones. To deprive communities of wealth, therefore, is to enhance their risks.

Wildavsky's argument is correct: Wealthier individuals are able to purchase better health care, enjoy more nutritious diets, and lead generally less stressful lives. Conversely, the deprivation of income itself has adverse health effects – for example an increased incidence of stress-related problems including ulcers, hypertension, heart attacks, depression, and suicides.

It is difficult to quantify precisely the relationship between mortality and the deprivation of income, but academic studies suggest, as a conservative estimate, that every *$7.25* million of regulatory costs will induce one additional fatality through this "income effect." The excess costs in the tens of billions of dollars required annually by precautionary regulation for various
• classes of consumer products would, therefore, be expected to cause thou sands of deaths per year. These are the real costs of "erring on the side of safety." The expression "regulatory overkill" is not merely a figure of speech.

Rationalizing precaution

DURING THE PAST few years, skeptics have begun more actively to question the theory and practice of the precautionary principle. In response to those challenges, the European Commission (Ec), a prominent advocate of the precautionary principle, last year published a formal communication to clarity and to promote the legitimacy the concept. The EC resolved that, under its auspices, precautionary restrictions would be "proportional to the chosen level of protection," "non-discriminatory in their application," and "consistent with other similar measures." The commission also avowed that EC decision makers would care fully weigh "potential benefits and costs." EC Health Commissioner David Byrne, repeating these points last year in an article on food and agriculture regulation in *European Affairs,* asked rhetorically, "How could a Commissioner for Health and Consumer Protection reject or ignore well-founded, independent scientific advice in relation to food safety?"

Byrne should answer his own question: The ongoing dispute between his European Commission and the United States and Canada over restrictions on hormone-treated beef cattle is exactly such a case of rejecting or ignoring well-founded research. The EC argued that the precautionary principle permits restriction of imports of U.S. and Canadian beef from cattle treated with certain growth hormones.

In their rulings, a WTO dispute resolution panel and its appellate board both acknowledged that the general "look before you leap" sense of the pre cautionary principle could be found within WTO agreements, but that its presence did not relieve the European Commission of its obligation to base policy on the outcome of a scientific risk assessment. And the risk assessment clearly favored the U.S.-Canadian position. A scientific committee assembled by the WTO dispute resolution panel found that even the scientific studies cited by the EC in its own defense did not indicate a safety risk when the hormones in question were used in accordance with accepted animal husbandry practices. Thus, the WTO ruled in favor of the United States and Canada because the European Commission had failed to demonstrate a real or imminent harm. Nevertheless, the EC continues to enforce restrictions on hormone-treated beef, a blatantly unscientific and protectionist policy that belies the commission's insistence that the precautionary principle will not be abused.

Precaution meets biotech

PERHAPS THE MOST egregious application by the European Commission of the precautionary principle is in its regulation of the products of the new biotechnology, or gene-splicing. By the early 1990s, many of the countries in Western Europe, as well as the EC itself, had erected strict rules regarding the testing and commercialization of gene-spliced crop plants. In 1999, the European Commission explicitly invoked the precautionary principle in establishing a moratorium on the approval of all new gene-spliced crop varieties, pending approval of an even more strict EU-wide regulation.

Notwithstanding the EC'S promises that the precautionary principle would not be abused, all of the stipulations enumerated by the commission have been flagrantly ignored or tortured in its regulatory approach to gene-spliced (or in their argot, "genetically modified" or GM foods. Rules for gene-spliced plants and microorganisms are inconsistent, discriminatory, and bear no proportionality to risk. In fact, there is arguably *inverse* proportionality to risk, in that the more crudely crafted organisms of the old days of mutagenesis and gene transfers are subject to less stringent regulation than those organisms more precisely crafted by biotech. This amounts to a violation of a cardinal principle of regulation: that the degree of regulatory scrutiny should be commensurate with risk.

Dozens of scientific bodies – including the U.S. National Academy of Sciences (NAS), the American Medical Association, the UK'S Royal Society, and the World Health Organization – have analyzed the oversight that is appropriate for gene-spliced organisms and arrived at remarkably congruent conclusions: The newer molecular techniques for genetic improvement are an extension, or refinement, of earlier, far less precise ones; adding genes to plants or microorganisms does not make them less safe either to the environment or to eat; the risks associated with gene-spliced organisms are the same in kind as those associated with conventionally modified organisms and unmodified ones; and regulation should be based upon the risk-related characteristics of individual products, regardless of the techniques used in their development.

An authoritative 1989 analysis of the modern gene-splicing techniques published by the NAS'S research arm, the National Research Council, concluded that "the same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods," but it went on to observe that gene-splicing is more precise, circumscribed, and predictable than other techniques.

> [Gene-splicing] methodology makes **it** possible to introduce pieces **of** DNA, consisting of either single **or** multiple genes that can be defined **in** function and even in nucleotide sequence. With classical techniques of gene transfer, a variable number of genes can be transferred, the **number** depending on the mechanism of transfer; but predicting the precise number or the traits that have been transferred is difficult, and we cannot always predict the [characteristics] that will result. With organisms modified by molecular methods, we are in a better, if not perfect, position to predict the [characteristics].

In other words, gene-splicing technology is a refinement of older, less precise techniques, and its use generates less uncertainty. But for gene-spliced plants, both the fact and degree of regulation are determined by the production methods – that is, if gene-splicing techniques have been used, the plant is. immediately subject to extraordinary pre-market testing requirements for human health and environmental safety, regardless of the level of risk posed. Throughout most of the world, gene-spliced crop plants such as insect-resis-tant corn and cotton are subject to a lengthy and hugely expensive process of mandatory testing before they can be brought to market, while plants with similar properties but developed with older, less precise genetic techniques are exempt from such requirements.

Dozens of new plant varieties produced through hybridization and other traditional methods of genetic improvement enter the marketplace each year without any scientific review or special labeling. Many such products are from "wide crosses," hybridizations in which large numbers of genes are moved from one species or one genus to another to create a plant variety that does not and cannot exist in nature. For example, *Triticum agropy rotriticum* is a relatively new man-made "species" which resulted from combining genes from bread wheat and a grass some

times called quackgrass or couchgrass. Possessing all the chromosomes of wheat and one extra whole genome from the quackgrass, *T agropyrotriticum* has been independently produced in the former Soviet Union, Canada, the United States, France, Germany, and China. It is grown for both animal feed and human consumption.

Gene-splicing technology is a refinement of older, less precise techniques, and its use generates less uncertainty.

At least in theory, several kinds of problems could result from such a genetic construction, one that introduces tens of thousands of foreign genes into an established plant variety. These include the potential for increased invasiveness of the plant in the field, and the possibility that quackgrass-derived proteins could be toxic or allergenic. But regulators have evinced no concern about these possibilities. Instead, they have concentrated on the **use of** gene-splicing techniques as such – the very techniques that scientists agree have improved precision and predictability.

Another striking example of the disproportionate regulatory burden borne only by gene-spliced plants involves a process called induced-mutation breeding, which has been in common use since the 1950s. This technique involves exposing crop plants to ionizing radiation or toxic chemicals to induce random genetic mutations. These treatments most often kill the plants (or seeds) or cause detrimental genetic changes, but on rare occasions, the result is a desirable mutation – for example, one producing a new trait in the plant that is agronomically useful, such as altered height, more seeds, or larger fruit. In these cases, breeders have no real knowledge of the exact nature of the genetic mutation(s) that produced the useful trait, or of what other mutations might have occurred in the plant. Yet the approximately 1,400 mutation-bred plant varieties from a range of different species that have been marketed over the past half century have been subject to no for mal regulation before reaching the market – even though several, including two varieties of squash and one of potato, have contained dangerous levels of endogenous toxins and had to be banned afterward.

What does this regulatory inconsistency mean in practice? If a student doing a school biology project takes a packet of "conventional" tomato or pea seeds to be irradiated at the local hospital x-ray suite and plants them in his backyard in order to investigate interesting mutants, he need not seek approval from any local, national, or international authority. However, if the seeds have been modified by the addition of one or a few genes via gene-splicing techniques – and even if the genetic change is merely to remove a gene — this would-be Mendel faces a mountain of bureaucratic paperwork and expense (to say nothing of the very real possibility of vandalism, since the site of the experiment must be publicized and some opponents of biotech are believers in "direct action"). The same would apply, of course, to professional agricultural scientists in industry and academia. In the United States, Department of Agriculture requirements for paper work and field trial design make field trials with gene-spliced organisms 10 to 20 times more expensive than the same experiments with virtually identical organisms that have been modified with conventional genetic techniques.

Regulators of gene-spliced products, seldom take into consideration the' potential risk-reducing benefits of the technology.

Why are new genetic constructions crafted with these older techniques exempt from regulation, from the dirt to the dinner plate? Why don't regulatory regimes require that new genetic variants made with older techniques he evaluated for increased weediness or invasiveness, or for new allergens that could show up in food? The answer is based on millennia of experience with genetically improved crop plants from the era before gene-splicing: Even the use of relatively crude and unpredictable genetic techniques for the improvement of crops and microorganisms poses minimal — but, as noted above, not zero risk to human health and the environment.

If the proponents of the precautionary principle were applying it rationally and fairly, surely greater precaution would be appropriate not to gene-splicing but to the cruder, less precise, less predictable "conventional" forms 'of genetic modification. Furthermore, in spite of the assurance of the European Commission and other advocates of the precautionary principle, regulators of gene-spliced products seldom take into consideration the potential risk-reducing benefits of the technology. For example, some of the most successful of the gene-spliced crops, especially cotton and corn, have been constructed by splicing in a bacterial gene that produces a protein toxic to predatory insects, but not to people or other mammals. Not only do these gene-spliced corn varieties repel pests, but grain obtained from them is less likely to contain Fusarium, a toxic fungus often carried into the plants by the, insects. That, in turn, significantly reduces the levels of the fungal toxin fumonisin, which is known to cause fatal diseases in horses and swine that eat infected corn, and esophageal cancer in humans. When harvested, these gene-spliced varieties of grain also end up with lower concentrations of insect parts than conventional varieties. Thus, gene-spliced corn is not only cheaper to produce but yields a higher quality product and is a potential boon to public health. Moreover, by reducing the need for spraying chemical pesticides on crops, it is environmentally friendly.

Other products, such as gene-spliced herbicide-resistant crops, have permitted farmers to reduce their herbicide use and to adopt more environment-friendly no-till farming practices. Crops now in development with improved yields would allow more food to be grown on less acreage, saving more land area for wildlife or other uses. And recently developed plant varieties with enhanced levels of vitamins, minerals, and dietary proteins could dramatically improve the health of hundreds of millions of malnourished people in developing countries. These are the kinds of tangible environmental and health benefits that invariably are given little or no weight in precautionary risk calculations.

In spite of incontrovertible benefits and greater predictability and safety of gene-spliced plants and foods, regulatory agencies have regulated them in a discriminatory, unnecessarily burdensome way. They have imposed requirements that could not possibly be met for conventionally bred crop plants. And, as the European Commission's moratorium on new product approvals demonstrates, even when that extraordinary burden of proof is met via monumental amounts of testing and evaluation, regulators frequent ly declare themselves unsatisfied.

Biased decision-making

WHILE THE EUROPEAN UNION is a prominent practitioner of ***the precautionary principle on issues ranging from toxic sub stances and the new biotechnology to climate change and gun control, U.S. regulatory agencies also commonly practice excessively precautionary regulation. The precise term of art "precautionary principle" is not used in U.S. public policy, but the regulation of such products as pharmaceuticals, food additives, gene-spliced plants and microorganisms, synthetic pesticides, and other chemicals is without question "precautionary" in nature. U.S. regulators actually appear to be more precautionary than the Europeans towards several kinds of risks, including the licensing of new medicines, lead in gasoline, nuclear power, and others. They have also been highly precautionary towards gene-splicing, although not to the extremes of their European counterparts. The main difference between precautionary regulation in the United States and the use of the precautionary principle in Europe is largely a matter of degree with reference to products, technologies, and activities and of semantics.***

In both the United States and Europe, public health and environmental regulations usually require a risk assessment to determine the extent of potential hazards and of exposure to them, followed by judgments about how to regulate. The precautionary principle can distort this process by introducing a systematic bias into decisionmaking. Regulators face an asymmetrical incentive structure in which they are compelled to address the potential harms from new products, but are free to discount the hidden risk-reducing properties of unused or underused ones. The result is a lop sided process that is inherently biased against change and therefore against innovation.

To see why, one must understand that there are two basic kinds of mistaken decisions that a regulator can make: First, a harmful product can be approved for marketing — called a Type I error in the parlance of risk analysis. Second, a useful product can be rejected or delayed, can fail to achieve approval at all, or can be inappropriately withdrawn from the market a Type II error. In other words, a regulator commits a Type I error by permitting something harmful to happen and a Type II error by preventing something beneficial from becoming available. Both situations have negative consequences for the public, but the outcomes for the regulator are very different,

Examples of this Type I-Type II error dichotomy in both the U.S. and ‘Europe abound, but it is perhaps illustrated most clearly in the FDA’S approval process for new drugs. A classic example is the FDA’S approval in 1976 of the swine flu vaccine — generally perceived as a Type I error because while the vaccine was effective at preventing influenza, it had a major side effect that was unknown at the time of approval: A small number of patients suffered temporary paralysis from Guillain-Barré Syndrome. This kind of mistake is highly visible and has immediate consequences: The media pounce and the public and Congress are roused, and Congress takes up the matter. Both the developers of the product and the regulators who allowed it to be marketed are excoriated and punished in such modern-day pillories as congressional hearings, television newsmagazines, and newspaper editorials. Because a regulatory official’s career might be damaged irreparably by his good-faith but mistaken approval of a high-profile product, decisions are often made defensively — in other words, above all to avoid Type I errors.

Former FDA Commissioner Alexander Schmidt aptly summarized the regulator’s dilemma:

> In all our FDA history, we are unable to find a single instance where a Congressional committee investigated the failure of FDA to approve a new drug. But, the times when hearings have been held to criticize our approval of a new drug have been so frequent that we have not been ‘able to count them. The message to FDA staff could not be clearer.
> - .‘ Whenever a controversy over a new drug is resolved by approval of the

/

> drug, the agency and the individuals involved likely will be investigated. Whenever such a drug is disapproved, no inquiry will be made. The Congressional pressure for *negative* action is, therefore, intense. And **it** seems to be ever increasing.

Type II errors in the form of excessive governmental requirements and unreasonable decisions can cause a new product to be "disapproved," in Schmidt's phrase, or to have its approval delayed. Unnecessary or capricious delays are anathema to innovators, and they lessen competition and inflate the ultimate price of the product. Consider the FDA'S precipitate response to the 1999 death of a patient in a University of Pennsylvania gene therapy trial for a genetic disease. The cause of the incident had not been identified and the product class (a preparation of the needed gene, encased in an enfeebled adenovirus that would then be administered to the patient) had been used in a large number of patients, with no fatalities and serious side effects in only a small percentage of patients. But given the high pro file of the incident, regulators acted disproportionately. They not only stopped the trial in which the fatality occurred and all the other gene-therapy stud ies at the same university, but also halted similar studies at other universities, as well as experiments using adenovirus being conducted by the drug com pany Schering-Plough — one for the treatment of liver cancer, the other for colorectal cancer that had metastasized to the liver. By these actions, and by publicly excoriating and humiliating the researchers involved (and halting experiments of theirs that did not even involve adenovirus), the FDA cast a pall over the entire field of gene therapy, setting it back perhaps as much as a decade.

Unnecessary or capricious delays are anathema to innovators, and they lessen competition and inflate the ultimate price of the product.

Although they can dramatically compromise public health, Type II errors caused by a regulator's bad judgment, timidity or anxiety seldom gain public attention. It may be only the employees of the company that makes the product and a few stock market analysts and investors who are knowledge able about unnecessary delays. And if the regulator's mistake precipitates a corporate decision to abandon the product, cause and effect are seldom connected in the public mind. Naturally, the companies themselves are loath to complain publicly about a mistaken FDA judgment, because the agency has so much discretionary control over their ability to test and market products. As a consequence, there may be no direct evidence *of,* or publicity about, the lost societal benefits, to say nothing of the culpability of regulatory officials.

Exceptions exist, of course. A few activists, such as the AID S advocacy groups that closely monitor the **FDA,** scrutinize agency review of certain

/

products and aggressively publicize Type II errors. In addition, congressional oversight *should* provide a check on regulators' performance, but as noted above *by* former FDA Commissioner Schmidt, only rarely does oversight focus on their Type II errors. Type I errors make for more dramatic hearings, after all, including injured patients and their family members. And even when such mistakes are exposed, regulators frequently defend Type II errors as erring on the side of caution — in effect, invoking the precautionary principle — as they did in the wake of the University of Pennsylvania gene therapy case. Too often this euphemism is accepted uncritically by legislators, the media, and the public, and our system of pharmaceutical oversight becomes progressively less responsive to the public interest.

The **FDA is** not unique in this regard, of course. All regulatory agencies are subject to the same sorts of social and political pressures that cause them to be castigated when dangerous products accidentally make it to market (even if, as is often the case, those products produce net benefits) hut to escape blame when they keep beneficial products out of the hands of consumers. Adding the precautionary principle's bias against new products into the pub lic policy mix further encourages regulators to commit Type U errors in their frenzy to avoid Type I errors. This is hardly conducive to enhancing overall public safety.

Extreme precaution

-FOR SOME ANTITECHNOLOGY activists who push the precautionary principle, the deeper issue is not really safety at all. Many are more antibusiness and antitechnology than they are pro-safety. And in their mission to oppose business interests and disparage technologies they don't like or that they have decided we just don't need, they are willing to seize any opportunity that presents itself.

These activists consistently (and intentionally) confuse *plausibility* with *provability.* Consider, for example, *Our Stolen Future,* the bible of the proponents of the endocrine disrupter hypothesis discussed above. The book's premise — that estrogen-like synthetic chemicals damage health in a number of ways — is not supported by scientific data. Much of the research offered as evidence for its arguments has been discredited. The authors equivocate wildly: "Those exposed prenatally to endocrine-disrupting chemicals *may* have abnormal hormone levels as adults, and they *could* also pass on persistent chemicals they themselves have inherited – both factors that *could* influence the development of their own children [emphasis added]." The authors also assume, in the absence of any actual evidence, that exposures to small amounts of many chemicals create a synergistic effect – that is, that total exp6sure constitutes a kind of witches' brew that is far more toxic than the sum of the parts. For these anti-innovation ideologues, the mere fact that such questions have been asked requires that inventors or producers expend

/

time and resources answering them. Meanwhile, the critics move on to yet another frightening plausibility and still more questions. No matter how outlandish the claim, the burden of proof is put on the innovator.

Whether the issue is environmental chemicals, nuclear power, or gene-spliced plants, many activists are motivated by their own parochial vision of what constitutes a "good society" and how to achieve it. One prominent biotechnology critic at the Union of Concerned Scientists rationalizes her organization's opposition to gene-splicing as follows: "Industrialized countries have few genuine needs for innovative food stuffs, regardless of the method by which they are produced"; therefore, society should not squander resources on developing them. She concludes that although "the mal nourished homeless" are, indeed, a problem, the solution lies "in resolving income disparities, and educating ourselves to make better choices from among the abundant foods that are available."

Many activists are motivated by their own parochial vision of what constitutes a "good society" and how to achieve it.

Greenpeace, one of the principal advocates of the precautionary principle, offered in its 1999 IRS filings the organization's view of the role in society of safer, more nutritious, higher-yielding, environment-friendly, gene-spliced plants: There isn't any. By its own admission, Greenpeace's goal is not the pru dent, safe use of gene-spliced foods or even their mandatory labeling, but rather these products' "complete elimination [from] the food supply and the environment." Many of the groups, such as Greenpeace, do not stop at demanding illogical and stultifying regulation or outright bans on product testing and commercialization; they advocate and carry out vandalism of the very field trials intended to answer questions about environmental safety.

Such tortured logic and arrogance illustrate that the metastasis of the pre cautionary principle generally, as well as the pseudocontroversies over the testing and use of gene-spliced organisms in particular, stem from a social vision that is not just strongly antitechnology, but one that poses serious challenges to academic, commercial, and individual freedom.

The precautionary principle shifts decision making power away from individuals and into the hands of government bureaucrats and environmental activists. Indeed, that is one of its attractions for many NGO5. Carolyn Raffensperger, executive director of the Science and Environmental Health Network, a consortium of radical groups, asserts that discretion to apply the precautionary principle "is in the hands of the people." According to her, this devolution of power is illustrated by violent demonstrations against eco nomic globalization such as those in Seattle at the 1999 meeting of the World Trade Organization. "This is [about] how they want to live their lives," Raffensperger said.

/

To ‘be more precise, it is about how small numbers of vocal activists want the rest of us to live *our* lives. In other words, the issue here is freedom and its infringement by ideologues who disapprove, on principle, of a certain technology, or product, or economic system.

The theme underlying the antitechnology activism of today is not new. It resonates well with historian Richard Hofsradter’s classic analysis half a cen tury ago of religious and political movements in American public policy, *The Paranoid Style in American Politics.* Hofstadter summarized the religious and political activists’ paranoia this way: “The central image is that of a vast and sinister conspiracy, a gigantic and yet subtle machinery of influence set in motion to undermine and destroy a way of life.” He goes on to note a characteristic “leap in imagination that is always made at some critical point in the recital of events.” Susanne Huttner, associate vice provost for research of the University of California system, has placed biotechnology critics squarely in Hofstadter’s sights. Viewed from Hofstadter’s model of the paranoid style, she has observed that the “conspiracy” here lies in large-scale agriculture performed with twenty-first century technology, and the “leap in imagination” lies in the assertion that biotechnology is at base bad for agriculture, farmers, and developing nations,

But can these generalizations apply to all biotechnologies? What about veterinary diagnostics and vaccines? Plants resistant to disease, insects, and drought? Grains with enhanced nutrient content? Fruits that act as vaccines and can immunize inhabitants of developing countries against lethal and hugely prevalent infectious diseases?

Precaution *v.* freedom

HISTORY OFFERS compelling reasons to be cautious about societal risks, to be sure. These include the risk of incorrectly assuming the absence of danger (false negatives), overlooking low probability but high impact events in risk assessments, the danger of long latency periods before problems become apparent, and the lack of remediation methods in the event of an adverse event. Conversely, there are compelling reasons to be wary of excessive precaution, including the risk of too eagerly detecting a nonexistent danger (false positives), the financial cost of testing for or remediating low-risk problems, the opportunity costs of forgoing net-beneficial activities, and the availability of a contingency regime in case of an adverse event. The challenge for regulators is to balance these competing risk scenarios in a way that reduces overall harm to public health. This kind of risk balancing is often conspicuously absent from precautionary regulation.

It is also important that regulators take into consideration the degree of restraint generally imposed by society on individuals’ and companies’ freedom to perform legitimate activities (e.g., scientific research). In Western

/

democratic societies, we enjoy long traditions of relatively unfettered scientific research and development, except in the very few cases where bona fide safety issues are raised. Traditionally, we shrink from permitting small, authoritarian minorities to dictate our social agenda, including what kinds of research are permissible and which technologies and products should be available in the marketplace.

Application of the precautionary principle has already elicited unscientific, discriminatory policies that inflate the costs of research, inhibit the development of new products, divert and waste resources, and restrict consumer choice. The excessive and wrong-headed regulation of the new biotechnology is one particularly egregious example. Further encroachment of precautionary regulation into other areas of domestic and international health and safety standards will create a kind of "open sesame" that government officials could invoke whenever they wish arbitrarily to introduce new barriers to trade, or simply to yield disingenuously to the demands of antitechnology activists. Those of us who both value the freedom to perform legitimate research and believe in the wisdom of market processes must not permit extremists acting in the name of "precaution" to dictate the terms of the debate.