

PRECAUTIONARY PRINCIPLE PROJECT

CLEAN WATER FUND ♦ LOWELL CENTER FOR SUSTAINABLE PRODUCTION ♦ MASSACHUSETTS
BREAST CANCER COALITION ♦ SCIENCE & ENVIRONMENTAL HEALTH NETWORK

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

- Wingspread Conference on Implementing the Precautionary Principle, January 1998

Risk Assessment & Risk Management

Introduction

The purpose of this brief is to inform and educate the layperson about risk assessment as it is currently practiced, and what it purports to achieve. Government agencies develop risk assessments as part of the decision-making process relating to public health and the environment. An understanding of its components and their bases will enable citizens to undertake critical analyses of risk assessment, and understand its current misuse, as well as the dangers of today’s risk management policies. Commonly, risk assessments are used to justify hazardous practices.

The goal of the Massachusetts Precautionary Principle Project is to redesign public policy on environmental hazards to follow the Precautionary Principle. A precautionary approach uses science to avoid or minimize dangers, not to justify hazards. Scientific analysis within a Precautionary Principle approach would admit real scientific uncertainties, illuminating what is known and what is not known, and would guide a democratic public decision-making process that assesses a full range of alternatives to potentially harmful activities. At the end of this paper we offer a brief overview of the Precautionary Principle.

What is Risk Assessment?*

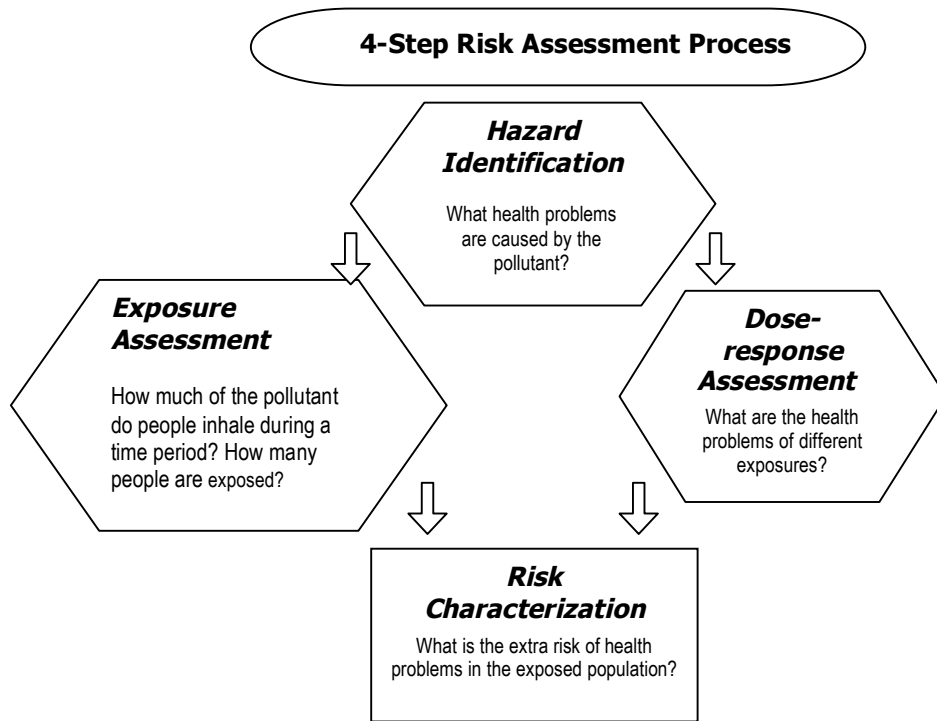
What follows is a description of the risk assessment process that is currently used by risk assessors along with a summary of common criticisms.

Risk assessment integrates the disciplines of toxicology and exposure assessment to attempt to understand and measure what types of harm humans or ecosystems might experience from exposure to a chemical or pollutant. It uses available scientific evidence as well as assumptions, mathematical modeling and policy judgements, to attempt to estimate *risk*.

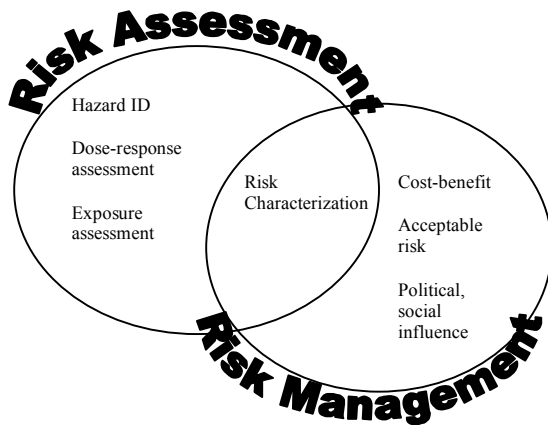
In human health terms, risk is a *measure* of the *chance* that a person or population will experience injury, disease or death (a hazard) *under certain circumstances or exposures*. It is a combination of:

- the *probability* that an undesired event (exposure to a toxic chemical) will occur, and;
- the *consequences* that occur as a result of that event (injury, disease or death).

Risk assessment attempts to measure the impact of the pollutant by going through a series of four major steps of analysis—



Theoretically, once a risk assessment is completed and an estimate of risk has been calculated (for example, 4 excess cases of cancer in 70 years expected in 1000 people living within 2 miles of an incinerator), **risk management**, the policy or regulatory response that attempts to regulate or “manage” the risk, takes over. **In reality, risk management and risk assessment are inextricably linked**, as shown by the following overlapping circles.



Policymakers make **risk management** decisions mainly to determine how to manage and reduce risks, *not* prevent them. Included in this decision-making is the subjective determination about how much risk others should bear. Without the participation in the decision-making of those who will bear the harm, and considering the high level of uncertainty of the data included in the risk assessment, this “acceptable risk” decision is often undemocratic and considered by many to be unethical. (See section on Risk Management for more details.)

Example: *In response to citizen complaints of health problems they suspect are being caused by a local incinerator, a state health department performs a risk assessment. Various health risks from specific identified pollutants are analyzed. Exposures to certain populations are estimated. A risk characterization is performed that takes into consideration some kinds of the toxicity of the pollutants and estimates the amount and duration of exposures to some of those living within 2 miles of the incinerator. The risk assessment also considers the current incinerator permit allowances and might consider costs to further reduce emissions of pollutants. Decision makers called “risk managers” then set an “acceptable” level of risk and permit emissions from the incinerator up to that level. This process does not address the inherent issue of the hazards of incineration or encourage analysis of alternative waste treatments that would prevent risk by preventing exposures to the incinerator’s emissions. It does not include those who might be harmed in the decision-making process. It does not include all types of toxicity of pollutants, all types of people exposed, or all routes of exposure.*

How Was Risk Assessment Developed?

Risk assessment was originally developed for well-defined and easily analyzed mechanical problems such as bridge construction. In the 1960s risk assessment first began to be used to estimate safety associated with exposures to carcinogens, particularly in foodstuffs. In 1983 the National Research Council published *Risk Assessment in the Federal Government: Managing the Process*, commonly known as the “Redbook.” This established the 4-step process that has become the dominant paradigm for risk assessment.

Do Risk Assessors Make Assumptions During the Process?

Yes, all during the 4 steps of the risk assessment process the risk assessor makes assumptions and judgements, from what health effects to include to what routes of exposure to consider. These judgements are sometimes scientifically founded, sometimes politically founded, and sometimes arbitrary. The choices made will alter the outcome of the risk assessment. Over 50 assumptions and other determinations are typically made during a risk assessment process. Examples of these assumptions or subjective choices include:

- the dose response model to use
- how to calculate potential impacts at low exposures
- how to model the cumulative individual exposure to one or multiple toxic substances
- how much and what a person eats, drinks
- how much a person weighs and breathes
- a person’s age and state of health
- dispersion of the pollutant
- distribution of exposures in the population
- which uncertainty/safety factors to use
- which toxicological data set is used (the doses in the experiments, the health effects or endpoints examined, etc.)
- other exposures/risks to which a person might be exposed which might intersect with the exposure, or might predispose a person to vulnerability
- uncertainties in the analysis and how they are measured

Making different assumptions leads to different conclusions by different risk assessors.

- Certain health effects such as immune system suppression may be omitted.
- If a hazard is not identified properly or completely as to its possible health effects, then the next step in the risk assessment, the dose-response assessment step (see below), may be inaccurate.
- Most of the 75,000 chemicals in commercial use have not been fully tested for toxicity, so huge information gaps exist. Some chemicals have no available toxicity data.
- The process usually does not consider additive or synergistic effects of chemicals.
- It usually looks at gross effects, and more subtle effects may be neglected.
- Both animal and human studies have various weaknesses. Our understanding of how toxicants affect the human body is an evolving process. Science is unable to predict with certainty most health outcomes.

Dose-response Assessment—What are the health problems at different exposures?

The dose-response step looks at:

- **How pollutants affect the body's normal functions** (cause chemical reactions, damage cells, redirect cell activity, disrupt hormones, etc.)
- The **association between exposure and observed response** (i.e., how different levels of exposure to the pollutant change the likelihood and severity of health effects)

The dose-response relationship varies with pollutant, individual sensitivity, and type of health effect. The EPA has previously assumed, for cancer only, that there was no "zero risk," and that any exposure created a risk of cancer. This is called a "non-threshold" model. This assumption may change based on the new proposed guidelines for cancer risk assessment that provide for a "threshold" response for certain types of cancer-causing substances that do not directly disrupt DNA.

The "threshold" model assumes that there is some level of damage from contamination that the body can repair or assimilate without causing harm. For non-cancer health effects, a threshold is generally assumed, although science shows that this assumption may be incorrect. For example, for hazards such as harm to the reproductive system or fetus, or to the nervous system, there may be no threshold. Or, for endocrine disruptors, timing of the dose (a small window during pregnancy or development) and not the dose itself (which may be tiny) may be more important.

The "threshold" response type of model may become the norm for cancer assessments involving chemicals that do not cause direct DNA damage, even though they may cause damage indirectly. There is no general agreement on which dose-response model is the correct one for different types of hazards. Some in the public health community have challenged the new EPA cancer risk assessment guidelines as not protective of children's health or the health of other vulnerable populations. They recommend that it be assumed that there is no threshold for cancer effects unless it can be proven otherwise.

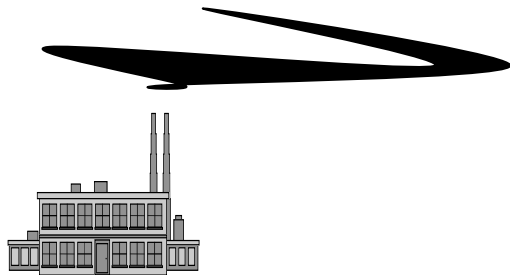
Some weaknesses of this process:

- Assumption of a non-cancer threshold effect below which no health effects occur is a matter of debate, particularly with endocrine disruptors—where a tiny exposure during a critical window of vulnerability, such as during fetal development, may exert lifelong effects.

For certain endpoints such as endocrine disruption, the dose response may actually be inverted, meaning that as more exposure occurs, risk to endocrine disruption goes down but risk of other effects, such as cancer, may go up.

- There are inherent problems in extrapolating animal data obtained in controlled laboratory conditions to humans living in complex ecosystems.
- The inherent problems with human studies that may leave out variables, may not include all those exposed, depend on memories of those affected etc.
- Cannot consider all additive or synergistic effects.
- May not consider vulnerable populations. Dose response will likely vary for the very young and very old or ill whose metabolic systems are either immature or compromised.
- Depending on the choice of dose-response model, risk assessment results could vary by as much as a million fold.

Exposure Assessment – *How much of the pollutant do people inhale, ingest or absorb in a specific time period? What is the duration of the exposure? How many people are exposed?*



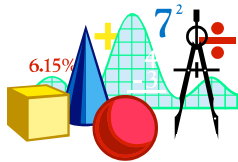
The exposure assessment addresses the environmental route(s) of exposure, and the extent of exposure. Steps include:

- Identify and locate sources of at least some of the pollutant(s) of concern.
- Estimate amount of pollutants released from the sources during a specific time period, and how they move away from the sources to the receptor.
- Estimate the number of people exposed at different distances, or even for the different places people are each day.
- Estimate the amount people inhale, absorb or ingest.

Some weaknesses of this process:

- May leave out important environmental route(s) or site(s) of exposure. For example, in a Massachusetts exposure assessment on mercury, food chain bioaccumulation was not considered, resulting in omission of the main route of exposure to humans, which is contaminated fish.
- May leave out relevant stressors (e.g., pollutants).
- May omit an important human route of intake.
- Cannot consider cumulative or aggregate exposures.
- Generally uses models instead of field testing for actual exposures.
- May not account for differences in human activities relating to personal, cultural or geographic factors.

Risk Characterization—*What is the extra risk of health problems in the exposed population?*



Risk characterization combines the results of the hazard evaluation with information about the route and extent of exposure, and also the number of persons exposed, to estimate the extent of risk to individuals, populations and to society. It describes the nature of the adverse effects and should include the strength of the evidence and uncertainties involved. The information regarding risk may be presented in different ways. They include:

--Maximum Lifetime Cancer Risk

Maximum lifetime exposure \times *Dose-response relationship* = *Maximum Individual Lifetime Risk*

Example: The maximally exposed individual faces an excess lifetime breast cancer risk of 3×10^{-4}
Or, 3 in 10,000.

--Population Cancer Risks

The expected increased incidence of cancer (number of new cases each year) for all people exposed to the pollutant.

Example: The incinerator is estimated to produce 4 excess cases of breast cancer every 70 years among the 20,000 people living within 2 miles of the facility.

--Distribution of Individual Risks

Expressed as the number of people estimated to be at various levels of risk

--Non-cancer Risks Based on Health Reference Dose (RfD)

The health reference dose (RfD) level of a toxicant is defined as “an estimate (with uncertainty spanning perhaps an order of magnitude, or 10 times) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.” Or, the human dose that EPA considers “safe” for humans.

The RfD is then compared to the amount of exposure to a substance to determine what margin of safety exists.

Some weaknesses of process:

- Risk is often expressed for a supposedly average person (usually an adult) at the average exposure level, when we know that exposures and susceptibility vary widely. Even when risk is expressed considering the individual that may be most exposed, it is difficult--if not impossible--to consider the full extent of variability in a population.
- Generally does not express who may be at higher or lower risk within the population (children, pregnant women, those with compromised immune systems, elderly).
- Ecological risk factors may not be considered.

- Considers only single risks and not the cumulative set of risks.
- It is based on a series of assumptions made in the first three steps that may be erroneous.

Scarce Resources Used for Risk Assessments

It should be noted that scarce government resources are being used to do risk assessments. Risk assessments can cost millions of dollars and many person years. This money could be used for prevention and action.

Government agencies may employ risk assessments to create defensible positions when industry challenges regulations or to defend actions before the public. However, even with these numbers in hand, government often loses in the courtroom.

Risk Management

The numerical risk estimate derived from the process of risk assessment is one of the major factors used to make governmental decisions on environmental and health hazards. The process of taking risk assessment results and arriving at a decision of action or inaction, such as permit decisions, or setting emission limits for pollutants, is called “Risk Management.” Judgements that are included in risk management include:

- **“Acceptable risk” determinations:** wherein action is taken only if the risk exceeds some numerical level. For example, it is often considered an “acceptable risk” if the activity or pollutant in question would create a risk of increased deaths of one in 100,000, or 1 in a million, people exposed to the hazard. This is an arbitrary number that the government has considered insignificant and that has not been democratically established. For workers, a risk of under 1 in 1000 for death or disease has been determined by federal regulators to be insignificant. **But is this acceptable to that worker who will die, that worker’s family, or people in a society where the individual life is valued and respected? Also, the total increased risk of all the hazards a group is exposed to is not added together and analyzed.**
- **“Cost-benefit” analyses:** where the risks reduced by taking a protective action (like imposing a stricter regulation on emissions) are equated to benefits (such as a life saved or reduced health costs). The “benefit” is then compared to the estimated “costs” of implementing the protective action (cost to the industry to install better pollution controls). Often a determination is made as to how much “cost” it is worth to save that life, usually 2 million dollars. If the cost of controls greatly exceeds the cost of the life saved regulatory actions may not be taken. Among other flaws, cost-benefit analysis fails to consider who reaps the benefits and who assumes the cost. It also perpetuates the myth that we must decide between economic growth and environmental protection. Cost benefit analysis is also heavily biased towards costs of regulation today, discounting less quantifiable costs such as health damage and benefits of prevention. Cost benefit analysis often overestimates costs of regulation. It also tries to quantify the unquantifiable, or translate the non-economic, i.e., namely pain and suffering, illness, and disease, into money. Many consider this unethical. (Contact Precautionary Principle partners listed below for a fact sheet on Cost-Benefit Analysis)

- **“Cost effectiveness” decisions:** where the minimum unit cost to reduce maximum risk is favored.
- The **political and social landscapes:** Political pressure is often a factor in risk management decisions. Citizen demands for health protection are weighed against the lobbying influence of those corporations or entities proposing a hazardous activity.

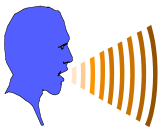
Efforts are being made to improve on the risk management process on a federal and state level so that it is more participatory, but there is a lot of distance to go before it is truly democratic. Also, the risk management process is still limited by the limits of risk assessment.

The injustices in current Risk Management decisions therefore include:

- the process is open to undue influence by those with money and vested interests
- setting a dollar figure (in cost-benefit analyses) on a human life is considered by many to be unethical and unconscionable
- it is usually an undemocratic process, as those who may be harmed are not identified and asked if the danger is acceptable to them.

Current decision-making processes must therefore be changed to meet the guidelines of the Precautionary Principle (described below).

What is Risk Communication?



Risk communication more often than not tells the public what was done for the risk assessment and what the acceptable risk is, rather than providing for an interactive process where the community helps define the research, the options, and the management. Given the complexity of most risk assessments (many scientists themselves have a hard time reading them) it is hard to involve the public in the process, and, the public usually ends up seeing only a brief summary of the risk assessment. As with risk management, efforts are underway to improve the process, but they will not fully be able to truly democratize the risk assessment process and the resulting decision-making.

Risk Assessment and the Precautionary Principle

The Precautionary Principle is based on the knowledge that that science, because of all its limitations and uncertainties, is not able to provide an accurate prediction of future hazards. The Precautionary Principle does not call for an abandonment of science. It simply requires that we:

- take action in the face of uncertainty
- place the burden of understanding impacts and acting to prevent them on the proponents of an activity, instead of potential victims

- explore alternatives to possibly harmful actions
- use democratic processes, which include decision-making by those who are most affected.

Implementing the Precautionary Principle demands that we thoroughly examine and consider alternatives to potentially harmful activities from the onset, and we seek to implement the safest alternatives. Rather than focus on acceptable levels of risk, precaution requires decision-makers to consider ways to avoid risk in the first place, a much more proactive and solutions-oriented approach. Under the Precautionary Principle, society does not accept the potential for harm as a given, but rather assesses the very best way of achieving a result. We would not accept sacrificing some for the good of others, but would be obligated to include the interests of both current and potential future victims into decision-making.

Risk assessment methods can be valuable as a secondary tool to help us better understand the potential hazards of an activity as part of a comprehensive assessment of alternatives examined through a democratic process. In the case of competing environmental threats such methods can be used to prioritize action. ***Qualitative risk assessment where options are compared or the risk of a single activity is estimated using multiple lines of evidence may be the best use of risk information.***

Example: Qualitative risk assessment was used by the International Joint Commission (IJC) in assessing the effects of pollution on people and wildlife in the Great Lakes Region of the United States and Canada. Information from a variety of sources including scientists and engineers of various backgrounds was considered. Based on expert opinions and data provided by people from the various disciplines, the IJC concluded that all persistent toxic substances should be phased out of the Great Lakes ecosystem.

The Precautionary Principle would incorporate multiple disciplines and types of evidence to focus science on means to identify what might cause harm, the nature of the potential harm and ways to prevent harm. Scientific research would develop better "early detection" methods, and help guide or prioritize policy decisions. The Precautionary Principle would focus public policy on **risk avoidance** and protection of those who would be most harmed.

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