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RISK ASSESSMENT: THE FUTURE OF ENVIRONMENTAL QUALITY?

**Being a Summary of Testimony
Presented at the Public Hearing
Sponsored by the New Jersey Clean Air Council
April 17, 1989**

Scope

Much of our environmental legislation and regulation represents a governmental effort to reduce adverse health effects associated with exposure of humans to toxic substances. What should be the role of risk assessment in this process? To obtain information regarding the current status of risk assessment and its appropriate use in the formulation of environmental legislation and regulation, the New Jersey Clean Air Council* held a public hearing on risk assessment in the Newark Public Library, April 17, 1989. The scope of this public hearing and the selection of panelists were guided by the following general questions:

What do you mean by the term "risk assessment" and how does this compare with the generally accepted meaning of the term?

What human and/or animal data is available to determine risks? What are the limitations, quality, and best use of this data?

* The Clean Air council is formed under the authority of the New Jersey Clean Air Act; its members are appointed by the governor; its business is to study and make recommendations to the Department of Environmental Protection concerning the implementation of federal and state legislation and regulation dealing with air quality and to advise the commissioner of DEP on air matters.

What are the currently accepted risk assessment methods and which should be preferred?

What should be the goals of risk assessment?

Should risk assessment be standardized through legislative mandate or regulatory rulemaking? If so, how? Should risk assessment be required for environmental regulation?

What is, or what should be, the relation between risk assessment and risk management?

How do we best communicate the technical details of risk assessment to the public?

The Clean Air Council drew the following conclusion from the discussions and materials generated by this public hearing. This conclusion forms the basis of the council's recommendations to the Commissioner regarding the use of risk assessment in the environmental regulatory process.

There are at least several different scientific procedures for developing an assessment of the risk resulting from an exposure to one or more environmental pollutants. In addition, the evaluator may, not infrequently, be working with insufficient epidemiological data. Thus, a risk assessment may be subject to significant uncertainty in its prediction of human effects per unit of exposure. Accordingly, all assumptions, information, and procedures upon which a risk assessment is based should be viewed critically.

Nevertheless, the Clean Air Council believes that risk assessment can provide a logical basis for the relative ranking of adverse impacts on human health, as long as both individual and population exposures have been taken into account, any newly acquired data are included, and all available scientific evidence has been evaluated.

Recommendations

- The Department must proceed with risk assessment. Not to proceed would render the Department at a distinct disadvantage in future environmental decision-making with respect to protecting the public, creating fair and supportable regulations, and maintaining a competitive edge among the various states in both private sector investment and quality of life for its citizens.
- Risk assessment can improve the effective use of public money. This is particularly important in view of the expanding role of public funding in areas where risk assessment is not applicable.
- The Department must educate decision makers, regulation developers, enforcers, and the legislature that risk assessment is NOT a single number, but a determination of the environmental/health impact of an activity.
- To use risk assessment effectively, the Department and the legislature must develop a mutual understanding of both the power and limits of risk assessment. The legislature must be willing to delegate responsibility to the Department where the legislative process is unable to determine specific and appropriate corrective remedies or restrictions of activities.
- Requirements concerning risk assessment should not be incorporated into legislation, rather risk assessment should be viewed as a flexible process to be used as a tool for achieving the desired goals.
- There is a particular need in New Jersey for more research on exposure assessment. This research would provide valuable information well beyond that collected for routine monitoring programs, which do not usually provide accurate estimates of actual intake of toxic substances by people.

Background

Statements about **Risk** are obtained by considering both the probability of an event's occurring and the consequences of that event should it occur. **Risk Assessment** is the name of the scientific process used to define this probability and these consequences. The definition of probability of an event's occurring is based on information such as historical evidence, including medical records, and an engineering analysis of the system involved. Consequences are determined by estimating the magnitude of health effects that could result from exposure to an "event." Epidemiology and animal experiments provide sources of information about health effects.

When the discussion of risk centers on low-level exposure to chemicals or radiation, an element of uncertainty must be expected, since knowledge about low-level exposure is usually based on extrapolations from information about high-level exposure. The assumptions, however, that underlie the extrapolation itself may or may not be valid. To counter this uncertainty, risk assessment of very low dosage exposures should also take into account some determination of the actual (not the theoretical) range of possible exposures for a given population.

Quantitative risk assessments result in numerical statements of risk based on data. When data are incomplete or not available, Qualitative risk assessment is used; this process does not produce a numerical statement. If rigorous scientific procedures and methodology, qualitative risk assessment can produce results that will be as valuable as those produced by quantitative assessment.

Although risk assessment, risk management, and risk communication all serve the same ultimate goal--to minimize the risks associated with an event--they are three different processes and should not be confused. **Risk management** concerns decision making. Risk managers look at the results of a risk assessment and then try to find ways to reduce risk, either by decreasing the probability of an event's occurring or by minimizing its consequences. Their aim is to achieve an "acceptable level" of risk, however that may be defined. **Risk communication** refers to the way the meaning and the management of risk are described to the public. It has been demonstrated that the kind of language used to communicate risk can influence the public's perception of risk.

Although not discussed at this public hearing, the factors involved in risk communication are receiving much attention today. One area of concern is the discontinuity between a single-number statement of risk and the

complexity of factors that must be taken into account during the assessment process. Although a single-number is relatively simple for the public to understand, the single-number may, in the end, over-simplify and thus actually put the public at greater risk. In addition, the single-number approach (for example, reducing all risks from every kind of event to a one-in-a-one-million risk of death) can place a heavy (if not impossible) burden on regulators, who may find themselves attempting to impose rules on an unwilling public.

According to the National Academy of Sciences Committee on the Institutional Means for Assessment of Risks to Public Health, a complete risk assessment includes four parts ("Risk Assessment in the Federal Government: Managing the Process," March 1, 1983, page 3). The first three concern determination of consequences; the fourth concerns the probability of an event's occurring and the probability of its producing given consequences. These four parts of risk assessment are:

- 1) *hazard identification: the determination of whether a particular chemical is or is not causally linked to particular health effects;*
- 2) *dose-response assessment: the determination of the relation between the magnitude of exposure and the probability of occurrence of the health effects in question;*
- 3) *exposure assessment: the determination of the extent of human exposure before or after application of regulatory controls; and*
- 4) *characterization of the risk: the determination of the nature and often the magnitude of human risk, including attendant uncertainty.*

The whole area of risk assessment and risk management is controversial. What are the meanings of "acceptable risk," "significant risk," and "*de minimus* risk"? Government agencies tend to be cautious in their protection of public health, reasoning that when scientific and epidemiological data are inadequate, it is better to err on the side of being too protective; the regulated industry, often dissatisfied with government "intrusions" into its operations, may argue that government definitions are too restrictive, reasoning that if adverse health effects are not clearly measureable in human populations, then significant risk may be illusory.

Both groups recognize the inadequacy of scientific information concerning the health effects of exposure to the more than 60,000 chemicals in today's human environment. They also recognize that it may be many years before research catches up with the practical need for information. In the meantime, prioritization, assumption, inference, and estimate must fill

the gap when risk assessments are needed. Thus, uncertainty is a normal aspect of both risk assessment and risk management. Uncertainties, however, must be reduced to ensure that both the public and the regulated industries are protected. This is a major area of discussion in the testimony of this hearing.

Summaries of Testimony

(1) Jorge H. Berkowitz, Ph.D.

Director of the Division of Water Resources

New Jersey Department of Environmental Protection

The US Food and Drug Administration (FDA) was the first government agency to apply quantitative risk assessment to management decisions. Initially, FDA proposed that a one in one hundred million lifetime risk for carcinogens was "virtually safe." Critics, however, called this level of risk "too stringent"; in 1977, for regulatory purposes, "acceptable risk" was redefined as a one in one million lifetime risk.

In 1988 EPA changed its risk management policy for pesticide residues. Previously no detectable levels of cancer-causing pesticides had been permitted in processed food, regardless of risk. Pesticides registered before 1972 were not subject to this regulation. Under the new policy, EPA allows food to possess pesticide residues that pose less than a one in one million 70-year lifetime risk; there are no exemptions. This shift in policy is, in my opinion, an example of prudent risk management.

In a sense, the one in a million standard represents an institutionalization of the easy position. Mathematically, a lifetime risk of one in one million is approximately the same as an annual risk of one in one hundred million. In other words, if the entire population of the United States (240 million people) were subjected within one year to the same catastrophe, two people would be affected. For all practical purposes, this effect would be undetectable by any known epidemiological method for real populations and therefore whether or not the effect had actually occurred would be unproveable in a court of law.

Superfund also uses the one in one million lifetime risk criteria, thereby reinforcing the value's supposed validity as an acceptable level of risk. Because of this repeated use for regulation and because of the public perception that nothing but the one in a million standard will do, it has become virtually impossible to talk much about imposing a higher level of risk for environmental pollutants. People, however, routinely and voluntarily assume a one-in-one-hundred lifetime risk, when they driving cars, for example.

But what really is an "acceptable risk"? Different situations call for different definitions. The standard for naturally occurring radon in homes (an annual average concentration of 4 picoCuries per liter of air) imposes a lifetime risk of between one in one hundred to six in one hundred. Drinking

water standards, on the other hand, are based on the one in a million risk concept. Why does government impose one standard for one pollutant and another standard for another pollutant? The answer does not appear to be that one pollutant poses a less significant risk than another. Between ten and forty-two thousand lung cancers may be caused by radon exposure annually in the United States; this is not insignificant.

Unfortunately, the acceptability appears to be related to economics and technology rather than health. Radon concentrations so high that the lung cancer risk is a near certainty can be easily reduced to a one in a hundred risk level for about \$1,200. To reduce that risk to a one in one thousand level, however, would cost ten to twenty times that much. To reduce indoor radon concentrations even further--towards a one in a million risk of lung cancer, for example--would be extraordinarily expensive, even if it were technically possible, which it is not since radon in outdoor air itself exceeds that concentration.

Risk managers often have to balance several different risks from different sources when making a decision. Quantitative risk analysis can help in such situations, but management decisions do not always follow slavishly the dictates of quantitative analysis. Factors such as politics, attitudes and cultural values, clarity of information, public interest, media attention, and the raw number of people involved, must also be taken into account. Not all of these factors are easily quantifiable. Indeed, risk management is best done case-by-case, with decisions being made to reduce the risk to somewhere between "insignificant" and "acceptable," whatever those terms mean.

Periodically, risk management decisions should be reviewed and possibly revised. Adjustments of policy should not be seen as an admission of scientific incompetence, rather they are an indication that new information and new technologies are emerging. Government is not infallible. I think we oversold the public on the health danger of environmental pollution, because we wanted their support for our regulatory program. We helped condition the public that nothing but a one in a million lifetime risk was acceptable. At the same time it is in the public interest to site resource recovery facilities and hazardous waste incinerators and to allow industries that deal with very hazardous substances to operate. The current climate of public opinion, however, makes such management decisions very difficult. Consistent and predictable procedures for making risk management decisions, procedures that do not remove all government flexibility, would be helpful. Finally, communication to the public regarding those decisions and the reasons for them is also an important aspect of regulating for "acceptable" levels of risk.

(2) Roy Albert, M.D.

**Chairman, Department of Environmental Health
University of Cincinnati Medical Center**

Risk assessment is both qualitative and quantitative. Qualitative assessment is just as valuable, and sometimes more valuable, than quantitative assessment. Qualitative assessment is particularly useful for developing a process of risk evaluation and for understanding its implications, although it is less useful for regulatory purposes.

In 1975 I took a sabbatical from NYU Medical School to administer the US Environmental Protection Agency's (EPA's) health and ecological research program. During this period EPA was under attack by the chemical industry for its regulation of the pesticides DDT and chlordane. EPA lawyers responded to these attacks by developing a set of principles of carcinogenic risk. They wanted principles that would be beyond question, so that they could focus their efforts on matters of law and regulation, thus shortening the lengthy administrative hearing process. Although understandable from a legal perspective, the principles they did develop represented gross oversimplifications of complex scientific material. When the limitations of this approach became clear, an alternative--risk assessment--was sought.

EPA at that time was a young agency and a conglomerate agency, with different offices established by different pieces of legislation, and thus with different mandates. However, EPA was trying to use a uniform approach, focused on socio-economic costs and benefits and technical fixes. It never got around to developing a standardized approach for evaluating public health risks. So, this was my job: to standardize the measurement of health risks from environmental exposures to possible carcinogens. Procedural guidelines were adopted in the spring of 1986.

Two very different perspectives on the determination of carcinogenicity emerged from discussions that led to these guidelines. One group insisted that laboratory testing on animals could not be extrapolated to humans and that epidemiology was necessary to show excess cancer deaths. The other group pointed out that long latency and multiple exposures rendered epidemiology useless. From these differences emerged a middle-of-the-road approach and a recognition of the practical need for guidelines concerning how to apply the information garnered from animal tests. Animal data could not be considered unequivocal, quantifiable proof of human carcinogenicity, but it could be used as part of a larger conglomeration of scientific information including: chemical structure, chemical behavior, metabolism, human effects data, short term tests of

mutagenicity, and neoplastic cell transformation. All of these factors taken together could be used to estimate cancer risk.

Risk assessment asks several questions: How much cancer will be produced in a population by exposure to various concentrations of the chemical? How likely is the exposure to occur? and What are the consequences of an exposure? Situations can range from those in which there is a very high likelihood of exposure but with fairly trivial consequences to situations having a very low likelihood of exposure but with potentially enormous consequences. Great uncertainty enters these calculations.

Epidemiology is a powerful, but insensitive tool: epidemiological methods can detect no less than a 20 percent increase in disease. Risk managers, however, are generally concerned with levels of risk well below this value. To determine such low risks, mathematical models must be used, in full knowledge that their results cannot be checked with reference to direct experience. The mathematical formulation of choice is the linear non-threshold dose-response model, which has been used in nuclear energy decision-making. It is a simple model and cannot take into account the complexities of cancer; nevertheless the model has enough regulatory precedent to make it difficult to abandon. This model assumes (a) there is no safe level of exposure and (b) that increased exposures will yield increased effects. While (b) is true for high exposures, there is some doubt about the validity of (a) at all and of (b) when exposures are low. The limitations of the model can be gleaned from pharmacology. Simply scaling up the dose that produces any effect in a mouse, for example, to a dose large enough for a horse, will kill the horse. The reluctance to change models is also encouraged by a recognition that if the model were changed, all past data and decisions would have to be reviewed. There are also questions about how to extrapolate lifetime risk from short term exposures. Thus, risk assessment contains a significant element of uncertainty, although it is an uncertainty that tends to be ignored by the regulators, who for obvious reasons prefer to deal with black-and-white situations.

To deal with uncertainty, EPA guidelines call for documentation of what is known and what is not known. They also call for a weighing of risks against benefits, something that can be difficult, since effects are often not comparable. For example, how does one measure increased corn production against increased cancer deaths? Only by placing an economic value on human life can it be done. And there is much disagreement about what this value should be. The guidelines also set some criteria for acceptable risk. The favored criteria is the one in one million risk (the *de minimus* risk). This criteria has much in common with Hollywood or folklore expressions for rarity, but there's not much scientific basis for it. We need something better; we don't have it.

Risk assessment for noncarcinogens is even more complicated and uncertain. Carcinogens at least do or do not produce disease; with other substances the response may be graded or a particular response may just fade away after a time. The linear non-threshold dose-response model doesn't work at all well for such exposures, but there is no other model.

A final problem is the simple lack of information about 90 percent of the chemicals to which people are exposed. There is also little information about the interaction of chemicals. Government support for basic chemical research is small and growing smaller. In sum, the quality of both risk assessment and risk management depends on the availability of scientific evidence. Lacking that, it depends on the energy and experience of the regulatory agency.

The alternative to risk assessment is a return to standards based on acceptable risks and safety factors. Standards produce a sense of comfort and control but make no demands for an understanding of underlying processes. Standards also lead back to where we came from: a situation where if the authorities say it is safe, then it must be safe. Unfortunately the public will no longer accept this kind of authoritarian stance.

Finally, carcinogens produce a unique kind of risk, different from risk associated with other toxins: the consequences of cancer are all the same. With other toxins, reduced dose means reduced severity of consequences.

(3) Thomas Starr, Ph.D.

**Director, Program on Risk Assessment
Chemical Industry Institute of Toxicology
Research Triangle Park, North Carolina**

Risk assessment as it is done today by government agencies is not trustworthy. First, the regulatory process does not make use of all available information about chemicals. Sometimes this is because the information is new, developed after an assessment was made; at other times, information is simply ignored. In addition, the carcinogenic effects of chemicals on lab animals may well be artifacts caused by experimental conditions or by the need to use excessively high doses of a chemical that overwhelm normal defense mechanisms.

Risk assessment means the prediction of exposure levels that are unsafe for people. But what does this mean? Safety is a judgment call dependent on political and comfort factors, not necessarily on scientific information. Indeed, the concreteness of a particular statement of risk may be an illusion, an illusion further compounded by a confusion of risk assessment (based on science) with risk management (based on political considerations).

Scientific risk assessment has four parts: 1) hazard identification, 2) dose-response evaluation, 3) a determination of the biological mechanisms and patterns of exposure for different recipients, and 4) characterization of the risk. EPA generally performs only the first two of these four parts, from which they develop a so-called unit risk factor, or, in other words, the risk associated with a single unit of exposure.

Risk assessment studies produce a wealth of data, which is hard to reduce to a simple statement of human risk. In the process, facts may be replaced by assumptions and results skewed by a decision to select data from the most sensitive animal species, sex, or tumor and extrapolate to others. The linear non-threshold model used for dose-response calculations is extremely conservative and often biased, particularly when the test sample is small. The use of dramatically high doses for bioassays tends to mask all other quantifiable information. I know of no risk assessment based on animal studies that has been demonstrated in human populations.

Formaldehyde offers an example. Formaldehyde is common in our environment; in fact, it is found in every living cell. At very low concentrations it is a fundamental building block of life; at concentrations only slightly higher than those found in industrial situations (10-15 parts per million), it causes cancer in rats. At concentrations in a middle range formaldehyde causes benign tumors. Should cancerous tumors be combined with malignant tumors for risk calculations? When they are, the results are vastly different from when they are not. If mice are tested instead of rats, similar exposures produce fewer tumors. Finally, high concentrations overwhelm the normal cellular clearance response and as a result formaldehyde attacks DNA, something that does not occur at lower concentrations. These are some of the reasons that the straight line non-threshold model does not work. For formaldehyde, exposure to very low levels is much less of a risk than one might predict from a simple extrapolation from a high dose response.

Tests on rhesus monkeys confirm the variability of response among species. And, what is more, it is a variability that is not necessarily predictable. Though one might expect to see more molecular binding of formaldehyde in a larger species, one actually gets less. The extrapolation to humans of formaldehyde risk based on rats is ten times higher than one based on monkeys. However, epidemiological studies of over 30 occupational groups (morticians, embalmers, pathologists, chemical workers, leather tanners, etc.) show no convincing evidence of any increased cancer risk. This demonstrates the difficulty of validating laboratory predictions in real human situations.

In conclusion, past risk assessments by EPA and other prestigious groups cannot be accepted today due to new information. Some lab experiments produce artifactual results and do not offer a sound basis for

regulation of human exposure. The process of risk assessment should be ongoing, and risk management decisions should be firmly based on scientific risk assessment and local exposure assessment. NJ should concentrate its efforts and resources on exposure assessment, ie., on determining the actual intake of toxic substances by people. These data may be unique to NJ. NJ should establish an expert panel to appraise it of new information on chemical toxicity and risk assessment.

(4) Curtis Travis, Ph.D.
Director, Office of Risk Analysis
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Chemicals are classed as carcinogens or noncarcinogens. Risk assessment methods differ for each group. Risk is calculated by multiplying the potency of a chemical times the dose received (the amount a person is exposed to) times a contact and deposition rate. Potency is a numerical representation of the ability of a chemical to produce disease; it is calculated by graphing doses of chemical given to lab animals and the percents of disease (cancer) produced by these doses. The slope of the line connecting the high dose-response in an experiment with the low dose-response is called the potency of the chemical.

Several problems occur with potency calculations. Experimental interest tends to focus at the low end of the scale, as scientists try to predict for regulatory purposes at what dose the one in a million risk will occur. As the size of the dose approaches zero on the graph, however, it becomes hard to determine what the slope of the dose-response function (potency) really is. Secondly, for most carcinogens, it's not the parent compound that causes cancer, but rather a metabolite of that compound (a chemical that is produced in the body after exposure). Potency calculations in risk assessments should reflect this, they usually don't.

For non cancer-causing chemicals a safety factor approach is used. To do this, one first establishes the dose below which there are no observable health effects for the recipient. If the dose is applied to lab animals, one divides this low dose by 10 to produce an "acceptable daily intake" or ADI of chemical. If the low dose is based on chronic human exposure data, one divides by 100 for the ADI. If the low dose is based on chronic animal data, one divides by 1000.

These two methods of risk assessment can produce very different results; thus the first important decision that must be made is whether or not to class a particular chemical as a carcinogen. Dioxin is a case in point. In

the US it is considered a carcinogen; in Europe it is not. As a result the US standard is 1000 time more strict than the European.

The acceptability of the one in a million risk has been more or less institutionalized, although it is not always reflected in either post-regulation standards or in the decision of whether or not to regulate a particular chemical. For example, a survey of risk assessments in EPA's announcements of "Intents to Regulate" in the Federal Register showed that chemicals with individual and population risks greater than one in a thousand were always regulated; those with risks of less than one in a million were not. In between the one in a thousand and one in a million points, chemicals were regulated on a case by case basis. A number of factors seemed to be at work in the decision about what constitutes acceptable risk for these chemicals in the middle range. The number of people exposed appears to be quite important: as the number of people exposed to a risk increases, the acceptable risk factor is reduced towards the one in a million level. Economics are also important.

Curiously, although the stated policy of the federal government appears to be regulation to a one in a million risk factor, in actuality 70 percent of the regulated chemicals have risk factors greater than that after regulation. So it appears the federal government is saying one thing ("nothing greater than one in a million is acceptable") and doing another (in 70 percent of the cases a risk of greater than one in a million is acceptable, and in 25-30 percent of the cases risks greater than one in ten thousand are acceptable).

People are exposed to chemicals through air, water, food, and soil. A single chemical can be spread throughout the environment. Risk is thus not limited to a single pathway of exposure--for example, inhalation. Both standards and risk assessments should take the whole picture into account. A study of dioxin, for example, shows that 98 percent of human exposure comes from food; only 2 percent from air. Nevertheless, government resources are concentrated on that 2 percent.

Studies are needed on what chemicals people are actually exposed to in various environments. Adipose tissue studies, which sample human fat tissue over a period time for chemical residues, would be helpful, for example. Though such studies have been (and are being) done, they tend to focus on only about a dozen of the hundreds of compounds to which people are exposed every day. We also need to know where the chemicals found in humans come from. This kind of information, not political considerations, should direct regulatory efforts. For example, according to a California study, cars put more dioxin into the environment than municipal incinerators--so do unregulated hospital incinerators. Yet government research is almost entirely focussed on incinerators.

There are many uncertainties in risk assessment. This does not mean that the whole process is worthless. Because risk assessments are standardized, different chemicals are treated similarly. Thus, although a specific potency calculation may be inaccurate for real experiences, risk assessment does permit the potency of various chemicals to be ranked relative to one another. Needless to say, the more data used in risk assessment, the better the results will be. Total exposure data is sorely missing.

**(5) Daniel M. Byrd, Ph.D., Consultant
Regulatory toxicology and risk assessment
Washington, D.C.**

To be credible, risk management must be based on scientific risk assessments and include a calculation of what the courts have called "significant risk." But what is a significant risk? There is a discontinuity between the kinds of risk people take every day and the kinds of risk we talk about in chemical regulation. Many factors appear to influence the acceptability of a risk--whether the risk is delayed or immediate, necessary or a luxury, ordinary or catastrophic, controllable or uncontrollable, voluntary or involuntary, old or new, occasional or continuous, natural or unnatural. We tolerate, for example, 50,000 automobile deaths annually, but if an airplane crashes with 200 people on board, it is a disaster. Vitamins can cause cancer, but taking them is not considered a risk because they are "natural."

This morning we have heard reasons why government's risk estimates might be too high, but risk can also be dramatically underestimated. The truth is we don't really know what the real risks are; we can, however, understand how the methodology used to assess a risk influences the resultant numbers. This would permit adjustments and modifications in how the numbers are used.

Risk assessments can have a variety of goals. One is persuasiveness, as in California's Proposition 65. If you can persuade a jury that there was (or wasn't) a significant risk, you win.

Another goal concerns safety--absolute safety or practical safety. Practical safety means safe unless the user makes a mistake beyond normal expectations. This is quite different from being risk free. Absolute safety on the other hand does mean risk free; it means that the user cannot make an unsafe mistake. Absolute safety tends, however, to mask consequences of an action--one may, for example, achieve absolute safety from a pesticide use by removing that pesticide from the market. But that pesticide may then be

replaced by a more dangerous one. Absolute safety is not really achieved and the risk is actually increased. The consequence of the removal should have been reflected in the risk calculation of the first pesticide. EPA recognizes this paradox.

A third goal of risk assessment concerns the effort to achieve negligible or "de minimus" risk. The usual goal here is the one in a million risk, which translates into a few seconds off a total life expectancy for a population. This seems negligible--in theory. In practice it's not negligible because a specific group of individuals have to accept the consequences of that risk and they may not consider those consequences to be negligible.

In New Jersey, DEP uses a Best Achievable Control Technology (BACT) or As Low As Reasonably Achievable (ALARA) goal. ALARA works fairly well for radiation, but BACT does not address risk at all, though it may make social and economic sense.

Risk-benefit calculations are also used. Though easy to do, they work only within a particular context. Risk-risk calculations should always be done and should take into account the total situation. Cost-benefit analyses put options into economic terms. Used correctly by environmentalists, cost-benefit analysis is child's play: for example, the cost of pollution control equipment can never get high enough to justify polluting drinking water, because the water costs so much to clean up. For the last 8 years the federal government has required cost-benefit analysis for all regulatory actions.

Different regulations have different goals. Although it's not always done, goals should be determined before regulations are written. Acceptability of risk means what people are willing to live with; a risk does not become acceptable simply because a regulator says it is. Significant risks are defineable, observable, and measurable in the real world. The total population risk can be (and should be) linked to individual risks to reveal which group will most likely accept the consequences of the imposed risk.

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Dr. Byrd submitted additional testimony after his oral presentation at the public hearing. The submittal was in the form of a copy of a letter from Drs. Byrd, Cross, and Lave to William Reilly, Administrator USEPA, regarding EPA's proposal to consider four risk policy approaches as alternatives to control certain radionuclide and benzene emission sources. The following summarizes the contents of this letter:

Each of EPA's four proposed risk policy approaches has "fatal flaws," including approach "D" (0.1×10^{-5} maximum individual risk, which is equal to a risk of 1×10^{-6}), which does not provide a serious definition of acceptable environmental risk. A substitute risk policy approach should be

used, one that looks at individual risk and exposed population size in relation to US life expectancy tables and the diseases involved. This approach would cause EPA to set a safety goal of a risk that was too small to be statistically observable.

The US Food and Drug Administration (FDA) regards one cancer in a million lifetimes as the practical equivalent of zero; this risk level is indeed the practical equivalent of zero, but so are higher risks. A risk level that separates trivial risk from significant risk is needed. Even a significant risk may be, statistically, the practical equivalent of a zero risk.

The mathematics needed to develop this substitute risk policy approach are included in this letter. Arbitrary numerical risk goals are avoided. The aim is prevention of any statistically observable, measurable or detectable increase in the risk to a specific population from a specific emission source or potential disease or diseases. All factors are integrated in a coherent manner.

The US life table presents data for specific diseases, and these data play an important role in the calculation of risk. The table also provides a means of obtaining realistic estimates of loss of life as well as life span from different causes. Both estimates are important.

EPA should not place different values on the prevention of a premature death of different persons. For example, it is not acceptable that a small population exposed to one emission source in a sparsely populated state should have billions of dollars spent on preventing a premature death, while city dwellers [exposed to many sources?] in another state have only a few thousand dollars spent for the prevention of a premature death. Objective measures exist to determine the appropriate risk levels needed to realize "fundamental fairness."

The substitute approach has many advantages, including compliance with earlier judicial decisions and with the Clean Air Act. It offers a reasonable definition of safety, takes into account health considerations exclusively, and meets criteria of explicitness, comprehensibility, consistency, flexibility, predictability, and practicality.

Written testimony

**Oliver G. Papp, Associate Director
New Jersey Petroleum Council**

We urge adoption of standardized definitions and procedures for risk assessment based on those outlined by the National Academy of Science (1983) and used by the US Environmental Protection Agency. Though not perfect, these procedures do offer a consistent framework for the assessment of risk that will lead to better risk management decisions.

In addition, formal procedures will increase public confidence in regulatory decisions. Procedures should provide for early input into discussions by interested parties as well as for peer review of the science by experts.

We urge consideration of the following three general principles:

- A risk statement alone, without a clear presentation of underlying assumptions, quality, and uncertainty is a poor regulatory tool;
- Risk assessment should be part of an overall regulatory strategy; and
- Risk assessment should be clearly distinguished from risk management.

Attachments to this testimony:

ATTACHMENT I Statement of the American Petroleum Institute before the USEPA on September 1, 1989, concerning CAA Section 112 Benzene rulemaking. Included are statements by Dr. Stephen Brown of ENVIRON Corporation and Dr. Terry Yosie, Vice President for Health and Environmental Affairs of the American Petroleum Institute. Also included are supplemental comments of the American Petroleum Institute on the Regulations of Benzene Emissions under Section 112 of the Clean Air Act.

Stephen Brown: Dr. Brown discusses the manipulation of mid-range risk estimates (those between one in a thousand and one in a million). He indicates that the federal use of maximum individual risk factors tends to overestimate risk. Risk managers will improve estimates if they make use of all available information about risk.

Terry Yosie: Dr. Yosie also argues that the "plausible upper bound" of chemical potency used by EPA to estimate risk is unrealistic, particularly when joined with assumptions regarding the "maximum exposed individual"

(MEI), and results in an overestimate of risk. If valid data exist, it should replace the conservative assumptions that form the basis for current EPA risk assessments.

Supplemental comments: Provision of further support that EPA risk assessments should incorporate more realistic quantitative estimates of risk and up-to-date data. If this is done, current emissions will fall within acceptable risk limits and no new regulation will be necessary.

ATTACHMENT II: Report summary of "Risk Assessment in the Federal Government: Managing the Process." Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences, National Research Council. March 1, 1983.

This report discusses institutional mechanisms that will promote a constructive relationship between science and public policy-making. The panel makes three general recommendations:

- That regulatory agencies take steps to establish and maintain a clear conceptual distinction between the assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.
- That uniform inference guidelines be developed for the use of regulatory agencies in the risk assessment process to structure the interpretation of scientific and technical information. Guidelines should address all elements of risk assessment, but allow enough flexibility to consider unique scientific evidence in particular instances.
- That a board on risk assessment methods be established to:
 - 1) assess critically the evolving scientific basis of risk assessment and make explicit underlying assumptions and policy ramifications of the various inference options in each component of the risk assessment process;
 - 2) draft and periodically revise inference guidelines for risk assessment; and
 - 3) identify research needs in the risk assessment field and in relevant underlying disciplines.

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Upper bound and worst case estimates, which are widely used in government risk assessemnt when adequate scientific data is unavailable, regularly exaggerate the risks associated with chemical exposures. This procedure should be replaced by a "full scientific evaluation of all relevant data needed to protect human health" and a determination of the range of values. The latter should be accompanied by an expert's interpretation of the meaning of this range.

Factors to be considered in risk assessment should include:

- evidence of toxicity and altered psychological state,
- cancerous tumors in test animals,
- comparative metabolic data to determine the relevance of animal surrogates to human risk factors,
- descriptions of how the substance is handled by the body,
- information to distinguish the causal relationship between exposure and disease,
- both positive and negative bioassay results,
- all toxicity data,
- human epidemiological information.

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