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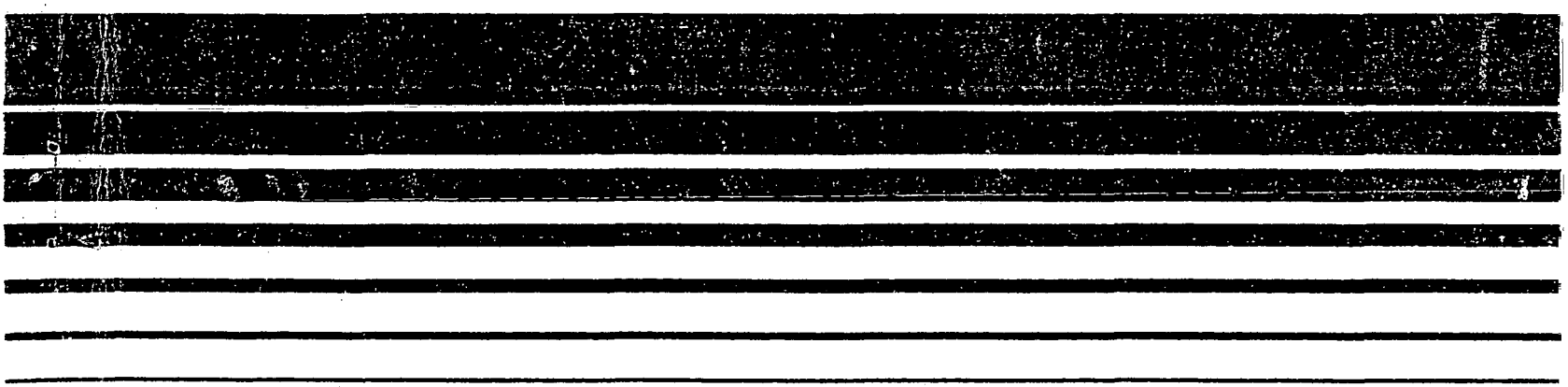
Analytical Perspectives on Setting Environmental Standards



ANALYTICAL PERSPECTIVES ON SETTING ENVIRONMENTAL STANDARDS

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PREFACE AND ACKNOWLEDGEMENTS

This report was prepared as part of the "risk analysis program" of the Office of Air Quality Planning and Standards (OAQPS) of the U.S. Environmental Protection Agency (EPA). For the purposes of this program, risk analysis is divided into two phases--risk assessment and risk evaluation. As defined by OAQPS, "risk assessment involves the process of making risk estimates that particular adverse events will occur in a given period of time and describing the nature or severity of harm that would result if those events were to occur" (Richmond, 1980). On the other hand, the objective of risk evaluation "is to aid or assist decision makers in grappling with clearly normative, social value judgements concerning which standard provides an adequate margin of safety (i.e., an acceptable level of risk)" (Richmond, 1981).

As a first step in the risk evaluation phase of this research program, OAQPS contracted with me to write a background report that:

1) highlights some of the key questions, issues, and perspectives that might be considered in research on risk evaluation,

2) develops a typology for classifying various approaches to risk evaluation, and

3) describes the approaches currently used by the major Federal agencies that set health, safety, and environmental standards.

The report is not supposed to be (too) prescriptive, but (mostly) descriptive; it is not supposed to provide answers, but to develop a framework for thinking about some key questions. Furthermore, the report is not supposed to duplicate existing work--doing so would make it far too lengthy; rather, the report is supposed to help guide the reader to relevant portions of the vast literature on decision-making methods and approaches.

Throughout, the primary aim is to contribute to the risk-analysis program of OAQPS.

I would like to acknowledge the important contributions of three EPA analysts, Thomas B. Feagans, Harvey M. Richmond, and Thomas McCurdy, who taught me not only much of what I know about the EPA, but also much of what I understand about the appropriate roles of scientists and analysts in environmental decision making. In addition, this report is based in part on my work as study director of the Committee on Risk and Decision Making of the National Academy of Sciences; I owe a particularly large intellectual debt to Howard Raiffa, who was chairman of that

committee, and to John Graham, who was research associate. I would also like to thank Wesley A. Magat, Philip J. Cook, Robert D. Behn, Meredith Golden, Howard Kunreuther, and Joanne Linnerooth for their helpful comments. Diane Levin was my principal research assistant in preparing this report; many of the facts and examples cited were uncovered by her diligent and probing research. The manuscript was typed and corrected with speed and grace by Rhonda Starnes.

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INTRODUCTION

Natural scientists, engineers, economists, political scientists, and policy analysts tend to perceive the process of health, safety, and environmental standard setting in radically different ways. Each of these five perspectives has some validity and value: the standard-setting process is so multi-faceted that, like sculpture, it can best be understood when viewed from several vantage points. In this report, I first view the standard-setting process from the angles of analytical vision of natural scientists, engineers, economists, political scientists, and policy analysts, in turn. Then, I try to explain how each of these disciplines (and others) can all contribute to the process of environmental decision making; in this concluding part of this report, I lay out a decomposition of appropriate roles for scientists and analysts and suggest some research needs.

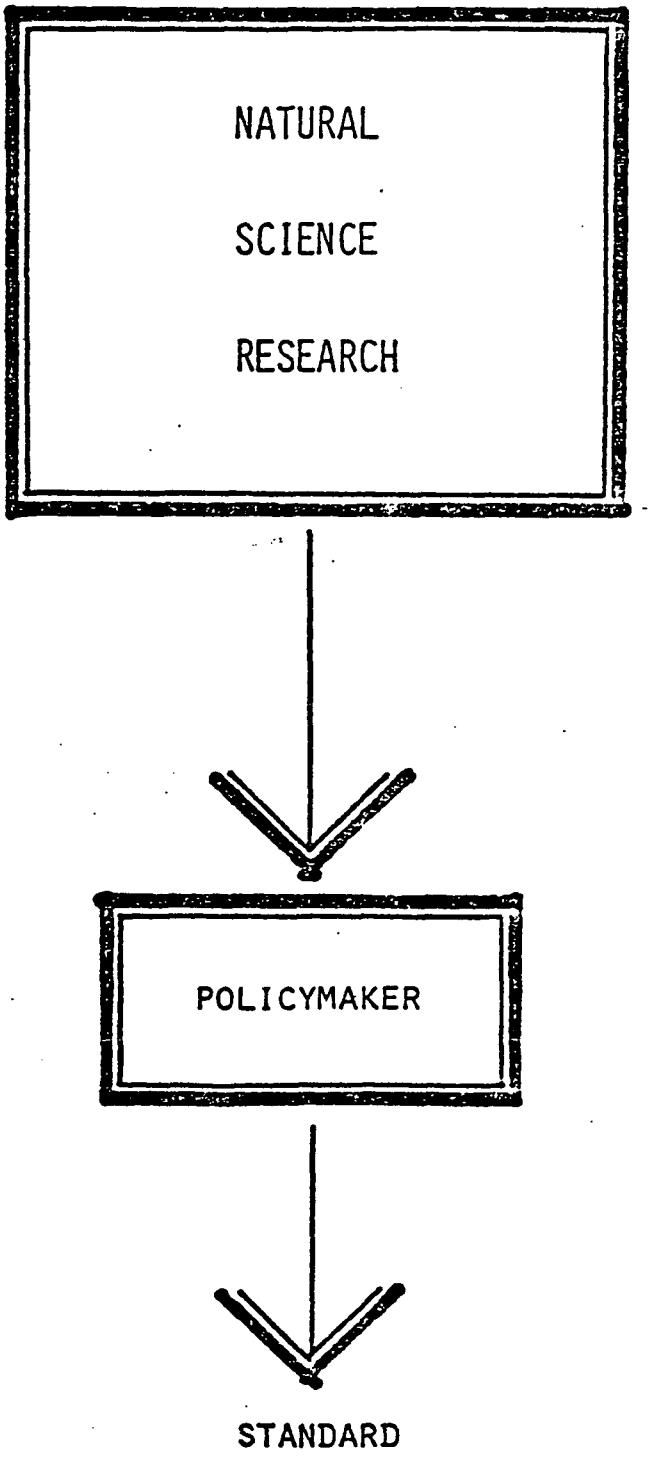
I. THE NATURAL SCIENCE PERSPECTIVE

Most natural scientists--and probably most laymen as well--have an image of the standard-setting process that might be caricatured as shown in Figure 1. According to this view, natural scientists do the crucial work of determining the health and environmental effects of a hazardous substance; once these facts are determined, the administrator of the appropriate regulatory agency has to use his or her judgement to make a decision about what level of the hazardous substance can be allowed if public health and the environment are to be protected. In some cases, the scientific facts speak so loudly that the administrator has virtually no discretion; in other cases, the uncertainties are such that the administrator's judgement plays a more significant role. In all cases, however, the standard is essentially the product of scientific fact.

This image underlies much health, safety, and environmental legislation. For example,

- The Clean Air Act prescribes "ambient air quality standards the attainment and maintenance of which in the judgement of the Administrator, based on (air quality) criteria and allowing an adequate margin of safety, are requisite to protect the public health". The air quality must "accurately reflect the latest scientific information" concerning "effects on public health or welfare." (42 U.S.C. 740 *et seq.* 1970, amended 1977; sections 108 and 109).

Figure 1: Environmental Standard Setting from the Perspective of Natural Scientists



-- Both the Resource Conservation and Recovery Act and the Solid Waste Disposal Act require standards "as may be necessary to protect human health and the environment" (42 U.S.C. 6921 *et seq.* 1976, and 42 U.S.C. 6901 *et seq.* 1976, amended 1978).

-- The Delaney Clause of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(3)) prohibits the use in food of any additive "if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animals".

-- The Federal Aviation Act requires regulation of aircraft safety to provide the "highest possible degree of safety in the public interest" (49 U.S.C. 1301 *et seq.* 1958, amended 1974, 1977, and 1978).

Furthermore, the natural scientist' image as depicted in Figure 1 roughly conforms to the actual division of labor in the EPA and in most of the other Federal health, safety, and environmental regulatory agencies as well: for a particular standard-setting decision, most of the available budget and most of the hours of effort are devoted to producing and assembling natural science facts.

Consequently, it should not be surprising that there has been considerable interest in methods of decision making that conform to the natural scientists' image--and that a number of health, safety, and environmental standards have been justified in terms of such methods. Six categories of examples follow; I have listed them roughly according to

the amount of discretion they permit the administrator, starting with the methods that allow the least discretion.

A. ZERO RISK

If something is risky, ban it. This simple decision rule is so clear-cut that it hardly seems to need explanation. Nonetheless, it is useful to consider three examples to gain some insight into the nature of the situations where bans have been proposed.

EXAMPLE: Tris

In March 1976, the Environmental Defense Fund petitioned the Consumer Product Safety Commission (CPSC) to require a warning label on children's clothes treated with Tris, a chemical flame-retardant used in children's clothes. This prompted the Commission to study the safety of Tris. The Commission also asked the National Cancer Institute to test Tris. Tris was found to be a carcinogen at multiple sites in two species of animals. The CPSC immediately decided to ban the use of Tris under the Federal Hazardous Substance Act:

> The Commission's Office of the Medical Director believes that once a substance is established as an animal carcinogen, it can never be assured as a safe substance for human exposure. (42 Federal Register 18350).

Although the Commission did an economic analysis, this was not considered to be relevant to the decision. Given the judgement that no level of Tris could be considered safe, the CPSC apparently concluded that there was no alternative but to ban.[1]

EXAMPLE: Saccharin

In a Federal Register notice on April 15, 1977 (42 Federal Register 19996), the FDA announced that "the Commissioner of Food and Drugs is proposing to revoke the interim food additive regulation under which saccharin and its salts (saccharin) are currently permitted as ingredients in prepackaged foods, such as soft drinks and as tabletop nonnutritive sweetners." The notice explained:

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[1] Having decided to ban Tris, CPSC had to decide how to implement the ban. The Administrative Procedure Act requires that a regulation be preceded by a notice of proposed rulemaking that allows for public participation and a delayed effective date. In this instance, the CPSC did not propose a rulemaking but an interpretation of a statutory provision. The Environmental Defense Fund suggested that the Commission interpret section 2(q)(1)(A) of the Federal Hazardous Substance Act, which bans "toy(s) or other article(s) intended for use by children which are hazardous substance(s)", to apply to children's clothes containing Tris. This sidestepped the complicated and time-consuming procedures normally required for rulemaking.

In the final notice, the Commission defends this action:

> Even if the rules were to be considered general rulemaking, the Commission for good cause finds that notice and public comment and a delayed effective date are contrary to the public interest because the statutory intent and structure of the Federal Hazardous Substance Act is that children's articles that present a substantial risk of illness based on toxicity must be banned without any delay. As the legislative history states, "toys or other articles intended for use by children which bear or contain a hazardous substance are banned by the language of the bill itself." (42 Federal Register 18853).

This method of banning Tris was apparently accepted by the various concerned parties. Thus, the agency was able to effect a ban of this product without resorting to formal regulatory proceedings.

The Commissioner's determination that saccharin must be banned as a food additive is based on a series of scientific studies conducted in accordance with currently accepted methods for determining whether compounds can cause cancer. The most recent of these studies, conducted by Canadian scientists under the auspices of the Canadian government, confirms what earlier American studies have suggested: that saccharin poses a significant risk of cancer in humans. Under these circumstances, conscientious concern for the public health requires that FDA prohibit the continued general use of saccharin in foods.

This conclusion is also dictated by the so-called Delaney clause of the Federal Food, Drug, and Cosmetic Act, which prohibits the use in food of any food additive which has been shown, by ingestion or other appropriate tests, to cause cancer in laboratory animals.[2]

[2] Congress subsequently considered the issue and, in November 1977, a bill was passed that required: an 18-month moratorium on the proposed saccharin ban; the Secretary of HEW to contract two scientific studies with the National Academy of Sciences, one on the risks of saccharin and the other on the issue of food additives in general, to be completed within 15 months; a provision for warning labels on saccharin-containing products; and warning signs in retail stores which sell such products, to be supplied by manufacturers (Link, 1977).

EXAMPLE: Red Dyes No. 10, 11, 12, and 13

Color additives in foods, drugs, and cosmetics are regulated under the Federal Food, Drug, and Cosmetic Act of 1938, as amended by the Color Additive Amendments of 1960. The amendments allow a color additive to be approved only if the data established that it is safe under the permitted conditions of use; if a chemical causes cancer, it cannot be used in any quantity (42 Federal Register 62475).

An interesting example of regulation under this act occurred in 1977 when the FDA banned the use of red dyes no. 10, 11, 12, and 13 because they possibly might be carcinogenic. The four dyes are formed with tobias acid. Tobias acid contains beta-naphthylamine, a suspected carcinogen, making the FDA worry that traces might remain after the production of the dye. Unfortunately,

> analysis for free beta-naphthylamine in each of the four colors was hampered by difficulties with the analytical methods and has not shown free beta-naphthylamine (42 Federal Register 62476).

Scientists were able to determine that beta-Naphthylamine was found in industrial grade lithol red; they concluded:

> Although the exact identity of the lithol reds tested by American Cyanamid is unknown, lithol reds are generally sufficiently similar to the four colors, D&C Red Nos. 10, 11, 12, and 13 to permit a conclusion that the latter colors would also contain free beta-

naphthylamine (42 Federal Register 62476).

On the basis of this finding, the Commissioner decided that since red dyes no. 10, 11, 12, and 13

> could result in exposure of the consumer to beta-naphthylamine..., use in drugs and cosmetics should be terminated because such action is necessary to protect the public health. (42 Federal Register 62471).[3]

[3] The case of red dye no. 2 may also be of some interest. As described in an unpublished paper by Elizabeth A. York written under my supervision:

> Before its ban in early 1976, red dye no. 2 was the most frequently used color additive in the United States.... The dye was developed in 1878.... In adherence to the Color Additive Amendments of 1960, the FDA placed the dye on the "provisional approval list". Through the utilization of extensions, red dye no. 2 remained on the provisional list until its 1976 ban; its listing was extended fifteen times in all. The first extensions were granted because manufacturers claimed that longterm studies were not complete. After 1965, extensions were issued because the FDA could not decide whether the submitted data warranted permanent approval....
>
> Numerous studies were done after 1965 and three successive review panels were appointed. The first, a committee of the National Academy of Sciences, concluded in June 1972 that restrictions on the dye's use were unwarranted. Because of the controversy surrounding the National Academy of Sciences committee, the FDA appointed a second advisory panel consisting of five outside scientists.... In the fall of 1974, the advisory panel reported that a study the panel had designed had cleared the dye of all safety doubts. But soon afterwards, it was revealed that the collaborative study had been "mismanaged and effectively botched". In the words of one FDA scientist, "it was the lousiest experiment I've seen in my life". He and other agency scientists contested the advisory panel's conclusions and urged that the dye be banned....
>
> In October of 1975, the FDA appointed a third advisory panel, the Toxicology Advisory Committee.... The Committee reviewed all studies of red dye no. 2 and initially announced that the dye was probably harmless.
>
> Alexander Schmidt, Commissioner of the FDA, appeared on "Face the Nation" in late December , 1975. Schmidt justified the FDA's fifteen year delay by arguing that "red dye no. 2 is probably the most studied chemical in the food supply.... There are no studies that prove red dye no. 2 causes cancer".
>
> Meanwhile, Dr. Gaylor, a statistician member of the Toxicology Advisory Committee, reinterpreted the data of the FDA's "botched" study.... His analysis revealed that the number of malignant tumors within the total number of tumors had increased significantly.... The Committee concluded that neither the safety nor

B. NATURAL LEVELS OF RISK

As noted in Fischhoff *et al.'s* excellent compendium of "Approaches to Acceptable Risk: A Critical Guide" (1980):

> An early natural standard was Agricola's (1556) philosophy of non-degradation of the environment in *De Re Metallica*. He advocated prohibiting human activities that would impose risks greater than those experienced in some "pre-existing natural state".

In commenting on the criteria for radioactive waste proposed in 1978 by the EPA, the Natural Resources Defense Council suggested that

> the entire nuclear fuel cycle be managed so that the overall hazard to future generations would be the same as those that would have been presented by the original unmined bodies utilized in these nuclear operations (Rotow *et al.*, 1979)

A related kind of proposal suggests that

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the danger of red dye no. 2 had been demonstrated and recommended further testing.

Shortly afterwards, Commissioner Schmidt announced the FDA's plans to ban red dye no. 2 because its safety had not been proven.

Red dye no. 2 had at that time still only "provisional approval". Section 81.1 of the color additive amendments allows a dye to be used on an interim basis only if there are pending scientific studies to determine its safety. Since no further tests of red dye no. 2 were pending, the dye was banned on this technicality.

rather than trying to determine the actual damage caused by very low radiation insult, and then setting an allowable dose, one instead compares the man-made standard with the background. Since man has evolved in the midst of a pervasive radiation background, the presumption is that an increment of radiation "small" compared to that background is tolerable and ought to be set as the standard. (Adler) suggests that small, in the case of gamma radiation, be taken as the standard deviation of the natural background--about 20 millirads per year (Weinberg 1979).

C. DE MINIMUS RISK

The "de minimus" approach sets exposure levels such that risks to humans are less than some small value, typically 10^{-6}, but sometimes 10^{-8} or 10^{-5}, usually on a life-time basis, but sometimes on an annual basis. In this approach, "risk" is almost always calculated on the basis of a well-specified formula that includes various "prudent" (i.e., risk-overstating) assumptions. Furthermore, the formula is usually based only on objective scientific findings; scientific judgements are not explicitly included. Many statisticians would argue that the "risk" of an adverse consequence calculated in this way is only tenuously related to the "probability" of an adverse consequence (Feagans and Biller 1981, and EPA 1981).

EXAMPLE: Carcinogens in Animal Feed

The FDA's interpretation of the so-called "DES proviso to the Delaney Clause" (sections 409(c)(3)(A), 512(d)(1)(H), and 706(b) (5)(B) of the Federal Food, Drug, and Cosmetic Act) provides an intriguing example. The DES proviso allows carcinogens to be used in animal feed if "no residue" is "found" in "any edible portion of such animals". As explained in detail in a Federal Register notice (44 Federal Register 17070 ff.), the FDA decided to implement this proviso by a two-step procedure. First, the chemical in question has to be shown to be a likely carcinogen, according to a specified procedure. Then, a "no residue" level is set based on a "risk level" of one in a million. As defined by the FDA:

> (a) The risk level of 1 in 1 million is an increased risk over the entire lifetime of a human being.
>
> (b) The upper 99-percent limit on the response data is used throughout the procedure, and the extrapolation is conservative by nature. For these reasons, the maximum concentration of residues of carcinogenic concern that will go undetected in edible tissues is expected to increase the lifetime risk of excess cancer in humans by less than 1 in 1 million.
>
> (c) This 1 in 1 million ***lifetime*** risk is expected only if the maximum concentration of residues potentially undetected in edible tissues is consumed every day over a lifetime. Because there is little likelihood that these residues will be so consumed by humans, the actual risk is likely to be lower than 1 in 1 million.

(d) The use of the procedures explained in the proposed regulations for deriving a concentration of residues that may go undetected in edible tissues rests on the assumption that the only risk to the exposed human population is that from residues of the sponsored compound. Other causes of disease or death are not considered. Because the population is constantly at risk from a wide range of factors, any increment of risk associated with residues subject to this proposed regulation is in comparison with other risks, likely to be vanishingly small.

(e) Several other prudent procedures apply to the derivation of the concentration of residues that will be permitted to go undetected. For these and the above reasons the most likely human risk is expected to be less than 1 in 1 million (44 Federal Register 17092).

In the Federal Register notice, the FDA notes that an earlier (1977) proposal suggested that an acceptable level of risk "could be 1 in 100 million over a lifetime":

Many comments argued that this level of risk was unnecessarily conservative in light of the many other cumulative, conservative restrictions already in the proposed regulations.... the Commissioner concluded that the 1 in 100 million level of risk was unduly limiting without substantial compensation in terms of public health. (44 Federal Register 17092).

Later, it is noted that

> An increase in the level of risk to 1 in 10,000 might significantly increase human risk. It is difficult to choose between 1 in 1 million and 1 in 10,000 but the agency chooses the more conservative number in the general interest of protecting human health (44 Federal Register 17092).

An interesting aspect of FDA's procedure is that "no residue" is interpreted as "a potential residue level corresponding to a lifetime risk of 1 in 1 million" (44 Federal Register 17093).

D. HEALTH THRESHOLD LEVELS

Some health standards are set at a level that falls below an estimated "threshold" that can be defined in various ways, including "no adverse health effects level," "no physiological response level," or "lowest convincingly demonstrated effect level." Often in this kind of approach a margin of safety is used to ensure that the standard is set at a level below the currently observed or estimated threshold. The essence of this risk-evaluation method is best explained in the context of a couple of examples.

EXAMPLE: Non- Carcinogenic Drugs in Food- Producing Animals

The approach used by the FDA to approve non-carcinogenic drugs for use in food-producing animals differs substantially from the approach, described above, used for drugs suspected of being carcinogens. As explained by an FDA scientist:

> Tolerances are established for non-carcinogenic drugs by first selecting the level demonstrated to have no adverse effect in the most sensitive test species used in toxicity studies. This no-effect level is then adjusted to account for the differences in food and consumption versus body weight between test animals and humans.
>
> (When) extensive toxicology testing (has been done), the acceptable daily intake for humans is calculated by applying a safety factor, usually 1:100.
>
> (In cases of less extensive testing), a safety factor of at least 1:2000 is applied. (Perez, 1978).

EXAMPLE: Airborne Lead

A roughly similar kind of health threshold analysis has been used by the EPA in setting national ambient air quality standards. Consider, for instance, the case of airborne lead. The EPA set the lead standard to protect the "most sensitive group" against the "first adverse health effect". As explained in the opinion of the U.S Court of Appeals (1980), 1 to 4

year-old children were selected as the most sensitive group and EP elevation (a kind of iron deficiency in red blood cells) was selected as the first adverse health effect. A target blood lead level of 30 micrograms per deciliter was then chosen as the level that 99.5% of the sensitive group should be protected against. Given the assumption that blood levels in the sensitive group were distributed log-normally with a geometric standard deviation of 1.3, it was then calculated that the mean blood lead level in the sensitive group would have to be 15 micrograms per deciliter. Next, it was estimated that non-air sources of lead contributed 12 micrograms per deciliter of lead to the blood and that 1 microgram per cubic meter of lead in the air would produce 2 micrograms per deciliter of lead in the blood. The standard was thus set at one half the difference between 15 and 12, i.e., as 1.5 micrograms per cubic meter.

It is important to note that a "health threshold," as used by the EPA in setting national ambient air quality standards (NAAQS), is not the same as a "no-effect" level, as used by the FDA. The EPA recognizes that the precise pollutant level where adverse health effects begin cannot be identified with certainty for NAAQS pollutants. Thus, in the case of carbon monoxide, the EPA recognized that no absolutely safe level existed, other than zero (45 Federal Register 55072). As indicated in this Federal Register and as explained by Jordan, Richmond, and McCurdy (1981):

> This does not mean that there is no threshold for a suitably defined effect and population group for carbon monoxide; it simply means that no *clear* threshold can be identified with certainty based on existing medical evidence. The best EPA could

do was to identify those levels at which scientists generally agreed that adverse health effects had been convincingly shown.

Discussion

Health threshold analyses permit a certain amount of discretion and judgement, considerably more than permitted by the zero-risk, natural-level-of-risk, and de-minimus-risk approaches. In other words, the health threshold approach requires that some decisions be made. The key decisions concern: (1) determining a threshold level, and (2) determining a margin of safety. Both these decisions involve what a recent report called "inherently imprecise concepts" (Jordan, Richmond, and McCurdy 1981).

Consider first the question of determining a health threshold. In the FDA approach described above, the threshold is set at "the level demonstrated to have no adverse effect in the most sensitive test species used in toxicity studies". Implicit in this rule is the assumption that "no adverse effect" has been defined. But how can harmless physiological responses be distinguished from responses which should be considered adverse health effects? Furthermore, the FDA approach is based on testing a number of species. But how many species and which species?

Similar questions arise with regard to the EPA approach described above. One to 4 year-old children were selected as the most sensitive group and EP elevation was selected as the first adverse health effect. The group could, however, have been defined more narrowly (e.g., one-year-old urban males) or more broadly (e.g., all children under age 15). Furthermore, a different health effect could have been selected.

Consider now the setting of a margin of safety. The FDA uses safety factors of 1:100 and 1:2000--why not 1:10 or 1:10,000? The EPA chose to protect 99.5% of the sensitive group: a case probably could be made for protecting 99%, or 99.9%, of the group. In determining the appropriate margin of safety, a number of factors might be weighed, including severity of the health effect, reversibility of the health effect, the number of individuals affected, the credibility and strength of the health-effect evidence, the lack of testing with multiple pollution exposures, uncertainties about animal to man extrapolation, etc. But how should such factors influence the margin of safety?

The FDA and EPA used radically different approaches to the concept of margin of safety. The FDA used the traditional approach of applying a safety factor. The EPA used the more innovative concept of protecting y percent of a distribution of individuals. But which of these approaches is superior, under what conditions and circumstances?

These various questions about health-threshold approaches are not, to my mind, objections so much as targets of opportunities for systematic thinking and research. Health-threshold approaches are considered in this report as just one of an array of risk-evaluation approaches, for two reasons: (1) the primary purpose of this report is to survey the variety of approaches used by the major Federal agencies that set health, safety, and environmental standards, and (2) the sponsors of this report are intimately familiar with health-threshold approaches. However, it seems clear that research intended to develop and clarify an appropriate health-threshold approach should be a central part of the continuing risk-evaluation program of the Office of Air Quality Planning and

Standards.

The main reason that different risk-evaluation approaches are used in setting health, safety, and environment standards is that different statutes govern the regulation of different hazards. As noted earlier, Section 109 of the *Clean Air Act* requires that national ambient air quality standards be set at a level "requisite to protect public health" with an adequate margin of safety. Furthermore,

> Both the *Clean Air Act* and its legislative history make it clear that an ambient air quality standard is to be solely health based, designed to protect the most sensitive group of individuals--but not necessarily the most sensitive members of that group--against adverse health effects. (Jordan, Richmond, and McCurdy 1981).

Unless the language of the *Clean Air Act* is amended or the interpretation of the language is radically changed, it would seem that health-threshold methods are perhaps the only kind of approach to risk evaluation legally open to the EPA in setting air quality standards. The reason other approaches may be of interest is that these other approaches may shed light on how to resolve some of the open questions posed by health-threshold approaches.

E. COMPARATIVE RISK

Sometimes it is useful to try to put a risk into perspective by comparing the risk with other kinds of risks. For example, there has recently been some concern about the fact that peanuts tend to be contaminated by a potent carcinogen known as aflatoxin. There also has been some concern that drinking water in some cities is polluted with chloroform, which is also a carcinogen. In thinking about whether to give up peanut butter and only drink bottled water, it may be informative to know that devouring an entire jar of peanut butter is roughly as hazardous as smoking a single cigarette and that drinking Miami drinking water for a full year is also only roughly as hazardous as smoking a single cigarette.

In addition to gaining some sense of perspective, a second use of comparative risk analysis is in setting priorities. Consider, for example, a person at high risk of coronary artery disease who chain smokes, has high blood pressure, and eats two or three eggs a day. A comparative risk assessment indicates that giving up cigarettes or controlling the high blood pressure would each be at least 25 times as efficacious in reducing the chance of a fatal heart attack as giving up all those eggs. (Vaupel and Graham 1980).

As noted by Fischhoff *et al.* (1980), "properly speaking... comparing existing hazards is not a decision-making procedure, but merely an aid to intuition." Nonetheless, if "risk evaluation" is viewed as being designed "to aid or assist the decision maker(s) in grappling with the clearly normative, social value judgement of what standard(s) provide an adequate margin of safety or acceptable level of risk" (Richmond, 1980), then com-

parisons of risks may be what a decision maker wants, at least in part.

EXAMPLE: Pesticide Regulation

The National Academy of Sciences' Committee on Prototype Explicit Analyses for Pesticides, chaired by Robert Dorfman, proposed a decision procedure that might be classified as a kind of "comparative analysis". The Dorfman committee was established because Dorfman, who was a member of the National Academy of Sciences' committee that wrote the report on *Decision Making in the Environmental Protection Agency*,

> wanted to make a case study of some reasonably manageable area of environmental regulation that would reveal in concrete form the issues and the problems involved. The Environmental Protection Agency nominated pesticides and that seemed as good a choice to me as any other. So under the sponsorship of the National Research Council (of the National Academy of Sciences) I recruited a team that included highly qualified specialists in most of the relevant disciplines and we conducted a detailed review of the kinds of decisions that had to be made and of how EPA is organized to make those decisions. (Dorfman 1981).

The Committee wound up proposing a subtle decision-making procedure that takes "advantage of many of the insights developed in decision theory" (NAS 1980). (The essence of decision theory and decision

analysis is described later in this report.) The Committee, however, did not believe that "it is practicable for the Office of Pesticide Programs to ascertain the 'preference functions' or 'objective functions' required by a full-blown decision analysis". They therefore recommended a "simplified, more *ad hoc* procedure".

The gist of this recommended procedure is conveyed by a simple example given in this report. The Committee asks the reader to imagine that there are "five available options (labeled A through E) for the regulation of a mythical pesticide called Pesticide". Option A is the most lenient regulation and option E the strictest. There is

> a mythical comparison compound, Visolin, about which two things are known. First, ... the lifetime dose scale for Visolin is one tenth the scale for Pesticide indicating, for example, that 0.06 μ moles/kg of Visolin produces an effect comparable to 0.6 μ moles/kg of Pesticide. Second, Visolin was denied reregistration on the basis of analyses that indicated that if it had been reregistered, a significant population group would have been exposed to lifetime doses of 0.06 μ moles/kg of Visolin.

In addition, there is "another mythical comparison compound", which the committee calls Safex:

> its scale is the same as Pesticide's multiplied by 15. Safex was reregistered and supporting risk analyses showed that the greatest lifetime dose to which any large population group would

be exposed was in the neighborhood of 3 μ moles/kg.

The committee suggests that

> the Administrator might reason as follows: if Pesticide is reregistered according to Option A, both the general population and the special exposure group would be exposed to lifetime doses greater than the one equivalent to the potential exposure to Visolin that led to the denial of its reregistration. That is, the general population would receive an estimated lifetime does of 0.68 μ moles/kg, the special exposure group would receive 0.86 μ moles/kg, and the Pesticide equivalent of the Visolin dose level at which Visolin was canceled is 0.6 μ moles/kg. Since the risks at 0.6 μ moles/kg (Pesticide equivalent) were unacceptable in the Visolin case, Option A can be eliminated (ignoring the benefits of Pesticide use versus those of Visolin use). Under Option B, both groups are exposed to doses below the Pesticide cut-off points suggested by the Visolin precedent. But... suppose the special exposure group is not sufficiently below the cut-off point and Option B cannot be regarded as entirely safe for it. Besides, Option C costs only slightly more than B and Provides significant reductions in the doses received by both groups. Options D and E cost considerably more than C without affording substantial reductions in the doses to which the special exposure group will be exposed. Although there is greater improvement in the exposure of the general population between Option

C and Options D and E than for the special exposure group, under Option C the general U.S. population is already virtually at the level that was found to be acceptable in the Safex case. So, all in all, Option C appears to be the wisest course to follow. (NAS 1980).

A noteworthy aspect of this proposed procedure is that the decision maker is *not* presented with estimates of human mortality or morbidity: the data pertain to *doses*. In a paper explaining why, Dorfman first presents a

> catalogue of the difficulties that have to be surmounted in assessing the risks imposed by the use of any pesticide. It is 6a discouraging catalogue. What we should like to obtain as as a result of all the work is estimates of the number of people who are likely to contract cancer from exposure to the pesticide when it is used in accordance with any of the available regulatory options. These estimates, if available, would be basic ingredients for making the choice among the alternatives including, of course, the status quo alternative. EPA tries manfully to make those estimates and, indeed, routinely produces figures that purport to convey the desired information. In my opinion, based on inspecting a number of such estimates and the methods used to derive them, this practice is misleading and imparts an unwarranted impression of scientific certitude. This opinion is fairly widely shared....

> The recommendation of the committee on pesticides was to be candid about the limitations of scientific knowledge and to abstain from making extrapolations and estimates for which no sound scientific basis exists. This means in effect, presenting the results of the laboratory experiments and any other hard data (e.g., data concerning doses) but not indulging in any guesswork. We felt that the guesswork and the exercise of judgement for which science provides little or no foundation, belongs in the province of the Administrator and his senior staff, and that scientists and subordinate staff should not substitute their judgements for those of responsible officials. (Dorfman 1981).

F. JUDGEMENT OF HEALTH PROFESSIONALS

Many health, safety, and environmental hazards are managed by professional health experts. Physicians, for example, are responsible for prescribing hazardous pharmaceuticals, and industrial hygienists are responsible for many of the health and safety practices of manufacturing firms. As discussed in Fischhoff *et al.* (1980),

> In balancing risks and benefits, these professionals rely on personal experience, accepted professional practice, and their clients' desires. The method for integrating this assortment of facts and values is professional judgement....
>
> Perhaps the most important codes are unstated; they represent

> the implied standards of professionalism inculcated during training and apprenticeship. One learns what a physician, engineer, or chemist does and does not do; what are the right and wrong ways to do things; what risks one does and does not take with others' lives; when to defer to higher authorities; when to admit defeat; when to call a colleague to task; what is "good enough for government work"; what short-cuts are legitimate; when one's job is done and a problem can be entrusted to others. These implied standards are sufficiently general to give the professional a feel for what might be acceptable actions in all of the varied problems that arise. Since they are reality- and compromise-oriented, such codes may lead to different solutions to the same technical problem in different economic and political contexts.

Two examples follow of health, safety, and environmental regulatory standards set essentially by the judgment of health professionals.

EXAMPLE: Small Toys

In 1979, the Consumer Product Safety Commission (CPSC) published a regulation that

> classifies as banned hazardous substances certain toys and other articles intended for use by children under 3 years of age. It covers products that the Commission believes present a choking, aspiration or ingestion hazard, based on their failure to

comply with specified size criteria. (44 Federal Register 34892).

After considering a variety of possibilities, the Commission decided on a simple test centering on

> a measuring device--a truncated, hollow cylinder--which separates toys and their components into two classes, according to their size and shape. The Commission proposed that a toy or component which fits entirely within the cylinder is too small for children under 3 and should be banned. (44 Federal Register 34894).

As explained in the Federal Register notice, the idea of using a truncated, hollow cylinder and the measurements of this cylinder--1 1/4" in diameter and 2 1/4" in length--were essentially based on the professional judgement of several groups of experts, including the Toy Manufacturers of America and the Accident Prevention Committee of the American Academy of Pediatrics. The CPSC had to act under conditions of little information:

> (little) is known about the sizes of children's mouths, throats, windpipes and other critical passages. No data currently indicate even that the passages increase in size with age.... the Commission believes it would take years to develop a method for measuring these passages.... (44 Federal Register 34900).

Consequently, the "test criteria represent a compromise between the existing data and practicality", a compromise resolved by professional judgement.

EXAMPLE: Ambient Water Quality

The EPA is required by Section 304(a) of the Clean Water Act to develop and periodically revise national water quality criteria. According to procedures published in 1976, no formal assessment process was used in setting these criteria; instead, the criteria

> represent scientific judgements based on literature and research about the concentration-effect relationship of a particular aquatic species within the limits of experimental investigation. (Moreau 1980).

These scientific judgements were made by the Criteria and Standards division within the EPA's Office of Water Planning and Standards; the judgements were based on information and comments provided by numerous scientists working for various federal and state agencies, corporations, universities, and other organizations.

In 1978, the EPA developed a revised procedure for setting water quality criteria. The new guidelines

> provide a more formalized, systematic approach to deriving criteria from scientific data. It is not expected that the numbers derived using (this approach)... will be very different from those

which would be derived from the less formalized method EPA has used in the past. It is expected, however, that the systematic treatment of all appropriate aquatic data will make the rationale for the criteria more obvious. (Moreau, 1980).

II. THE ENGINEERING PERSPECTIVE

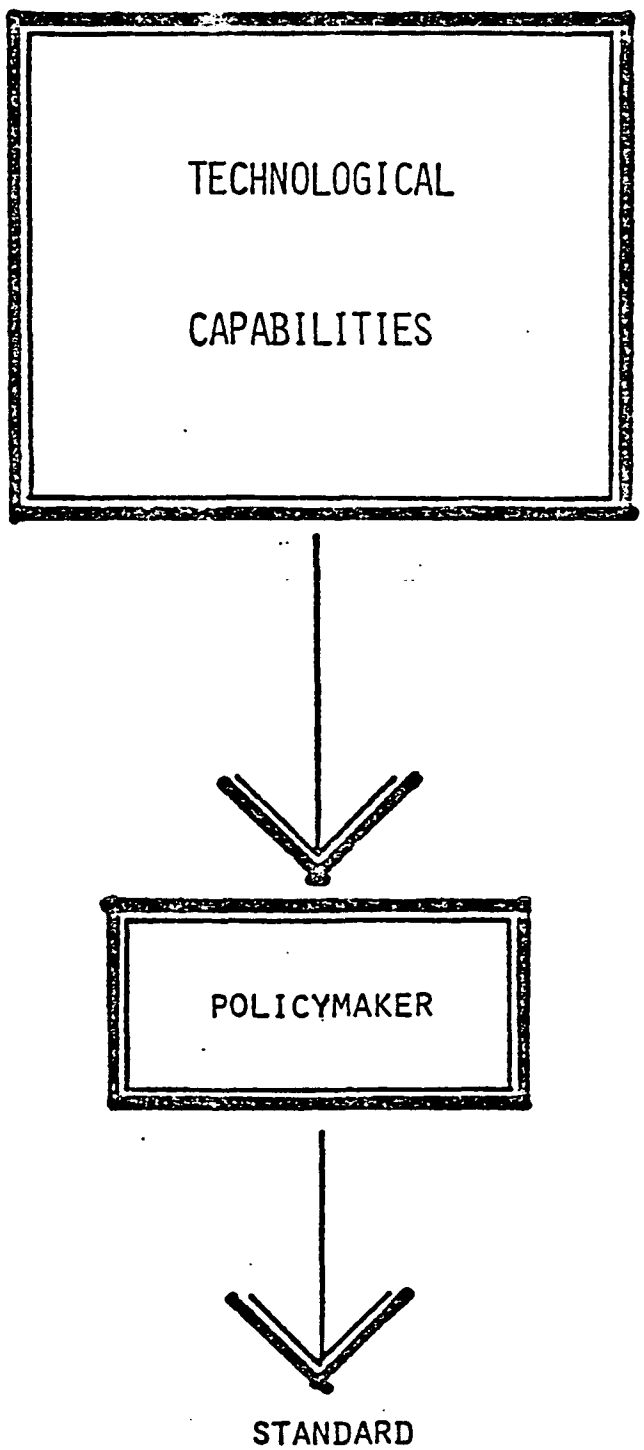
The six kinds of "natural science" approaches laid out in Section I--i.e., setting standards (1) at zero risk, (2) at natural levels of risk, (3) at *de minimus* levels of risk, (4) below no-effect levels or health thresholds, (5) by comparing risks, and (6) by the judgment of health professionals--all focus on health and environmental *effects*. An engineer, in contrast, might focus on *how* to achieve a reduction of some risk and on related questions of feasibility and attainability. In this view, technological capabilities constitute the crucial information for, and constraint on, policymakers, as illustrated in Figure 2.

A number of health, safety, and environmental statutes are written with this image in mind. For example,

-- Section III of the Clean Air Act instructs the Administrator of the EPA to set performance standards for new stationary sources of pollution (e.g., coal-burning power plants) as follows:

> a standard of performance shall reflect the degree of emission limitation and the percentage reduction achievable through application of the best technological system of continuous emission reduction which (taking into consideration the cost of achieving such emission reduction, any non-air quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated. (42 U.S.C. 740 *et seq.* 1979, amended 1977, section III).

Figure 2: Environmental Standard Setting from the Perspective of Engineers



- The Clean Air Act Amendments of 1977 permit the Administrator of the EPA to require any polluting source built within the last ten years that threaten to impair visibility in pristine Class I areas to install "best available retrofit technology."
- The Federal Water Pollution Control Act of 1972, as amended in 1977, requires standards for effluent limitations based on the "best practicable control technology" and the "best available control technology."
- The Occupational Safety and Health Act of 1970 (29. U.S.C. 651 *et seq.* 1970) requires the Secretary to protect employees' health "to the extent feasible."

Three methods of standard setting might be classified as fitting under this "engineering perspective." As before, I discuss them in turn, starting with the method that permits the least discretion and exercise of administrative judgment.

A. LOWEST DETECTABLE LEVELS

The permitted level of a hazardous substance might be set at the lowest detectable level, given the best available--or, perhaps, some specified--measurement method.

EXAMPLE: Carcinogenic Animal Seeds, Revisited

Consider, again, the regulation by the FDA of carcinogens in animal feed. Before the FDA adopted the procedure outlined earlier--which essentially defines "no residue" as the level that according to certain "conservative" assumptions produces a 1 in 1 million level of lifetime risk—the FDA interpreted "no reside" as meaning no residue detected. In justifying this interpretation, the FDA noted that the language of the relevant statute

> specifies that no residue" may be "found ... by methods of examination prescribed or approved by the Secretary ... in any edible portion of such animals ..." This language conspicuously avoids such words as "occur" or "remain" and instead, by use of the word "found" emphasizes detectability. (44 Federal Register 17073).

EXAMPLE: Vinyl Chloride

A second informative example concerns OSHA's regulation of vinyl chloride in the workplace. As described by Mendeloff (1979):

> After a third worker at its Louisville, Kentucky, vinyl chloride plant died from a rare form of liver cancer, B.F. Goodrich informed NIOSH (National Institute of Occupational Safety and Health) of the fatalities. Less than three months later, on April 5, 1974, OSHA issued a temporary emergency standard that

reduced the permissible exposure level from 500 parts per million (ppm) to 50 ppm .... Shortly after ..., a new study revealed that cancers developed in mice exposed to the proposed 50 ppm level.... Spurred by this new evidence, ... NIOSH recommended that "no detectable level" of exposure be permitted. Given NIOSH's skepticism about the possibility of accurate measurements, this really constituted a 1.5 ppm ceiling on exposures. OSHA accepted the NIOSH arguments and proposed a permanent standard calling for "no detectable level."

The standard that OSHA promulgated on October 4, 1974, set an exposure limit of 1 ppm TWA (time weighted average), with a ceiling exposure of 5 ppm, not to be exceeded for more than fifteen minutes. Since NIOSH had believed (incorrectly, it later turned out) that exposures could only be measured with an accuracy of 1 ppm ±50 percent, the final standard deviated very little from the proposed standard.... George Taylor, head of the AFL-CIO's Standing Committee on Occupational Health and Safety, describes the vinyl chloride standard as the best OSHA has promulgated. "It has come closest to what a standard should be, mainly because it essentially includes the criterion of 'no detectable limit'."

B. BEST CONTROL TECHNOLOGY

As noted above, several health, safety, and environmental statutes include phrases like "best technological system," "best practicable control technology," best available control technology," or, more vaguely, "to the extent feasible." Two examples follow of how agencies have used and interpreted these provisions.

EXAMPLE: Air Pollution from Aircraft

As explained in a 1978 Federal Register notice (43 Federal Register 12615):

> In 1973 EPA promulgated gaseous emission regulations for several classes of newly manufactured and newly certified aircraft engines.... This notice proposes changes to the existing rules and supersedes the earlier proposal.... The proposed changes to the gaseous emission standards will require only engines of 6,000 pounds thrust (or equivalent power) or greater, used in commercial applications, to comply with gaseous emission standards. This action will withdraw emission control requirements from... (among other engines)... auxiliary power units (APUs).

Thus, in an interesting contrast to most regulations, this notice *relaxes* a standard. A technological-feasibility argument is used to justify this reduction:

> The APU standards are being withdrawn for several reasons. These are: (1) No NO_x control technology has been developed in spite of extensive good faith efforts; (2) only minimal *CO* control is obtainable, yet significant costs would be incurred by both industry and the government....
>
> EPA will monitor the further development and refinement of the emerging NO_x control technology, and if in the future it appears this technology is reasonably capable of being retrofitted additional rulemaking will be considered. (43 Federal Register 12615 and 12616).

EXAMPLE: Acrylonitrile

In the case of vinyl chloride, discussed above, OSHA set a standard at the lowest detectable level. In setting subsequent standards with regard to cotton dust (43 Federal Register 27350), which may cause byssinosis (brown lung disease), and benzene (43 Federal Register 5918), coke oven emissions (41 Federal Register 46742), and acrylonitrile (43 Federal Register 43762), all of which may cause cancer, OSHA justified its proposed standards not in terms of detectability but rather in terms of "feasible engineering controls" (43 Federal Register 46742). in each case, OSHA argued that: (1) there was no demonstrated safe level of exposure, (2) the standard proposed was "technologically feasible," i.e., could be achieved at existing levels of engineering know-how, and (3) the standard was "economically feasible" in the sense that it could be implemented without imperiling the existence of the affected industry.

Consider, specifically, the case of acrylonitrile (AN), a clear volatile liquid used primarily in the manufacture of various plastics. OSHA's proposed standard laid out three alternative permissible levels of exposures (PEL's):

(1) 2 parts per million, time weighted average (ppm/TWA), with a 10 ppm ceiling;

(2) 1 ppm/TWA with a 5 ppm ceiling; and

(3) 0.2 ppm/TWA with a 1 ppm ceiling.

OSHA justified offering three alternatives as follows:

> By including several sets of alternative permissible exposure limits in the proposal, OSHA acknowledges that there is much data and information yet to be gathered as to what constitutes the lowest feasible level of exposure to AN in the affected industries. It should be noted that although OSHA has expressly proposed three alternative sets of permissible exposure limits, the PEL in the final rule will be the lowest feasible levels based on the entire record of the proceeding, and may differ from the proposed levels. (43 Federal Register 2610).

OSHA's final rule set the PEL at 2 ppm/TWA with a 10 ppm ceiling--the highest of the three proposed PEL's. OSHA summarized its rationale for choosing this PEL as follows:

> The technology either exists or can reasonably be developed to meet the proposed 2 ppm standard in most processes most of the time through engineering controls.
>
> The technology does not exist to retrofit most existing AN processes to meet the proposed 0.2 ppm standard through engineering controls.
>
> No one, either in industry or Government, knows the precise extent to which compliance with the 1 ppm standard is possible through the use of engineering controls. (43 Federal Register 45775).

C. ENGINEERING JUDGMENT

A large number of health, safety, and environmental standards--including most of OSHA's safety standards, many of the Nuclear Regulatory Commission's (NRC's) standards, and many of the National Highway Traffic Safety Administration's (NHTSA's) standards--are based on engineering judgment reflected in technical, design criteria.

EXAMPLE: Ladders

Perhaps OSHA's most frequently castigated set of safety standards were the more than 140 regulations it issued governing the use and construction of wooden ladders. One of them reads:

> The general slope of grain and that in areas of local deviations of grain shall not be steeper than 1 in 15 in rungs and cleats. For all ladders cross grain not steeper than 1 in 12 are permitted in lieu of 1 in 15, provided the size is increased to afford at least 15 percent greater calculated strength for ladders built to minimum dimensions. Local deviations of grain associated with otherwise permissible irregularities are permitted. (U.S. Code of Federal Regulations, Section 1910, 25 (b)(3)(ii), quoted in Smith 1976).

In late 1977, then Secretary of Labor Ray Marshall announced that more than 10% of the safety regulations OSHA had issued would be eliminated, included "10 of the current 12 pages of complex specifications for wooden ladders." (New York Times, December 6, 1977).

EXAMPLE: Nuclear Reactor Design

As noted in Fischhoff *et al.* (1980),

> the federal code known as 10 CFR 50 specifies the criteria for a minimally acceptable nuclear power generating reactor design. Some parts were created specifically for the code, in other instances, it defers to standards like those published by ASME (American Society of Mechanical Engineers) ... (whose) Boiler and Pressure Vessel Code gives technical specifics for that sub-system of nuclear power generating facilities....

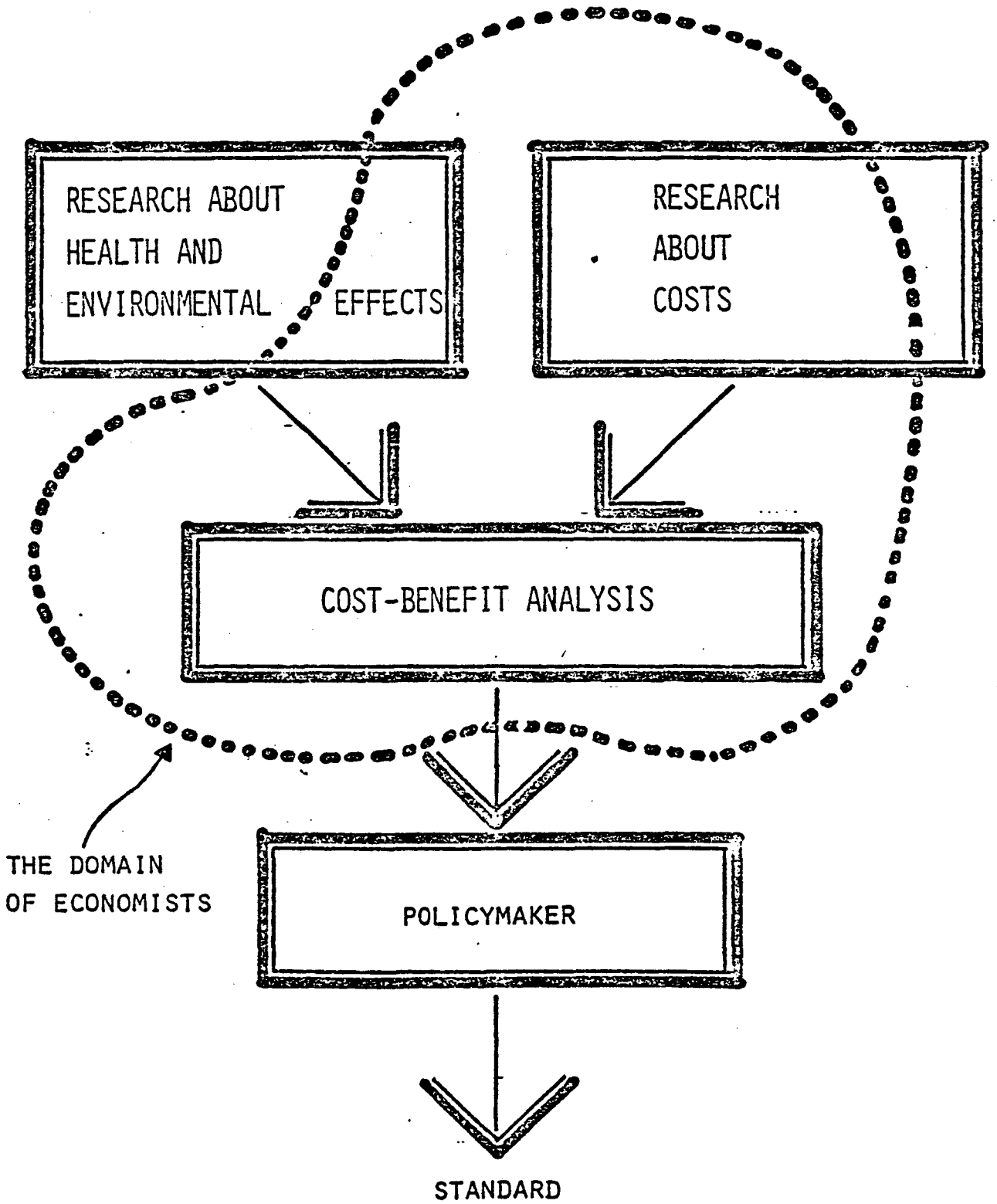
For example, 10 CFR 50 offers design parameters like "materials for bolting and other fasteners with nominal diameters exceeding 1 inch shall meet the minimum requirements of 20 mils lateral expansion and 45 ft. lbs. in terms of Charpy V-notch tests conducted at the preload temperature or at the lowest service temperature, whichever temperature is lower."

III. THE ECONOMICS PERSPECTIVE

Most economists believe that the natural science and engineering images of health, safety, and environmental regulations are inadequate because in these two images costs are not explicitly balanced against benefits. Economists have a different image, as caricatured in Figure 3. In this view, natural scientists (with the help of some economists who do epidemiological research) do part of the work--essentially, they estimate an exposure-response curve that describes the health and environmental effects of any particular level of exposure to a hazardous substance. Economists, perhaps with the help of some engineers, estimate how much it would cost to achieve any particular level of exposure. Economists then put the costs and benefits together in an analysis that informs the decision maker about the incremental costs of achieving the incremental benefits of stricter standards. Since it is not clear how much we as a society are willing to pay for health, safety, and environmental protection, the decision maker has some discretion. Most economists, however, think that in most cases they would be able to roughly agree on a reasonable standard. Hence, the discretion in setting standards is not perceived as being large.

This narrow "cost-benefit analysis" point of view lies at one end of a continuum of methods; at the other end of the continuum, "cost-benefit analysis" is very broadly defined as meaning a balancing of advantages and disadvantages. For the most part, the various methods along this continuum are formal, analytical methods developed by economists and such kindred souls as decision analysts, systems analysts, operations

Figure 3: Environmental Standard Setting from the Perspective of Economists



researchers, and management scientists. The distinguishing characteristic of all these methods is that they explicitly address the problem of making trade-offs among various kinds of costs and benefits.

If the phrase "cost-benefit analysis" is broadly defined, then a number of health, safety, and environmental statutes might be classified as being, at least in principle, congenial with the "economics perspective." For instance:

- The Toxic Substances Control Act calls on the Administrator of the EPA to explicitly consider various costs and benefits. Section 5(c)(1) reads

> ... the Administrator shall consider and publish a statement with respect to --
>
> (A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,
>
> (B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,
>
> (C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and
>
> (d) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on

> the national economy, small business, technological innovation, the environment, and public health. (15 U.S.C. 2601 *et seq.* 1976).

-- The Federal Insecticide, Fungicide, and Rodenticide Act, as supplemented by the Federal Environmental Pesticide Control Act, requires EPA to refuse to register a pesticide unless it is determined that

> when used in accordance with widespread and commonly accepted practice it will not cause unreasonable adverse effects on the environment.

The phrase "unreasonable adverse effects on the environment" is defined as

> any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. (7 U.S.C. 135 *et seq.* 1972, sections 3(c)(5) and 2(bb)).

-- The Surface Mining Control and Reclamation Act of 1977 instructs the Secretary of the Department of the Interior to set standards and issue permits to protect the environment from the effects of surface mining. The regulations must

> protect society and the environment from adverse effects of surface coal mining...,

but they must also

> strike a balance between protection of the environment and agricultural productivity and the Nation's need for coal .... (30 U.S.C. 1201 *et seq.* 1977).

As noted above, "cost-benefit analysis" is a slippery phrase since it is sometimes used very broadly to mean any kind of attempt to balance advantages and disadvantages and it is sometimes used narrowly to refer to a particular method developed by some economists. The four sections that follow distinguish among: (1) cost-benefit analysis, narrowly defined; (2) cost-effectiveness analysis; (3) decision analysis; and (4) *ad hoc* balancing. Since there are a vast variety of analytical methods arranged along a continuum here, this breakdown does not capture the full richness of possibilities. The breakdown does, however, suggest the general nature of the range of possibilities. As before, these methods are ranked in order of the degree of increasing discretion they permit the decision maker. In addition to the references given, an excellent guide to useful analytical methods is Raiffa, Schwartz, and Weinstein (1977); Jennergren and Keeney (1979) may also be of considerable value.

A. COST-BENEFIT ANALYSIS, NARROWLY DEFINED

The classic description of cost-benefit analysis, narrowly defined, is that given by Mishan (1976). The two central principles underlying Mishan's exposition are:

(1) The Potential Pareto Criterion, also called the Kaldor-Hicks Criterion. According to this criterion, a public policy is acceptable if and only if the gainers gain enough that they would theoretically be willing to compensate the losers for their losses. This criterion implies that the best policy alternative is the one that maximizes the difference between aggregate benefits and aggregate costs, regardless of their distribution among different members of society.

(2) Compensating Variation. The monetary values of many costs and benefits are determined by the market. But how should costs and benefits that do not have a market price be valued? Mishan's answer involves a concept known as "compensating variation." Essentially, a potential benefit to some person is worth the maximum monetary amount that person would be willing to pay for that benefit, and a potential cost to some person is worth the minimum monetary amount the person would have to be paid to induce him or her to bear that cost.

Given these two principles, a cost-benefit analysis theoretically can be done to compute the net benefits, in dollar equivalents, of any proposed public policy. In practice, there are great difficulties in, for example, determining appropriate monetary-equivalents for lives and limbs saved and for discounting future costs and benefits into current dollars. Freeman (1979) and Thompson (1980) contain informative discussions of some of the issues here; Graham and Vaupel (1981) may also be of interest.

Because of these practical difficulties and (more importantly, I think) because of fundamental disagreements with the theory of cost-benefit analysis--in particular, the neglect of distributional consequences--no agency, to the best of my knowledge, has used a cost-benefit analysis, narrowly defined, as the sole basis for setting a health, safety, or environmental standard. There have, however, been some instances where cost-benefit analyses have played a role in an agency's deliberations. As a result of Executive Order 12291 such use of cost-benefit analysis may substantially increase during the Reagan administration.

EXAMPLE: Power Lawn Mowers

In 1974, the CPSC "accepted the offer of Consumers Union... to develop a consumer product safety standard applicable to power lawn mowers." (44 Federal Register 9990). As part of its report to the CPSC, Consumers Union prepared a cost-benefit analysis. This analysis was the subject of a detailed critique by the Regulatory Analysis Review Group (Lenard 1979). Subsequently, the CPSC's economic division did a number of cost-benefit calculations, some of which were included in the final standard proposed by the CPSC in the Federal Register.

The flavor of these various cost-benefit calculations is captured by the following excerpt from the Federal Register justification for the final standard:

The foot probe and related requirements are expected to reduce the number of blade contact injuries to the foot by 13,000 each year.... The cost of these requirements is estimated to be about $4.00 per mower....

Since 5.4 million mowers are sold, and since the average injury expected to be eliminated by the standard costs approximately $3,500, these foot probe requirements should result in a cost increase of about $22,000,000 and undiscounted injury savings of about $46,000,000, exclusive of any allowance for pain and suffering. (44 Federal Register 9996).

B. COST-EFFECTIVENESS ANALYSIS

As explained by Fischhoff *et al.* (1980):

In some problems, all alternatives have the *same benefits*. For examples, a chemical firm may have several ways to reduce workers' inhalation of a toxic substance by a fixed amount. Since the benefits of the methods are equal, cost becomes the only issue. In other problems, all alternatives may have the *same cost*. For example, the chemical plant may allocate a fixed sum of money for protecting workers. The problem then becomes choosing the alternative that achieves the greatest reduction in toxic inhalation for that amount of money.

In neither case is there any need to reduce costs and benefits to

a common metric. Cost-effectiveness analysis is designed to reveal which alternative produces the greatest effect for the amount of money one has to spend or which produces the desired effect with the smallest expenditure. As a result, it avoids the sticky task of directly assessing the economic value of a given reduction in exposure. Of course, the value placed on workers' health enters the analysis indirectly, through the decision about how much to reduce exposure or how much to spend.

EXAMPLE: Emission Standards for New Motorcycles

As described in an article (Mallet 1979) that was edited from a report of the Council on Wage and Price Stability:

> In October 1975, EPA proposed regulations for all new motorcycles designed for street or highway use that would eventually set permanent standards for crankcase and exhaust emissions of carbon monozide, nitrogen oxides, and hydrocarbons equivalent to those already established for automobiles and small trucks....
>
> ... the proposal will produce significantly different cost-effectiveness results for different classes of motorcycles....
>
> ... the proposed 1980 standard would be most effective for the large two-stroke motorcycles, for which the costs per ton on hydrocarbon controlled would range from $77 to $386. On the other hand, the class of motorcycles least effectively regulated

by the 1980 standard would be the small four-stroke motorcycles. In this case, it would cost between $1,777 and $9,060 to regulate a ton of hydrocarbons.

(Furthermore) the EPA proposal is significantly less cost-effective for motorcycles than for light-duty vehicles (that is, automobiles and light-duty trucks.) EPA currently estimates that the average cost of control per ton of hydrocarbons for light-duty vehicles under the interim 1977 standards to be $303, with the cost increasing to $437 when the new federal statutory standards are implemented. These figures are substantially less than those estimated for every class of motorcycle for 1980, except perhaps the large two-stroke cycle. Similar cost figures (can be calculated) for control of motorcycle emissions of carbon monoxide....

Moreover, ... it can be shown that--at least for the four-stroke motorcycles--EPA's proposed standards for 1980 would be a less cost-effective means of controlling hydrocarbon emissions than several alternative technologies that have been employed for controlling automobile and gasoline station hydrocarbon emissions....

EPA should reconsider its proposed emission control standards for motorcycles (since) the estimated 1980 costs for controlling emissions from certain motorcycles appear to be very high compared with the cost-effectiveness of regulation other sources of

air pollution.

A postscript to the article notes:

> In adopting the final motorcycle emission regulation, EPA stated that ... "statutory standards were not technically feasible as early as 1980, and that control to that level would not be cost effective".... The agency made it clear that it may propose more stringent controls in the future if ... cost-effectiveness relationships between motorcycles and various other sources of air pollution change.

C. DECISION ANALYSIS

As described by Fischhoff *et al.* (1980):

> Decision theory is an axiomatized theory for making choices in uncertain conditions. It is also a prescriptive theory; if you accept the axioms and their interpretations in practice, you *ought* to make the recommended choices. Decision analysis implements decision theory with the aid of techniques drawn from economics, operations research, and management science....

A thorough decision analysis has five main steps:

(1) Structuring the problem. The analyst defines the decision problem by identifying the relevant alternatives, the set of possible consequences, and the sources of uncertainty. Structural models are used to express the interrelationships among these elements; the construction and application of such models requires both technical expertise and good judgment.

(2) Assessing probabilities. Uncertainties about the present and future state of the world are quantified as probabilities. Decision analysts view probabilities as expressions of individual's beliefs, not characteristics of things. As a result, probabilities are elicited as judgments from the decision maker or from experts.

(3) Assessing preferences. Unlike cost-benefit analysis, which quantifies preferences by analysis of market data, decision analysis uses subjective value judgments, that is, utilities. Thus, decision analysis can, in principle, accommodate any consideration that the decision maker deems appropriate. Values for such "soft" considerations as aesthetics or "satisfying Senator X" can be judged and included as easily as "hard" considerations like monetary cost. In this process attitudes toward risk are also accommodated....

When a particular outcome has several kinds of values associated with it (e.g., a successful operation can lead to both

reduced pain and prolonged life), cost-benefit analysis simply adds together the various costs and benefits. In decision analysis, other combination rules are also available (e.g., a multiplicative rule when the utility of one aspect of value depends on the level of another).

(4) Evaluating alternatives. The attractiveness of each alternative is summarized by its expected utility, which is equal to the sum of the utilities of each possible outcome, weighted by their probabilities of occurrence. The alternative with the greatest expected utility is the indicated choice.

(5) Sensitivity analysis and value of information. The analysis is reexamined from two perspectives.

> (a) Can it be simplified by omitting components that do not affect the final decision? For example, an alternative that was inferior to another in all aspects could be dropped.
>
> (b) Are there places where a reasonable change in the structure, a utility or a probability could lead to the selection of a different alternative? Two tools are used for this reexamination ... sensitivity analysis ... (and) value-of-information analysis.

Since the key elements in a decision analysis (probabilities, utilities, problem structure) are subjective, they must come from someone. However, in societal decisions, there is rarely one entity (i.e., individual, organization) that is the final arbiter of these questions. When more than one set of utility or probability judgments must be

considered, decision analysis may be used in one of several ways to guide acceptable-risk decisions.

For a start, the analyst can prepare several complete analyses, each reflecting the perspective of one party....

Another approach is to try to generate agreement on the judgments needed to produce a consensual analysis.... That consensus could be seen as representing the views of a hypothetical Supra-Decision-Maker.

... a Supra-Decision-Maker (might also be used) even when the various parties cannot agree .... Integrating different values would require the assumption, often made by public policy makers, that they can accurately reflect an entire society's values....

Extended discussions of various aspects of the theory and practice of decision analysis may be found in Raiffa (1968), Keeney and Raiffa (1976), Howard, Matheson, and Miller (1976), and Behn and Vaupel (1982). Fischhoff *et al.* (1980) discuss the advantages and limitations of decision analysis--and other approaches to decision-making—in setting health, safety, and environmental policies.

EXAMPLES: Four Illustrative Applications

I know of no instance of "thorough decision analysis," as described above, being used to set a health, safety, or environmental standard. There have, however, been a number of illustrative applications. Two often-cited examples are (1) an analysis of the decision to seed hurricanes (Howard, Matheson, and North 1972), and (2) an analysis of the problem of chronic oil discharges in the North Sea (von Winterfeldt 1978).

In addition, a report to the Assistant Secretary for Environment of the U.S. Department of Energy describes a "methodology for evaluation of intertechnology tradeoffs" that is essentially a kind of decision analysis (Buehring *et al.* 1980). A follow-up report (Whitefield *et al.* 1980) presents "an illustrative case study":

> The problem is to select the best R&D strategy for developing long-term energy technologies that use coal. Best is defined in terms of 11 attributes, or measures of performance. Uncertainties were determined for the many, complex outcomes that may result from each strategy, and the information was systematically structured for evaluation. Preferences for the various outcomes were quantified by assessing a multiattribute utility function over the 11 single attributes. The best alternative was chosen using maximization of expected utility as a guide. Extensive sensitivity analyses showed that one strategy, evolutionary development, was best over a wide range of plausible assumptions. This is partly because the alternative coal technologies are quite similar. However, the insights gained justify the

extra effort spent in doing the utility analysis.

The 11 attributes were:

1) R&D costs,
2) Electricity costs,
3) Coal-mining health and safety impacts (measured by person-days lost),
4) Coal transportation accidents (measured by person-days lost),
5) Premature deaths from air pollution,
6) Solid waste production,
7) Water consumption,
8) SO_2 pollution,
9) NO_x pollution,
10) Particulate air pollution,
11) Global climatic effect of CO_2 (measured by tons of CO_2 emitted).

A fourth noteworthy study was written by Dyer (1978). Dyer prepared an evaluation of "several decision analysis techniques as potential aids in managing the occupational health and safety activities of the U.S. Navy." In his report, "a hypothetical example" of how decision analysis "might be applied to a specific problem, the exposure of workers and others to asbestos fibers" is discussed, in general terms.[4]

[4]Dyer later served as a consultant in the design of a "Management Procedure for Assessment of Friable Asbestos Insulating Material (U.S. Navy 1980). Although the procedure reflects the wisdom of decision analysis, no description is given of how decision analysis was used in

D. *AD HOC* BALANCING

Many health, safety, and environmental standards are set by *ad hoc* procedures that balance multiple objectives, using quantitative methods to some extent, but ultimately relying on judgments. Calculation of various kinds of costs and of benefits and some comparison of costs and benefits are a part, but only a part, of such methods: decision makers are given a vector of information rather than a single net benefit estimate.

The EPA endorsed this kind of procedure in its document (44 Federal Register 58642) on "National Emission Standards for Identifying, Assessing and Regulating Airborne Substances Posing a Risk of Cancer" (1979):

> In contrast to the zero-oriented and fixed-decision rule approaches..., "judgmental" approaches posit that the degree of control which is appropriate for airborne carcinogens cannot be predetermined in the abstract for all cases and, to some extent, depends on the particular circumstances. Circumstantial factors which might be considered, in addition to the risk to public health, include the costs of further control, the benefits of the activity, the distribution of risk versus benefits, and the availability of substitutes.
>
> The use of a judgmental approach appears desirable to the Administrator because it permits him to take advantage of the strong points of various available approaches without suffering

designing the procedure.

their drawbacks...

> Although protection of public health must be paramount, the relative importance of other factors can vary. Society may be willing to pay more for control or accept higher health risks associated with activities viewed as important or essential. The distributional aspect of a control situation can differ even when the magnitude of risk, costs and benefits are similar. Moreover, differing degrees of certainty in the cancer incidence, economic, and benefits estimates can call for different regulatory responses. Given this variety of circumstances and the frequent uncertainty of analyses, the Administrator believes that such responsibility, while heavy, is unavoidable if protection of public health is to be maximized within the constraints of a world of finite resources.

EXAMPLE: Power Lawn Mowers, Revisited

As discussed above, a variety of cost-benefit analysis calculations were done as part of the CPSC's deliberations concerning its "safety standard for walk-behind power lawn mowers." The Commission, however, did not justify its standard on the basis of these calculations; rather the Commission followed the more general "*ad hoc* balancing approach." As reported in the Federal Register (44 Federal Register 9990 ff), the Commission considered:

(1) The degree and nature of the risk of injury (the standard) is designed to eliminate or reduce.

(2) (The nature of) consumer products subject to the rule.

(3) Need of the public for the products subject to the rule.

(4) Probable effect of the rule upon the utility of the product.

(5) Probable effect of the rule upon the cost of the product.

(6) Probable effect of the rule upon the availability of the product.

(7) Alternative methods ... for achieving the objective of the standards.

The Commission then justified its decision as follows:

> Therefore, after considering the anticipated costs and benefits of (the standard) and the other factors discussed above, and having taken into account the special needs of elderly and handicapped persons to determine the extent to which such persons may be adversely affected by the rule, the Commission finds that (the standard) is reasonably necessary to eliminate or reduce the unreasonable risk of injury associated with walk-behind power lawn mowers and that promulgation of the rule is in the public interest. (44 Federal Register 9990).

No explicit tradeoff analysis of the kind used in decision analysis or the kind implied by cost-benefit analysis is mentioned; the tradeoffs were apparently made by the Commissioners using their "judgment."

EXAMPLE: Noise Labeling

Labeling requirements were included as part of the Noise Control Act of 1972 (42 U.S.C. 4901 *et seq.)*. Section 8:

> states that the Administrator of the Environmental Protection Agency shall promulgate regulations designating and labeling products or classes of products which emit noise capable of adversely affecting the public health or welfare or which are sold wholly or in part on the basis of their effectiveness in reducing noise. (42 Federal Register 31722).

The EPA wanted to create a label that was a simple as possible. However, the issue of whether a noise level had an adverse affect on health had to be approached on a product-by-product basis. The EPA devised a set of twenty criteria for selecting initial candidates for noise labeling, including:

- Is the product noise level sufficiently high to be potentially capable of producing an adverse health or welfare impact?
- Dose the product noise affect a large number of people?
- Is the noise from the product likely to impact more non-users (i.e., third parties) than purchasers and/or users?
- Is there a high frequency of purchase so that purchasers have the opportunity to use the labeled noise information often in making a purchase decision:

-- Would Federal labeling be a significant improvement on any existing product noise labeling:

-- Is there a readily available measurement methodology for the products types? (44 Federal Register 56122).

Despite the long and complex list of criteria, the Federal Register notice implies that the EPA did not believe that this would be an expensive regulation to implement; rather, the EPA believed that only a relatively small staff was required and that enforcement would be relatively simple. Apparently, reliance was to be placed on *ad hoc* balancing and the judgment of the responsible officials in synthesizing and making tradeoffs among the various criteria.

IV. THE POLITICAL SCIENCE PERSPECTIVE

Most political scientists--and most politicians as well--believe that all three of the images discussed so far, from the natural science, engineering, and economics perspectives, are over-simplified because these images do not emphasize the dynamics of political interaction. Like other major social decisions, health, safety, and environmental standards are set by a complex, iterative process involving numerous players contending in the political arena. The EPA Administrator, for instance, has severely circumscribed decision-making powers since he or she has to perform a complex balancing act to avoid antagonizing too many other power-holders, both within the Agency and outside. Congress determines budgets and can change statutes: Congress as a whole, the relevant oversight committees, and the key members and staff of these committees represent various levels of Congressional authority. The White House, represented by the domestic policy staff of the President and by the Office Management and Budget can wield great power when the President decides to exercise it. Various business, labor, environmental, and consumer interest groups gain leverage through their influence on Congress, the courts, and the White House, exerted through the press, through lobbying, and through campaign support.

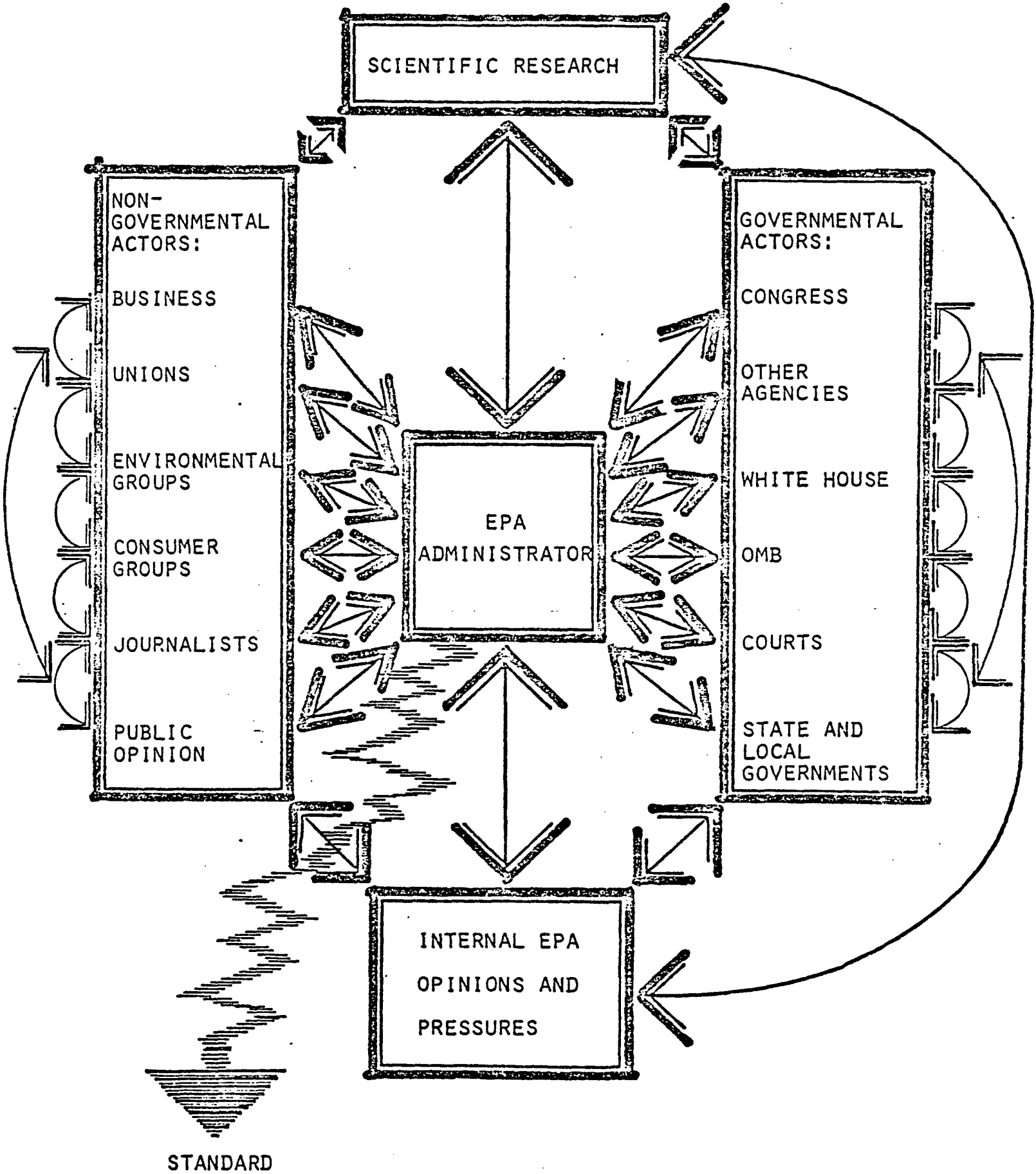
Most political scientists agree that the process not only does but also *should* work this way in a liberal, pluralistic democracy. Natural scientists, economists, and other experts are seen as actors in the on-going political process, partially affecting environmental standards with their judgments, but in turn, being influence by the other actors and by the

changing climate of opinions. Figure 4 caricatures this image: an assiduous political scientist would include many more boxes and arrows and would attempt to convey the continuing flow of the evolving process.

Natural scientists, engineers, economists, and other experts often slip unintentionally into an undemocratic arrogance. If reminded, however, of the severe short-comings of their knowledge and methods, and of the many advantages of a liberal society, at least the more realistic and judicious experts would have to agree that it would be a mistake to place health, safety, environmental policymaking in the hands of a scientific elite insulated from politics. Even if experts could determine all the necessary facts about health, environmental, and economic effects with precision and consensus, and even if experts could be trusted to be honest, unbiased and disinterested, social value judgments would still have to be made in setting standards. Different standards will benefit some people more than others and will be more consistent with some ethical beliefs and ideological perspectives than with others. In a democracy, such conflicts among competing interests and objectives are resolved by political process in which many individuals have a voice.

Given this perspective, political scientists tend to do research that is largely descriptive: how *are* health, safety, and environmental standards actually set?; what factors *explain* the standards set? Often the descriptive research is justified not only as being interesting *per se*, but also as being a necessary basis for efforts to reform decision-making procedures and institutions.

Figure 4: Environmental Standard Setting from the Perspective of Political Scientists



Political science research often requires painstaking and systematic detective work, since health, safety, and environmental standards are the resultant of a multitude of decisions made by numerous individuals. This process may be so intricate and involuted that even the most savvy insider within the agency and the most astute observer outside only partially understand it. Often it turns out that certain factors that play a major role only appear "obvious" after some deep thinking has uncovered them. For example, McKean (1980) conjectures

> that the CPSC gives high priority to several projects with low benefit-cost ratios--power mowers, gas space heaters, upholstered furnitures, and television sets--because the products appear to be *comparatively* easy to regulate, requiring the monitoring of relatively few producers.

It may be that even the commissioners of the CPSC do not realize how important this factor has actually been in their decisions.

EXAMPLE: Water- Pollution Effluent Standards

An on-going research project at Resources for the Future, Inc., seeks to develop a theory "which possesses explanatory and predictive power" concerning "rulemaking in a regulatory agency." (Magat 1979). As a case study, the project focuses on how EPA in the period from 1973 to 1976 "promulgated effluent standards for industrial (water) discharges based on 'best practicable control technology currently available (BPT)'":

> The BPT rulemaking process at EPA was selected as an example for several reasons. EPA is perhaps the most important new "social" regulatory agency, while the BPT water standards affected much of American industry. Also the rulemaking process developed to promulgate BPT standards has served as a model for other rulemaking activity at EPA, both in water and air, and at other federal regulatory agencies that promulgate technology-based standards. In addition, the data on BPT standards are rich enough to allow the use of statistical analysis to test empirically the hypothesis about the rulemaking process generated (by this project).

One study completed as part of this research project notes:

> The effluent guidelines rulemaking process provides an excellent example both of the discretionary power conferred on rulemakers in implementing legislation and of the relationship between the degree of economic impacts and the specifications of the rules. EPA administrators found it necessary to define and extend critical elements of the Water Pollution Control Act Amendments of 1972 to make the policy operational. The particular way in which "best" and "practicable" were defined, for example, as well as the administrative structure of the rulemaking process, unquestionably affect the success of the program and its efficiency and equity impacts on industry. (Magat *et al.* 1980).

As part of the study, a model of EPA decision making developed:

> ... let us assume that EPA attempts to maximize the strength of the external signals it receives from political pressure of all types. In (the) stylized version where citizens vote either for regulators or for elected officials who directly control the regulatory decisions, EPA would be assumed to select decisions to maximize votes. Two groups primarily determine the level of external signals or the vote margin, M-- the n water users who benefit from clean water and the m polluting firms in the industry which discharge wastes into the water. Clearly groups other than water users benefit from clean water (e.g., abatement equipment suppliers) and groups besides polluting firms benefit from dirty water (e.g., customers of the polluting firms pay lower product prices). All such groups are combined into these two categories to simplify the analysis of the problem. EPA is assumed to maximize the level of external support, or votes, rather than to be satisfied with gaining a "sufficient" number (e.g., fifty-one percent) because the level of support or votes it receives is highly uncertain. More support or votes allows more assurance of maintaining the members' jobs, expanding the agency's powers, being allocated higher budgets and larger staffs, and the like. (Magat *et al.* 1980).

The authors argue that:

> Such a theory is a logical first step for reform in the rulemaking process, for it helps us predict how specific changes in the process would affect the outcomes, e.g., the stringency of the standards. Regulatory rulemaking reform is difficult without a good model to provide an understanding of the process because the model links the inputs (e.g., information from various sources) and the time of those inputs to the outcomes of the process (e.g., decisions about which pollutants to regulate, how finely to divide up each industry into subcategories, and the effluent discharge standards for each pollutant in each subcategory) (Magat *et al.* 1980).

EXAMPLE: Swine Flu

In the example discussed above, a mathematical model is being developed; regression analysis is being used to fit the model to the available data and to test the explanatory power of the model. Although the research is largely being done by individuals trained in economics, it is political science research, albeit of a somewhat more mathematical and formal kind than customary.

Another useful kind of political research presents an "analytical narrative" of some decision or decision process. Excellent examples are Allison (1971) and Redman (1973). More directly relevant to health, safety, and environmental decision making is a superbly-researched report, commissioned by then Secretary of HEW Califano, that "anatomized the swine flu affair--in search of lessons for the future" (Neustadt and

Fineberg 1978). As noted in the forward to that report:

> The swine flu program of the Federal government was launched in March 1976 with a White House announcement by President Gerald R. Ford....
>
> The National Influenza Immunization Program, the official title for this venture, was unprecedented in intended timing and in scope among American immunization efforts. It aimed at innoculating everyone before December 1976 against a new flu strain that might conceivably become as big a killer as the flu of 1918, the worst ever ...
>
> The killer never came. The fact that it was feared is one of the many things to show how little experts understand the flu, and thus how shaky are the health initiatives launched in its name. What influenza needs, above all, is research.

Decision-making for the swine flue program had seven leading features. To simply somewhat, they are:

– Overconfidence by specialists in theories spun from meagre evidence.

– Conflict fueled by a conjunction of some preexisting personal agendas.

– Zeal by health professionals to make their lay superiors do right.

– Premature commitment to deciding more than had to be decided.

– Failure to address uncertainties in such a way as to prepare for reconsideration.

– Insufficient questioning of scientific logic and of implementation prospects.

– Insensitivity to media relations and the long-term credibility of institutions.

V. THE POLICY ANALYSIS PERSPECTIVE

It is time to shift gears. So far, I have tried to be descriptive--to factually explain four different kinds of perspectives on health, safety, and environmental standard setting and to provide the reader with some guidance to the relevant literature. My descriptions have been brief and are more sketches and caricatures than detailed portraits. Nonetheless, I have tried to be even-handed and non-judgmental, in order to give some insight into four different mind-sets.

The natural science, engineering, and economics perspectives are consistent in that they all envision a health, safety, or environmental standard as being a decision. Thus, it is natural from these perspectives to imagine the decision being made by a single "decision maker" who is given some facts and then decides what to do. Sometimes this "decision maker" is thought of as a person who has some discretion and can exercise some judgment; sometimes the "decision-maker" is, in effect, a formula or rule; sometimes the "decision maker" is a reification of the consensus of a group of individuals.[5] In any case, the implicit image is that of a decision rather than that of a decision process. Table 1 summarizes the various approaches discussed in this report that fit into this single-decision mode.

Fischhoff *et al.* (1980) offer an excellent "critical analysis of the viability of various approaches as guides to acceptable-risk decision." They consider most of the approaches listed in Table 1, and although their implicit focus is more on the needs of the Nuclear Regulatory Commission

[5]Cf. the discussions of "supra-decision-makers" in section III.A. above.

Table 1. A Typology of Risk-Evaluation Methods

Methods that Allow the Decision Maker:	METHODS FROM: Natural Science Perspective	Engineering Perspective	Economics Perspective
Little Discretion	+ Zero Risk + Natural Level of Risk + De Minimus Risk	+ Lowest Detectable Levels	+ Cost-Benefit Analysis, Narrowly Defined
Some Constrained Discretion	+ Health Threshold Levels	+ Best Control Technology	+ Cost-Effectiveness Analysis
Considerable Discretion	+ Comparative Risk + Judgment of Health Professionals	+ Engineering Judgment	+ Decision Analysis + Ad Hoc Balancing

than on the needs of the EPA, they have much to say that is relevant to standard setting. One of the most useful aspects of their report is that they critique various decision-making methods in terms of seven distinct criteria:

- comprehensive,
- logically sound,
- practical,
- open to evaluation,
- politically acceptable,
- compatible with institutions, and
- conducive to learning.

I do not think it is worthwhile for me to summarize this report more than I have, for two reasons. First the report is so excellent that it should be carefully read in full by anyone seriously interested in methods of health, safety, and environmental decision-making. Second, the report fails to consider the political science perspective and thus, to my mind at least, is only indirectly relevant to the decisions that have to be made by the Office of Air Quality Planning and Standards of the EPA.

This second argument implies a criticism not only of the Fischhoff *et al.* report, but also of all the various methods listed in Table 1. There *are* a vast variety of health, safety, and environmental decisions that are essentially made by a single decision maker. Consider, for example, all the personal decisions about whether to fasten a seat belt, whether to eat eggs, whether to install a smoke detector in a home, whether to jog, etc.

And consider all the social decisions that are delegated to professionals, eg.g., decisions made by architects, engineers, physicians, industrial chemists, and so on. But I do not think that the setting of national ambient air quality standards by the EPA can usefully be viewed as being made by a single decision maker; these standards are so important that, as any political scientist could predict, they are the resultant of a complex process of interplay among many actors.

This by no means implies that the various methods listed in Table 1 are of no interest or value, even for decisions embedded in political processes. At the very least, they may be useful in *justifying* standards. Federal regulatory agencies are required by law to explain most of their regulations in the Federal Register. In addition, most important regulations are taken to court: the agencies then have to defend their regulations in judicial review. The rationales used in the Federal Register and in court do not have to detail exactly how the regulatory decision was reached; the rationales merely have to justify the regulations in terms of existing law. The natural science, engineering, and economics perspectives may be appropriate for this kind of regulatory justification, since a regulatory standard, once reached, is, in effect, a decision that can be envisioned as having been made by a single decision maker.

Given, however, the reality (and desirability) of complex, democratic political processes, can the standard-setting insights of natural scientists, engineers, and economists be used in actually setting air quality and other major standards. I think some of them can, to some extent. My thinking here is based on a fifth perspective--the policy analysis perspective. The following part of this report explains this point of view.

A. A FIFTH IMAGE

A follower of the small and relatively new discipline known as policy analysis would not begrudge natural scientists and engineers credit for their key roles in health, safety, and environmental standard setting. A policy analyst would also sympathize with the economists' concern about costs and tradeoffs. And a policy analyst would agree with political scientists that most important health, safety, and environmental decisions are and should be produced by the interaction of a large number of actors who jointly determine the trajectory of a policy.

The policy analyst, however, would view this interactive process not descriptively, but prescriptively from the following perspective. Consider one of the actors in the process--not necessarily the Administrator of the EPA, but perhaps a deputy assistant administrator, or perhaps a Congressman, an official in the Office of Management and Budget, the leader of an environmental organization, or the Vice President for governmental relations of a large corporation. Furthermore, consider this actor at some specific time when he or she has some discretion and thus has to make a choice about what to do. The choice does not have to concern which environmental standard to recommend--decisions also have to be made about how to influence, constrain, persuade, and educate others, about how to enforce decisions, about what kinds of authority to delegate and to whom, about what new information to gather, if any, about how to monitor and evaluate current policies, about how to defend policy decisions before courts, legislatures, superiors, outside interests, and the public and so on. The policy-analysis question is: What kinds of informa-

tion and analytical assistance might this decision maker find useful in helping him think about his particular decision problem?

This question constitutes a good, short definition of what is often meant by "policy analysis." Moore (1980) gives a similar, if somewhat broader, definition; he equates policy analysis with "the task of providing information useful in making policy choices." In this paper, "policy analysis" will be used in the narrower sense of "the tasks of providing information (and analytical assistance) directly useful to particular decision makers in making particular choices that influence the trajectories of public policies." The tasks included in Moore's definition but excluded from mine might be called "policy-relevant analysis."

B. A SUGGESTIVE ANECDOTE

That the policy-analysis perspective is far from obvious or trite was brought home to me at a doctoral examination. I was asked to help question a student who was studying environmental policymaking in a graduate department of environmental studies. The student, whom I had not met beforehand, had several years practical experience as a former employee of the EPA. I asked him the following question. The Administrator of the EPA has to make a decision shortly concerning which national ambient air quality standard to recommend for ozone. He has asked you to prepare him a memo to help him make this decision. How would you organize the memo and what would you include in it?

The student had three days to prepare an answer to this question, as well as some other questions posed by other examiners. He came back with an outline of his memo to the EPA Administrator. This outline, which ran on and on for ten pages, was largely devoted to an impressively detailed breakdown of the results of various scientific studies of the health effects of ozone; a brief final section summarized the results of studies of "methods of control and costs."

Later, I asked an economics student, who had some familiarity with environmental issues, the same question. Her reply essentially was that she would do a cost-benefit analysis. She would first estimate the costs of a fairly broad range of standards. Then she would estimate the monetary value of the health and environmental benefits of this range of standards. Finally, she would calculate the standard such that the estimated marginal costs just equaled the estimated marginal benefits.

Still later, I posed the same question to a group of students, in a policy-analysis seminar, who had done some reading about the ozone issue. The gist of their proposed memo ran roughly as follows:

> Currently, the national ambient air quality standard for ozone is 0.08 parts per million. Business is pushing for a relaxation to 0.16 p.p.m.; environmental groups want to maintain or even tighten the current standard. As discussed in section A, the available scientific and economic evidence, the weight of precedent, the balance of political pressures, and the protection of the agency's political base and internal morale constrain you to three possible recommendations--0.08, 0.10, or 0.12 p.p.m. The

nature, distribution, and uncertainty surrounding various health and environmental benefits, economic costs, and political benefits and costs of 0.10 vs. 0.08 and of 0.12 vs. 0.10 are described in sections B and C. If you propose 0.08, you will probably be forced to retreat to 0.10 or even 0.12: strategic considerations of this sort are discussed in Section D.

C. THE DIFFERENCES BETWEEN SCIENCE AND POLICY ANALYSIS

This example is idiosyncratic, and like Figures 1, 2, 3, and 4, a caricature. And, of course, none of the students I questioned had a detailed--or entirely accurate--understanding of the ozone issue. Nonetheless, I believe the anecdote is suggestive. Many natural scientists have a tendency to view policy problems in terms of a listing of the facts rather than a listing of the decision alternatives and the consequences of those alternatives. Many economists are willing to march relentlessly to a single cost-benefit comparison, rather than presenting an array of different kinds of advantages and disadvantages. Any many scientists and economists confuse the general question of what is the socially optimal policy concerning ozone with the very specific question of what kinds of information a particular decision maker, with particular responsibilities and interests, at a particular moment in history and in a particular political context, might want to have to help him think about his particular decision problem.

Policy analysts are second-cousins to product designers, architects--and engineers. But they are not *social* engineers who envision themselves as supra-decision-makers maximizing the public interest; rather, they are *client- oriented* engineers who are helping some particular decision maker play his specific role in a complex political process. Policy analysts are thus related to physicians who care for patients but have little in common with biomedical researchers. Policy analysis is more craft and art than science, albeit it is an analytical craft and an art informed by research.

Some of the main contrasts between scientists and policy analysts might be summarized as follows:

- Scientists--and this includes not only natural scientists but also economists and other social and behavioral scientists in their role as scientists--seek to discover the truth; policy analysts seek to marginally improve the consequences of particular decisions.
- Scientists worry about statistical significance; policy analysts worry about social significance.
- Scientists are descriptive; policy analysts are prescriptive.
- The agenda for scientific research is set by the location of the points on the frontier of knowledge where breakthroughs are believed likely: the agenda of a policy analyst is set by the dilemmas faced at the moment by a specific decision-making client.

- Scientists rarely have to confront tradeoffs among conflicting objectives; such tradeoffs are the meat of policy analysis.
- Science aims for objective results; policy analysis is fundamentally subjective and deeply embedded in politics.
- Scientists strive for generalization, parsimony of theory, and elegance of formula; policy analysts focus on the specific details of unique problems.
- Scientists persevere in their research until the results are publishable; policy analysts attempt to do the best they can in the all-too-short time available.
- Scientists rejoice in research projects of breathtaking scope and grandeur--a theory of gravity, say, that governs atoms as well as galaxies or a theory of market transactions that explains the price of wine in 1920 in Canada as well as the price of wheat in 1990 in Portugal; policy analysts, to conserve their meager analytical resources, frugally tailor their highly selective and incomplete studies to focus on those few elements of a specific dilemma about which a particular decision maker is uncertain or perplexed.

Economists and other social scientists often enter into political debates--and think of themselves as policy analysts. But economists and other social scientists are also scientists. This dual role is the cause of much confusion. As penetratingly described in an essay on "Social Science and Policy Analysis: Some Fundamental Differences" (Moore 1980):

> In the typical social science publication, elaborate efforts are made to establish some relationship among some variables--say drug abuse and crime. The discussion of the data and methods of investigation is careful and restrained. The current investigation is placed in the context of other theories and findings. All this is consistent with the desire to build firm structures of knowledge slowly and carefully. Once the author has painstakingly established the existence (or non-existence) of a relationship, however, he turns to the "policy implications" of his finding. At this moment all the caution that characterized his analysis often leaves him, and he rushed toward conditionally prescriptive propositions at a pace that would make a serious policy analyst blush. Suddenly, goals are being suggested and governmental action conditionally prescribed all on the basis of *one* more or less firmly established empirical finding.

The author of this essay concludes that social scientists, if they were more aware of the nature of policy analysis, could be more constructive policy analysts. A more pessimistic conclusion seems at least equally justified: the differences in methods, perspectives, and concern for truth vs. consequences between (social) science research and policy analysis are so profound that only rare ambidextrous geniuses will excel at both.

D. THE METHODS OF POLICY ANALYSIS

Most policy analyses are at least as qualitative as quantitative. The analyses suggest a framework of thought, they structure the decision alternatives, they describe the most important impacts of the alternatives, and they provide some guidance as to the most important tradeoffs that have to be made. Sometimes the impacts and uncertainties surrounding the impacts are summarized numerically; other times, crude qualitative rankings suffice (e.g., do asthmatics fare better, about the same, or worse with policy A vs. B). Partial simplification of the array of costs and benefits may be made by collapsing sets of similar costs and benefits--not necessarily collapsing 20 different cost figures and 20 benefit figures down to one cost and one benefit figure, but, say, collapsing 20 cost figures into 4 cost indices and 20 benefit figures into 6 benefit indices. By simplifying a morass of data down into a manageable set of summary indices, the decision maker may be in a better position to concentrate his or her attention on the crucial tradeoffs among a few incommensurable indices. The choice is not between no collapsing of costs and benefits and a mindless drive to a single number: Partial analyses can be used to highlight just where political and social judgments have to be made.[6]

How, then, does "policy analysis" differ from some of the decision-making methods described earlier? Clearly policy analysis involves balancing competing objectives; clearly it gives a decision maker consid-

[6]This paragraph is based on a draft, unpublished report prepared by the Committee on Risk and Decision Making of the U.S. National Academy of Sciences.

erable discretion and relies heavily on a decision maker's judgment. Consequently, policy analysis can be compared with the kind of comparative risk analysis recommended by Dorfman's pesticide committee, with decision analysis, and with *ad hoc* balancing. It is hard to draw sharp boundaries here. Nonetheless, the spiritual heartlands of these three methods, as described above, are distinct from the spiritual heartland of policy analysis. The key difference is that the three methods--again, to avoid misunderstanding, let me emphasize *the three methods as described above* --focus on the general problem of what is the socially optimal policy with regard to some health, safety, or environmental problem, whereas a policy analysis focuses on the specific problem faced by some particular decision maker who is part of a complex political process.

This distinction means, in large part, that policy analyses include idiosyncratic political considerations, whereas the other kinds of analyses do not. For example, neither the comparative risk analysis suggested by Dorfman's committee, nor any of the four illustrative applications of decision analysis to hurricane seeding, North Sea oil spills, asbestos, or coal-energy research, nor the *ad hoc* balancing examples involving lawn mowers and noise labeling--none of these include any mention of specific political factors and constraints, not even on so abstract a level as how many Congressional districts will be adversely affected, let alone on so specific a level as "how will Kennedy react?"

Decision analysis, both in its more and less formal variants, *can* take into account idiosyncratic, political factors. Indeed, I have co-authored a book (Behn and Vaupel 1982) that is largely about how to apply decision analysis to the kinds of specific problems faced by policymakers. But this

kind of decision analysis is quite distinct in flavor from the "thorough," "full-blown", "societal" decision analysis described in, e.g., Fischhoff *et al.* (1980). The underlying methods are similar; the outlook, however, is that of a radically different mind-set. In short, decision analysis (and related analytical methods) can usefully be applied in policy analysis; but "full-blown" decision analysis should not be confused with policy analysis.

The relationship of policy analysis to comparative risk analysis or *ad hoc* balancing is of a different nature. In these two cases, policy analysis essentially takes over where the other two methods leave off. Policy analysis helps the decision maker *after* he or she has received the information provided by a comparative risk analysis. Similarly, policy analysis helps the decision maker think about the balancing of the various pieces of information requested by *ad hoc* balancing procedures.

VI. A DECOMPOSITION OF ROLES

"Policy analysis," as defined above, is clearly only a small part of the work of the EPA; it is a highly specialized task to be done by a relatively small number of individuals. Furthermore, policy analysis is, I think, only one aspect of "risk evaluation." In other words, the dichotomy I have drawn between policy analysis and scientific research by no means implies that natural and social scientists do not have crucially important roles to play in the process of health, safety, and environmental standard setting. Policy analysts are the people who help the various decision makers pick up the pieces and make do: if they had better and more appropriate information to work with, they could be of more help.

In the following sections of this report, I briefly lay out some of the various ways scientists and analysts can contribute to improving the quality of environmental (and other health and safety) decision making.

A. SCIENTIFIC RESEARCH ON EFFECTS

When asked to suggest useful research topics to inform environmental decision making, natural scientists and social scientists tend to think about the hottest topics in their own disciplines. They usually fail to consider research needs in terms of the information a policymaker might want, and they also tend to be far too narrow in the range of topics they suggest. In setting an environmental standard, a policymaker might be interested in a broad range of human health effects, including:

1. How many people are or will be affected:
    a. in the entire population?
    b. in sensitive groups?
2. How much are they affected by
    a. mortality,
    b. morbidity,
    c. severe pain and suffering,
    d. discomfort,
    e. anxiety
3. Who are they?
    a. age distribution.
    b. income distribution.
    c. race/ethnic background/sex.
    d. occupation.
    e. geographical location.
    f. quality of life/health status.
4. When will they be affected?
    a. now.
    b. with some time lag.
    c. future generations.

In addition, the decision maker may be interested in various impacts on plant and animal life and on the aesthetic quality of the environment.

Similarly, a policymaker might value input from social science research about a wide range of policy effects, such as:

1. Economic costs (and to whom),
2. Effects on economic growth, productivity, and innovation,
3. Effect on business competition,
4. Economic and political effects on other countries,
5. Effects on the distribution of income,
6. Effects on public satisfaction with government,
7. Legitimacy/fairness/symbolic importance as perceived by public,
8. Level and nature of political support and opposition,
9. Effects on the quality of business and personal decision making,
10. Ease or difficulty of justification
    a. in court,
    b. in Congress,
    c. to the President,
    d. to the public.
11. Enforcement costs, including costs of disrespect for the law engendered by unpunished violations.[7]

Because many natural scientists fail to appreciate the nature and value of social science, and because many social scientists confuse their role as scientist with their role as political participant and policy advisor,

[7]These two lists of considerations are based on a draft, unpublished report of the Committee on Risk and Decision Making of the U.S. National Academy of Sciences.

it is worth emphasizing that the role of social scientists in doing research about policy effects is exactly parallel to the role of natural scientists in doing their empirical research. This research is descriptive and predictive, rather than prescriptive and normative; it is the factual study of what is, rather than the evaluative study of what should be. As Max Weber (1946) painstakingly explained more than half a century ago, factual research is by no means value free: "the choice of the object of investigation and the extent or depth to which investigation attempts to penetrate into the infinite casual web, are determined by the evaluative ideas which dominate the investigator and his age." However, although the choice of topic and depth of study are subjective, the methods and results of factual study are objective in the sense that they are not "valid for one person and not others" but rather they are "valid for all who seek the truth."

Thus, the results of scientific research should be valid for all the various parties interested in environmental decision making--in Congress, the Courts, other agencies, state and local government, business, labor, public interest groups, academia, and the general public--regardless of their preferences, moral values, political beliefs, or ideological perspectives. A good piece of policy analysis, on the other hand, will incisively and concisely focus on the particular concerns of a specific decision maker.

Most scientists are not only parochial in their views about the nature and range of policy-relevant research on health effects, economic effects, social effects, and so on, but they also fail to appreciate that three other kinds of research can be as useful to policymakers in setting environmental standards as research on effects. This blindness is reflected in the

fact that hardly any of the EPA's internal research or sponsored research lies in these three areas and, indeed, relatively little research is being conducted here by anybody anywhere. Consequently, a few dollars of research support--by EPA, NSF, other agencies, or private foundations--in these three areas will almost surely yield disproportionately large harvests.

The three areas involve assessment, research about preferences, and research about policy design. Figure 5 lays out the relationships of these three kinds of research to each other, to scientific research about effects, and to policy analysis.

B. ASSESSMENT

The need for assessment arises because it so often turns out that the various facts uncovered by natural science and social science research are only indirectly relevant to the decision at hand, are in partial conflict with other facts, and are not sufficient or well enough established to remove uncertainty. For instance, evidence may be available about the effect of high doses of some environmental pollutant on rats, whereas the decision maker is concerned about the effect of low doses on humans. A number of rat experiments may have been done, some showing little or no effect and others a substantial effect. Evidence from epidemiological investigations of human populations may be so weak as to only suggest a wide probability distribution on the possible effects. Experts may have formed judgments about the possible effects, not on the basis of some single, objective experiment, but on the basis of their wide experience

with related phenomena: these judgments, although subjective, may be highly informative. Consequently, assessment involves the synthesis of disparate and indirectly relevant evidence, both objective and judgmental, in order to assess estimates or probability distributions of the quantities of primary concern in the decision problem. Assessment is not a substitute for evidence, but a systematic synthesis of the available evidence. Although assessment is partially judgmental, the judgment here is scientific judgment rather than moral or political judgment about what ought to be. Thus, like scientific research, assessments should, given this definition, be valid for all parties concerned about environmental policymaking.

The process of eliciting scientific judgments, of synthesizing these judgments with the available array of disparate and indirectly-relevant information, and of expressing the results, when necessary, in probabilistic terms requires specialized skills and methods that have largely been developed (to the extent they have as yet been developed) by mathematical statisticians, decision analysts, and cognitive psychologists. That the methods of assessment are, as yet, weak, that few people understand them, and that a great deal of research, development, and training is required cannot be denied. In any logical scheme of environmental policy analysis, however, it seems to me to be undeniable that the assessment phase plays a crucial role. Whether done well or poorly, assessment has to be done, even if it simplistically involves selecting the "best" study and making some extrapolations from it.

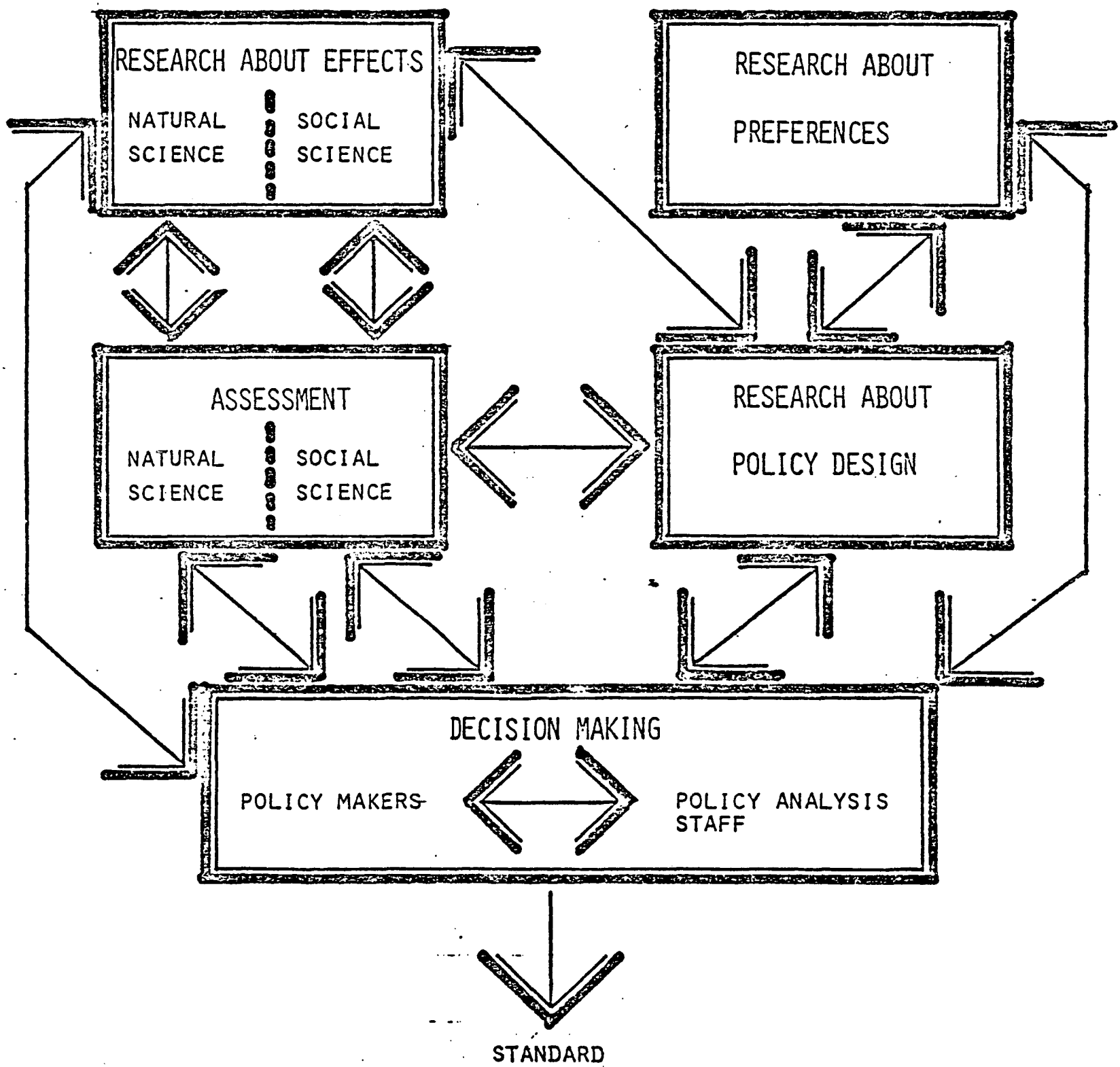
Since the EPA's Office of Air Quality Planning and Standards is conducting a major research prospect that focuses on the methods of assessment, it is not necessary to review those methods here. Nonetheless, the task of assessment is so crucial but so neglected that it seems appropriate to briefly point out four especially important but largely unrecognized research needs.

First, as indicated in Figure 5, assessment is required not only for natural science facts but also for social science facts, such as, for example, the cost of a regulation. Much of what research is being done to develop better methods of assessment focuses on natural science assessment; parallel research is needed on social science assessment.

Second, given that decision makers do not want to be inundated with information, a key set of issues in assessment involves how to aggregate and summarize information, including:

- How to summarize over different kinds of health and non-health effects (e.g., over different states of morbidity),
- How to summarize over effects on different individuals,
- How to aggregate and synthesize different experts' judgments,
- How to indicate the range of uncertainty,
- How to indicate the volatility of the estimates (i.e., how much new information might change the estimates), and
- How to indicate the degree of expert confidence, consensus, and disagreement.

Figure 5: A Decomposition of Roles in Environmental Standard Setting, from a Policy Analysis Perspective



Third, beyond the fact that policymakers tend to be busy, they also, like the rest of us, have limited cognitive abilities. For example, some policymakers may not have a good intuitive feel for what a gamma distribution with a shape parameter of 2 and a scale parameter of 3.5 looks like. Thus, in addition to pruning and synthesizing information, an assessment should present information in a way that is meaningful and intelligible to the intended audience. Tables 2a and 2b illustrate one way to present information in a fairly simple way on the morbidity effects of three alternative environmental standards. The tables are not intended to be an example to be followed, but rather an example of how much synthesis and simplification might be required to make the available factual information useful to some of the numerous decision makers who may be involved in setting a standard. Clearly, different kinds of presentations of information may be appropriate for different decision makers and members of their staffs.

Fourth and finally, although an important and widely used approach to the task of assessment is to convene a panel of experts--e.g., a National Academy of Science's committee or a panel of the EPA's Scientific Advisory Board--little is known about how to bring out the best of an expert committee. The internal dynamics of group behavior, coupled with external pressures, can lead to group reports that fail to capture the various experts' true judgments and uncertainties and disagreements about these judgments. It would be useful to do research on how an appropriate staff could be trained to help expert committees better understand the statistical methodology of assessment, the intricacy and subtlety involved in the elicitation of judgments, and the peculiar patterns of group behavior.

Table 2a. How Many People Will be Affected Under Alternative Standards

Standard	Percentage of U.S. population suffering one or more EDRA's* per year: Best Estimate	Percentage of U.S. population suffering one or more EDRA's* per year: 98% Credence Range	Percentage of most sensitive 1% of U.S. population suffering one or more EDRA's per year: Best Estimate	Percentage of most sensitive 1% of U.S. population suffering one or more EDRA's per year: 98& Credence range**
A	5%	1-30%	20%	3-50%
B	9%	2-41%	35%	5-62%
C	12%	4-49%	50%	10-74%

Table 2b. How Much Will People be Affected Under Alternative Standards

Standard	Average number of EDRA's per year suffered by U.S. population: Best Estimate	Average number of EDRA's per year suffered by U.S. population: 98% Credence range	Average number of EDRA's per year suffered by most sensitive 1% of U.S. population: Best Estimate	Average number of EDRA's per year suffered by most sensitive 1% of U.S. population: 98% Credence range
A	0.3	0.1-0.8	2.3	0.4-5.2
B	0.6	0.2-1.0	3.9	0.6-6.5
C	0.8	0.4-1.2	5.7	1.1-7.8

*An EDRA is an "Equivalent Day of Restricted Activity."

**The 98% credence range is the range such that there is a 98% chance that the true value falls within the range. Statisticians differ widely about how to define such ranges and how to assess them--and, indeed, many statisticians would dismiss such ranges as meaningless. I merely want to suggest here that a policymaker might be interested in some information about the uncertainties surrounding an estimate; whether this information is conveyed by a "credence range," "confidence interval" or some other device is, for my purposes here, not crucial.

It would, I believe, be highly productive for the EPA to devote a small fraction of its research budget--a few million dollars a year, say--to research on these four issues in assessment, as well as some of the statistical issues. Even when natural science and social science facts are plentiful, if these facts and resulting scientific judgments are not synthesized and presented adequately, decision makers are forced to make their choice in a dense fog of confusion and ignorance. Although, in some theoretical sense, a decision-maker's discretion may not be affected by the way a risk is assessed and presented, it seems clear that the nature and quality of the decision may be affected by how well the assessment procedure meets the decision maker's informational needs.

C. RESEARCH ABOUT PREFERENCES

Although neglected, objective research about subjective preferences, including ethical beliefs, political judgments, and ideological perspectives, is not a paradox but an activity highly useful and relevant to policymaking. The two fundamental sources of complexity and controversy in making environmental decisions are pervasive uncertainty and perplexing tradeoffs. The tradeoff problem is probably the more basis problem since continuing scientific research will tend to reduce the uncertainties and, in doing so, clarify--and hence heighten--realization of the competition between different objectives. Even if there were no uncertainty and the future could be foretold perfectly, decision makers would still have to wrestle with such puzzling questions as:

- How much of our limited resources should be allocated to life-saving activities versus other, pressing social concerns?
- How important is the psychological well being associated with clean air and blue skies?
- How much weight should be placed on an asthma attack suffered by a thirty-year old compared with a bout of emphysema suffered by a sixty-year old?
- How should our society react to saving the lives of 100 Americans a millenium from now versus 100 starving Africans today?
- Do we have the responsibility for maintaining ecological balances, for nature's sake rather than--or in addition to--for man's sake?
- Should we as a society be willing to impose costs and risks on a few members of society in order to benefit most members of society?
- What are the occasions when paternalism is a legitimate stance for governmental agencies?[8]

Since questions like these complicate all important environmental decisions, it is absolutely clear that there can and will never be an objectively scientific method for environmental decision making. Nevertheless, researchers may be able to help policymakers grapple with tradeoff problems, in several ways.

[8]This list is based on a draft, unpublished report of the Committee on Risk and Decision Making of the U.S. National Academy of Sciences.

First, researchers can trace out the consequences of adherence to different systems of preferences and values. More specifically, researchers can formulate persuasive systems of ethical axioms and then logically derive various normative conclusion. Three recent and widely read philosophical books, by Rawls (1971), Nozick (1974), and Ackerman (1980) do this starting from three different sets of basic axioms.

Second, researchers can check for consistency and coherence between different ethical beliefs. In particular, they can check whether some normative position (e.g., all carcinogens should be banned) is consistent with another ethical belief (e.g., that no policy should be undertaken that makes the worst off group in society even worse off). Arrow's impossibility theorem is a famous example of this line of research.

Third, researchers can describe and measure how various people view specific tradeoff problems, e.g., how much the general public and different interest groups are willing to pay for some aspect of environmental quality.

Fourth, researchers can develop methods to facilitate the sharing of different points of view among the various parties interested in some policy problem.

Fifth, researchers can develop formal analytical methods for structuring tradeoff problems. The most notable example is Keeney and Raiffa's book on *Decisions with Multiple Objectives: Preferences and Value Tradeoffs* (1976).

D. RESEARCH ABOUT POLICY DESIGN

A diverse array of strategies can be employed to cope with health, safety, and environmental hazards, including:

- medical care,
- insurance and compensation,
- consumer demand,
- regulatory standards or bans,
- labeling,
- tort liability,
- tax penalities
- restrictions on behavior,
- collective bargaining,
- effluent fees,
- personal protective action,
- economic progress,
- biomedical research,
- safety engineering research, and
- risk analysis research.[9]

Although each of these strategies is, on occasion, useful, all of them suffer from serious limitations and deficiences. Consequently, it is useful to try to devise improved strategies, including better variations of existing stra-

[9]This list is based on a draft, unpublished report of the Committee on Risk and Decision Making of the U.S. National Academy of Sciences.

tegies and multiple, combined strategies.

Within narrower policy areas, policy design may also be useful. Consider for example, the setting of national ambient air quality standards. Such standards have to be defined

> in such a way that compliance with the standards can be operationally determined. [The standards] are stated in terms of time averaged pollutant concentrations and expected number of exceedences of those concentrations allowed per unit of time. (Feagans and Biller 1981).

Thus the "design" of a standard requires that choices be made about three inter-related quantities--averaging times, pollution levels, and allowable exceedences.

Policymakers usually want to be provided with a set of options that they can choose amongst. They do not want to be told what to do or to be constrained by an overly limited range of alternatives. By providing options, policy designers can play a valuable role in policymaking processes.

Architecture and engineering demonstrate that the endeavor of design is a complicated but rewarding pursuit. It is somewhat surprising, then, that policy design, as an analytical pursuit in its own right, has been so neglected, although some politicians, arbitrators, and mediators have acquired great skill at it. In any case, policy design is conceptually different from the other tasks diagrammed in Figure 5.

Policy design starts with an understanding of why various given alternatives are relatively strong or weak along different dimensions in order to fuel creativity about devising new alternatives. The understanding of pro's and con's can be gained, in part, by listening carefully to the various points of view expressed in a policy debate. Since these points of view are seldom diametrically opposed, with equal and opposite weight given to all objectives, it is often possible to design solutions that go considerably further than halfway in meeting each interested group's desires and demands. The policy debate might not thereby be resolved, but instead of a raging dispute between lackluster policy alternatives A and B, the debate could be raised to a more cordial disagreement between the innovative and superior alternatives C and D.

E. INTERACTIONS AMONG ROLES

Two-way communication will clearly be required among individuals engaged in the various roles sketched above and in Figure 5. If scientists are to provide policymakers with relevant factual information--whether about natural science effects, social science effects, or preferences--they have to have some idea of what the policymakers' interests are. This is true to an even greater extent for the assessors and for the policy designers who serve as bridges between the research community and the policy community. To the extent, however, that the reported results of the scientific endeavors of research and assessment become distorted by scientists' subjective preferences about the social good and the public interest they will cease to be the descriptive and objective truths that

constitute "science."

Scientific experts cannot and should not be disenfranchised from the political process. They hold value opinions and are entitled to have their voices heard. Indeed, it can be argued that scientists who can understand the biological, physical, or economic subtleties of complex policy questions have a special obligation to serve society by speaking out on controversial issues. Such scientists do society and the endeavor of science a disservice, however, if they fail to try to make clear where their scientific expertise ends and their non-expert value judgments begin. Otherwise, in the short run their personal opinions will receive too much weight and, in the long run, scientific research will become tainted, mistrusted, and discounted.[10]

[10]This paragraph is based on an unpublished draft report prepared by the Committee on Risk and Decision Making of the U.S. National Academy of Sciences.

VII. CONCLUDING OBSERVATIONS

"Risk evaluation" is an umbrella phrase that encompasses a variety of concepts. A crucial distinction can be drawn between the risk-evaluation *processes* that produce health, safety, and environmental standards, and the risk-evaluation *justifications* that are used to explain, defend and advocate the resulting standards. The justifications are clearly not independent of the standard-setting process; the justifications are based, in large measure, on fact-finding and analysis done as part of the process. The justifications, however, do not have to recount, document, and defend all the details of the standard-setting process. The primary purpose of a risk-evaluation justification is to demonstrate that the standard meets the requirements of the relevant statutes; a secondary purpose may be to persuade various interested people that the standard is reasonable. On the other hand, the purpose of a risk-evaluation process is to *produce* a standard that is legally defensible and publicly acceptable.

The first three parts of this report surveyed a variety of approaches to risk-evaluation justification. The approaches were classified under the rubrics of the "natural science perspective," the "engineering perspective," and the "economics perspective"; in each category, various approaches were distinguished depending on how much discretion they allowed and how much judgment they demanded. The survey strongly suggests that there is no ideal approach to justifying a standard; rather, the approach that is appropriate depends on the nature of the hazard being regulated and on the details of the relevant statutes, including

their legislative history and judicial interpretation.

In the specific case of national ambient air quality standards, it appears that the only kind of justification that currently would be acceptable has to be based on some variant or other of the category of methods I have called "health-threshold approaches."[11] Consequently, an important part of the program of research on risk evaluation that is being sponsored by the EPA's Office of Air Quality Planning and Standards should probably focus on developing and refining an appropriate health-threshold approach. Three issues seem especially significant:

(1) How should the distinction be drawn between physiological responses of no health significance and responses deemed to be adverse health effects,

(2) How should the sensitive population be defined, and

(3) How should a margin of safety be determined?

Even though other kinds of approaches to risk evaluation may not be as appropriate in justifying national ambient air quality standards as a health-threshold approach, some of these other approaches may suggest ways to resolve these three open questions.

The second half of this report essentially focused on the risk-evaluation *process* that produces a standard. The essence of the research problem here is systematic study of how the capabilities of various kinds of scientists and analysts can be better harnessed to provide more relevant and helpful information and analysis to the various actors who

[11] See Section I.D.

play a role in interactively influencing the evolving trajectory of a policy.

Since the various actors play different roles, come from different backgrounds, and hold different values, it seems clear that it would be useful to produce a variety of different kinds of information and analysis. Furthermore, the problem of determining a reasonable standard is so complex that it is undoubtedly the case that an array of natural and behavioral scientists, engineers, economists, applied mathematicians, statisticians, decision analysts, policy analysts, and others, could all make a contribution.

The interactive character of risk-evaluation processes implies that the contribution of any particular kind of scientist or analyst will--and should--be limited. On the one hand, scientists who do not understand the complexities of policy formulation should not be permitted to usurp the legitimate role of policy analysts and policymakers. On the other hand, policy analysts and policymakers need to be informed by science and should be constrained by scientific and analytical findings. Furthermore, the risk evaluation process should be designed such that the policy analysts and policymakers are harnessed to serve the public interest rather than maximizing their private interests in a socially harmful way.

To clarify the nature of risk evaluation processes, the sixth section of this report developed a decomposition of roles--scientific research on effects, assessment, research about preferences, research about policy design, policy analysis, and decision making. The process of risk evaluation embraces all of these roles and their interactions.

Some aspects of this overall process of risk evaluation are better understood than others. I believe that a particularly important but relatively neglected field of inquiry concerns the question of what kinds of information should be generated, how should this information be presented, and what kinds of analytical assistance should be available in order to help the key policymakers responsible for proposing a standard. In the case of national ambient air quality standards, these policymakers would be the Administrator of the EPA and his or her leading policy advisors on air pollution.

A research program focusing on the information and analytical needs of policymakers clearly should be conducted with the close involvement of people with policymaking experience. Furthermore, it would seem appropriate to involve researchers from a number of disciplines, including decision analysis, policy analysis, cognitive psychology, and political and organization behavior.

In sum, my overall conclusions from this investigation of the theory and practice of standard setting is that a research program on risk evaluation organized by EPA's Office of Air Quality Planning and Standards could fruitfully focus on either improving the process by which standards are determined or on strengthening the logic of the justifications used to defend the standards. A program with sufficient funding might do both. In any case, it is important to distinguish process from justification. Furthermore, it is important to bear in mind: (1) that different kinds of processes and justifications will be appropriate depending on the hazard and the relevant statute, (2) that there are a variety of useful but limited roles to be played by several different types of scientists and analysts,

and (3) that different decision makers will have different informational and analytical needs.

REFERENCES

Ackerman, Bruce. 1980. *Social Justice in the Liberal State*. (New Haven: Yale University Press).

Allison, Graham. 1971. *Essence of Decision*. (Waltham, Massachusetts: Little, Brown).

Behn, Robert D., and James W. Vaupel. 1982. *Analytical Thinking for Busy Decision Makers*. (New York: Basic Books). (In press: manuscript available from Robert D. Behn, 4875 Duke Station, Durham, NC 27706, USA).

Buehring, W.A., R.G. Whitfield, and T.D. Wolsko. 1980. "Methodology for Evaluation of Intertechnology Tradeoffs," (Argonne, Illinois: Argonne National Laboratory Report ANL/AA-22).

Dorfman, Robert. 1981. "The Lessons of Pesticide Regulation," (Durham, North Carolina: Center for the Study of Business Regulation, Duke

University).

Dyer, James. 1978. "Applications of Decision Analysis to Occupational Health and Safety Problems," (Washington, DC: Office of Naval Research, Contract N00014-78-c-0589).

Feagans, Thomas B., and William F. Biller. 1981. "Risk Assessment for Primary National Ambient Air Quality Standards," (Durham, North Carolina: U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards).

Fischhoff, Baruch, Sarah Lichtenstein, Paul Slovic, Ralph Keeney, and Stephen Derby. 1980. "Approaches to Acceptable Risk: A Critical Guide", (Washington, DC: U.S. Nuclear Regulatory Commission, CR-1614).

Freeman, A. Myrick. 1979. *The Benefits of Environmental Improvement.* (Baltimore: John Hopkins University Press).

Graham, John D., and James W. Vaupel. 1981. "The Value of a Life: What Difference Does it Make?", *Risk Analysis*, vol. 1, no.1., pp.89-95.

Hopkins, Thomas D., and Gerald G. Threadgill. 1979. "Crash Protection for Auto Occupants", in Miller and Yandle (see below).

Howard, R.A., J.E. Matheson, and D.W. North. 1972. "The Decision to Seed Hurricanes," *Science*, vol. 176, pp.1191-1201.

Jennergren, L.P., and R.L. Keeney. 1979. "Risk Assessment", in *Handbook of Applied Systems Analysis* (Laxenburg, Austria: International Institute for Applied Systems Analysis, in press).

Jordan, Bruce C., Harvey M. Richmond, and Thomas McCurdy. 1981. "Regulatory Perspectives on the Use of Scientific Information in Air

Quality Standard Setting." Presented at the Annual Meeting of the American Association for the Advancement of Science, Eugene, Oregon, June 15-16.

Keeney, R.L., and H. Raiffa. 1976. *Decisions with Multiple Objectives.* (New York: John Wiley).

Lenard, Thomas M. 1979. "Lawn Mower Safety," in Miller and Yandle (see below).

Link, Mary. 1977. "Saccharin Ban Delay--Final Action", *Congressional Quarterly Weekly*, 12 Nov., p.2415.

Magat, Wesley A. 1979. "Rulemaking in a Regulatory Agency," (Durham, North Carolina: Center for the Study of Business Regulation, Duke University).

Magat, W.A., Alan J. Drupnick and Winston Harringon. 1980. "Regulatory Rulemaking in Theory and Practice", (Durham, North Carolina: Center for the Study of Business Regulation, Duke University).

Mallet, Roger J. 1979. "Emission Standards for New Motorcycles" in Miller and Yandle (see below).

McKean, Roland. 1980. "Enforcement Costs in Environmental Safety Regulation," *Policy Analysis*, vol. 6, no.3, pp.269-290.

Mendeloff, John. 1979. *Regulating Safety.* (Cambridge, Massachusetts: MIT Press).

Miller, James C. III, and Bruce Yandle. 1979. *Benefit- Cost Analysis of Social Regulation.* (Washington, DC: American Enterprise Institute).

Mishan, Ezra. 1976. *Cost- Benefit Analysis.* (New York: Praeger).

Moore, Mark H. 1980. "Social Science and Policy Analysis: Some Fundamental Differences" (Cambridge, Massachusetts: Kennedy School of Government, Harvard University).

Moreau, David H. 1980. "Quantitative Assessment of Health Risks by Selected Federal Regulatory Agencies" (Durham, North Carolina: U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards).

National Academy of Sciences. 1980. *Regulating Pesticides*. (Washington, DC: National Academy of Sciences).

Navarro, Peter J. 1980. "The Politics of Air Pollution," *The Public Interest*, Vol. 59, pp.36-44.

Neustadt, Richard E., and Harvey V. Fineberg. 1978. "The Swine Flu Affair," (Washington, DC: U.S. Department of Health, Education and Welfare).

Nozick, Robert. 1974. *Anarchy, State, and Utopia*. (New York: Basic Books).

Perez, Marilyn K. 1978. "Analytical Methodology and the Interface with Animal Drug Approval," *J. Assoc. Official Analytical Chemists*, vol. 6, no.5, pp.1183-1191.

Raiffa, Howard. 1968. *Decision Analysis*. (Reading, Massachusetts: Addison-Wesley).

Raiffa, Howard, William B. Schwatz, and Milton C. Weinstein. 1978. "Evaluating Health Effects of Societal Decisions and Programs," *Decision Making in the Environmental Protection Agency*, vol. IIb, (Washington, DC: National Academy of Sciences).

Rawls, John. 1971. *A Theory of Justice.* (Cambridge, Massachusetts: Harvard University Press).

Redman, Eric. 1973. *The Dance of Legislation.* (New York: Simon and Schuster).

Richmond, Harvey M. 1980. "A Proposed Framework for Qualitative Risk Assessment and Decision Analytic Approaches in the Review of National Ambient Air Quality Standards." Presented at the 73rd Annual Air Pollution Control Association Meeting, Montreal, Canada, June 22-26.

Richmond, Harvey M. 1981. "A Framework for Assessing Health Risks Associated with National Ambient Air Quality Standards," *The Environmental Professional*, Vol. 3, pp.225-233. (in press).

Rotow, D., T. Cochran, and A. Tamplin. 1978. "NRDC Comments on Criteria for Radioactive Wastes," (Washington, DC: Natural Resources Defense Council).

Smith, Robert Steward. 1976. *The Occupational Safety and Health Act.* (Washington, DC: American Enterprise Institute).

Thompson, Mark. 1980. *Benefit- Cost Analysis for Program Evaluation.* (Beverly Hills, California: Sage Publications).

U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards. 1981. "Conceptual Approaches to Health Risk Assessment for Alternative NAAQS." (Durham, North Carolina: US Environmental Protection Agency, Office of Air Quality Planning and Standards).

U.S. Navy. 1980. "Management Procedure for Assessment of Friable

Asbestos Insulating Material." (Washington, DC: US Navy).

von Winterfeldt, D. 1978. "Modeling Standard Setting Decisions: An Illustrative Application to Chronic Oil Discharges," (Laxenburg, Austria: International Institute for Applied Systems Analysis).

Weber, Max. 1949. *The Methodology of the Social Sciences*, ed. and trans. by E.A. Shils and H.A. Finch.

Weinberg, A.M. 1979. "Salvaging the Atomic Age," *The Wilson Quarterly*, Summer.

Whitfield, R.G., W.A. Buehring, M.J. Jusko, and T.D. Wolsko. 1980. "Application of a Methodology for Evaluation of Intertechnology Transfers", (Argonne, Illinois: Argonne National Laboratory ANL/EES-TM-127).

York, Elizabeth A. 1978. "Red Dye No. 2," (unpublished paper, Institute of Policy Sciences and Public Affairs, Duke University, Durham, North Carolina).

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Natural scientists, engineers, economists, political scientists, and policy analysts view the process of health, safety, and environmental standard setting from diverse analytical perspectives. This report describes these five perspectives; indicates why, how, and when each is useful; annd suggests a decomposition of appropriate roles in the standard-setting process for scientists and analysts with different interests and skills.

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