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A Survey of Safety Levels in Federal Regulation

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Abstract and Summary

Each agency regulating health or safety must set a safety goal, implicitly or explicitly. In some cases Congress has given specific guidance to work toward zero risk or to balance risks and benefits; more generally, Congress has given immense discretion to the agencies.

Eight frameworks for regulating health and safety are described: 1) market regulation, 2) no-risk, 3) risk-risk, 4) technology based standards, 5) risk-benefit, 6) cost effectiveness, 7) regulatory budget, and 8) benefit-cost analysis. All frameworks except (3) and (7) are currently used. Important issues in deciding which framework to select include: (a) the required amount of data collection, analysis and value judgments for each, (b) whether risk can be quantified in each case, (c) how each framework affects priority setting, (d) the residual level of uncertainty after analysis, (e) safety goals, and (f) the general costs of regulating.

We examine the legislation and case studies of the major health and safety agencies: CPSC, OSHA, EPA, and FDA. Extended treatment is given to FDA's regulation of food additives since there are many analogies with NRC's regulation. We find that, although there have been unfortunate cases and vast controversy, safety levels have been quantified by many agencies and used in their regulation. Perhaps the greatest difficulty has not been the ability to analyze and quantify risk, but rather the lack of safety goals from Congress. Congress, either directly or though agency oversight, must clarify the goals and framework for each agency in order to improve the quality of regulation.

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A SURVEY OF SAFETY LEVELS IN FEDERAL REGULATION

I. Introduction

In making policy decisions involving the use of nuclear technologies, the Nuclear Regulatory Commission is faced with the complex problems of assessing the risks associated with these technologies. In attempting to arrive at a workable notion of "acceptable" risk, the NRC confronts issues that in many respects are similar to those faced by other government agencies whose concerns involve health and safety. These issues center on the desirability and feasibility of setting quantitative safety goals. A large amount of evidence is now available on various approaches to the analysis of safety issues in policy making. In this report, we summarize the ways that a number of federal regulatory agencies have dealt with the problem of quantifying risk in their attempts to set, implicitly or explicitly, a safety goal.

The applications that we survey provide numerous examples that are directly relevant to NRC concerns. They include questions related to safety of technical design and failure due to operator behavior, as well as risks associated with hazardous materials and toxic substances. Some of the cases involve rather straightforward calculations, but others pose subtle and challenging questions of quantifiability and valuation. There is considerable variation in the degree to which the analyses we discuss succeed in providing clear and convincing assessments of the relevant issues. Nonetheless, the overall import of our survey is that a quantitative approach to the analysis of safety is not only feasible but is almost certainly the only meaningful way to sort out the many conflicting considerations involved in setting a safety goal.

Our survey is not intended to represent an exhaustive examination of safety regulation in federal agencies concerned with health and safety. This is an immense, complicated subject and this report can provide only a cursory view. Our primary goal has been to present a discussion of some frameworks for analysis, and to provide examples that usefully illuminate the strengths and weaknesses of each framework. In the remainder of this introductory section, we list the principal federal regulatory agencies concerned with safety and health regulation. In Section II we go on to describe six frameworks used for making health and safety decisions by these agencies and two additional frameworks that have been proposed. Section III highlights some

general considerations involved in implementing the frameworks. Section IV sketches the legislative mandates under which the principal agencies must operate. Section V presents examples of recent regulatory decisions by a number of agencies and attempts to infer the nature of the decision had the agency used one of the other frameworks. Finally, we attempt to summarize our findings in Section VI.

Aspects of health and safety are regulated by a large number of federal agencies. The principal agencies include:

- Consumer Product Safety Commission (health and safety aspects of consumer products): CPSC
- Food and Drug Administration (safety and efficacy of drugs and medical equipment, safety of food additives and contaminants, and of cosmetics): FDA
- Environmental Protection Agency (emissions and ambient standards for air, drinking water, toxic substances generally, insecticides, fungicides, rodenticides, ionizing radiation): EPA
- Occupational Health and Safety Administration (health and safety aspects of occupational exposure): OSHA
- Nuclear Regulatory Commission (civilian use of nuclear technology and materials): NRC
- Federal Aviation Administration (safety and health aspects of commercial and general aviation): FAA
- National Highway Traffic Safety Administration (highway accidents and equipment of vehicles): NHTSA
- Mine Health and Safety Administration (health and safety aspects of underground mining): MHSA
- Interstate Commerce Commission (safety aspects of buses and trains): ICC

In addition there are many agencies with lesser roles in regulating health and safety including:

- U.S. Coast Guard (safety aspects of boats in U.S. waters)
- Department of Energy (safety aspects of pipelines, liquid energy gasses): DOE
- Bureau of Standards (safety and health are integral in setting standards)

Simply listing the principal agencies and their principal responsibilities shows the possibility of extensive overlap. For example, ionizing radiation falls under the jurisdiction of EPA, DOE, and NRC; consumer products fall under the jurisdiction of CPSC, EPA, FDA, NHTSA, FAA, and other agencies. While Congress settled a small number of jurisdictional matters, such as forbidding CPSC to regulate automobiles or cigarettes, overlapping responsibilities pose a major problem. Each agency has its responsibilities, its pressure groups, and its priorities. Thus, OSHA and EPA undertook to regulate coke oven emissions at different time and their analyses rest on different premises. For example, EPA emphasizes quantitative risk assessment as an input to decision making while OSHA (at least until the benzene

decision) attempted to protect workers against any risk, even one that was so small as to be regarded as negligible by most people.

The role of the National Bureau of Standards and of other agencies that define standards or "good laboratory practice" is worth emphasizing. In setting such standards, one is implicitly setting safety and health standards. However, few of these agencies are aware of the health and safety implications of their decisions and these rarely are considered explicitly.

One common organizational model is research by one agency, standard setting by a second, and enforcement by a third. For example, the National Institute of Environmental Health Sciences (NIEHS), EPA, and DOE can form such a trio for ionizing radiation. More common is having one agency perform two of the three functions while another agency handles the third, e.g., National Institute for Occupational Safety and Health (NIOSH) and OSHA or FDA and USDA for food contaminants. Splitting the functions almost invariably leads to friction and inefficiency.

II. Alternative Regulatory Frameworks

Regulatory decisionmaking is conditioned by the framework used to structure issues. Six basic frameworks have been used for regulating risk: (1) market regulation: decisions by consumers and producers; (2) no-risk: attempting to lower risks to zero; (3) technology based standards (e.g., best available technology); (4) risk-benefit: a rough balancing of risks and benefits; (5) cost-effectiveness: equating the cost of saving lives across programs; and (6) formal benefit-cost analysis (Lave 1979). In addition, two new frameworks have been proposed: (7) regulatory budget; and (8) risk-risk: balancing of various risks to the consumer. The choice of a regulatory framework is fundamental, driving other concerns. Each framework has important implications for the nature of problems examined and type of analysis undertaken by each agency.

The frameworks can be ordered in terms of the amount of information and analysis required by the policymaker: Market regulation, no-risk, technology based standards, risk-risk, risk-benefit, cost-effectiveness, regulatory budget, and benefit-cost analysis. We will characterize each of these briefly.

A. Market Regulation

In a world of perfect competition and full information, market equilibria will be Pareto optimal, i.e., no rearrangement of

production or distribution could make anyone better off without making someone worse off. This efficiency property also holds for allocation of risk due to hazardous products, services, or jobs. Each individual would consult his feelings about risk and select an occupation and set of products that maximize utility; producers would examine the premiums consumers and workers were willing to pay for safe products and occupations and modify the mix offered. Under restrictive assumptions, there would be either necessity nor role for government regulation.

Clearly, our economy does not satisfy the host of restrictive assumptions; both buyers and sellers can often influence price, externalities abound, and often both buyer and seller are ignorant of the health and safety implications of a product. The market equilibrium does not yield the full-information, Pareto optimal allocation. A case based on efficiency and informational considerations may sometimes be made for government intervention. However, government intervention also brings costs and inefficiencies unrecognized in simple theory. Regulation itself requires resources. More important, it is virtually impossible to regulate so that incentives are not distorted, often leading to even greater inefficiency than would prevail with the unregulated market (e.g., transportation regulation, particularly of trains). Economists have concluded that regulation is justified only by "serious" violations of the assumptions, and then only if the regulation can be relatively efficient.

An outstanding controversy concerns whether the current U.S. economy is essentially competitive and consumers well informed; some claim the economy has hardly a hint of competition and most consumers and workers are ignorant. Each side can muster persuasive examples, although general proof is impossible. Society has tended to sway with the winds of intellectual discourse, with waves of regulation and then deregulation, e.g., transportation (Keeler 1979). Economic efficiency is rarely the sole factor in regulatory policy, and often it is not even the most important. Many regulatory initiatives can best be understood in the light of such considerations as the drive to maintain or establish property rights. Others are motivated by the desire to provide "social insurance" to protect people against particularly adverse events. While there is general agreement that the economy is basically governed by the free market, it is also the social consensus that some regulation is necessary. Thus, doctrinaire positions concerning government control or laissez faire have little influence. Instead, regulation is decided on an ad hoc basis, depending on the nature of price control, consumer and worker ignorance, and magnitude of risk. Whether to license auto mechanics or regulate sodium nitrite is decided by appeal to the specific facts and risks, rather than being settled by the reaction to regulate all risky situations or none.

B. No-Risk

No-risk is exemplified by the Delaney Clause of the Food Drug and Cosmetic Act which prevents the addition of any carcinogen in food (Merrill 1980, Hutt 1978). Similarly, the Clean Air Act Amendments of 1970 instruct the EPA to set primary air quality standards which protect the health of even the most sensitive people. These statutes embody the notion that no unnecessary risk is acceptable, even one that is minuscule. No improvements in the appearance, taste, and convenience of food are sufficient to justify even the smallest risk of cancer.

The Supreme Court recently wrote that all human activity involves risk. People willingly assume greater risks in order to increase their income, increase the appeal of their food, and even to increase their pleasure in recreational activities. While no-risk has appeal as rhetoric, it is a pernicious guide to regulatory decisions. Trying to make people safe in spite of themselves is doomed to failure, as legislation on alcohol and seat belts has shown.

While a uniform attempt to achieve zero risk must fail, society could focus on a number of cases, such as carcinogenic food additives, and insist on zero risk. However, the controversies over saccharin and nitrite demonstrate that there is no consensus here.

C. Technology Based Standards

Technology based standards have been the basis of EPA's water regulation and have played important roles in air regulation, particularly the control of new sources. By mandating best technology, EPA is spared any formal attempt to estimate either costs or benefits; thus the framework appears to require relatively little data or analysis. However, in practice, the best available technology is never required; instead there is a careful look at the level of costs the industry can bear. In practice EPA and OSHA appear to be copying NRC's "as low as reasonably achievable" or ALARA concept.

D. Risk-Risk

This framework was proposed by the FDA because the Delaney Clause appeared to require them to take actions that would cost more lives than it would save (Green 1978). Some toxic substances,

such as food additives and fungicides, protect our food against contamination. Their use requires balancing the good they do in expanding the food supply and lowering its cost against the inherent toxicity of the substance. Even if someone believes that health is paramount and that no risk would be justified by an expansion of the food supply or decrease in its cost, one would still need to balance protection against possible toxic effects of the substance.

E. General Balancing of Risks Against Benefits

The three previous frameworks do not allow consideration of nonhealth effects, such as the quantity and price of food, or its appearance, taste, and convenience. The folly of refusing to consider these other effects is illustrated by the possibility of protecting against biological contamination by cooking food until it is mush. Most of us are willing to risk biological contamination rather than overcook all food. We are not even willing to boil our water in order to get rid of the minute chance that it is contaminated by harmful bacteria.

This framework proposes to account for cost, convenience, and even preferences in an attempt to balance these against risk (Starr 1972, NAE 1972, Hutt 1978, Merrill 1980, Clark and Van Horn 1978). Unfortunately, this term is used loosely to describe a vast array of frameworks. It sometimes refers to narrow conceptions of balancing perceived benefits against risk without considering other attributes. At other times, it amounts to little more than general handwaving. The framework has an immediate appeal to Congressmen and regulators since it is a vague instruction to consider all social factors in arriving at a decision. While no one can oppose considering all relevant factors, no one has specified precisely how this is to be done.

F. Cost-Effectiveness

Cost-effectiveness analysis attempts achievement of some goal given the constraint of a fixed budget (Hitch and McKean 1965). Formal development was closely associated with the Department of Defense; the goal was paraphrased by President Eisenhower's Secretary of Defense, Charles Wilson: "Get the most bang for the buck." Most organizations must live within a fixed budget for the next planning period. This framework is appealing sinced it poses the question in a way that combines both efficiency and budgetary considerations. More importantly, almost all organizations, other than those directly producing some good or service, cannot measure their output or contribution to the institution they serve; their budget is determined by some informal process encompassing past

expenditures, perceived contribution, and current availability of funds. When budget is not directly related to current output, cost-effectiveness is the relevant framework for guiding actions.

G. Regulatory Budget

This framework is a variant of cost-effectiveness (DeMuth 1980a, 1980b). Congress would set a budget for each regulatory agency determining the total costs that implementing its actions could impose on society. At present, few regulatory agencies face any constraint other than the time of their staff and their ability to defend their actions in litigation. The regulatory budget would provide an additional constraint that would focus agencies' attention on the costs they impose on the economy to act as a counterbalance to their mission of enhancing health and safety.

There is much to be said for this framework. It poses an understandable constraint on the agencies and asks Congress familiar questions. Without doing anything so objectionable as requiring that the agencies or Congress state the amount society should spend to avert a premature death, it provides a constraint on the agencies (Cohen 1978). This is not to say that implementation would be easy. It is extremely difficult to estimate the cost to an industry of some regulation; one could be confident that each agency would select a cost estimate at the lower bound of credibility, or even below that. However, the most important virtue is that this framework poses the proper question in a felicitous fashion, one that is familiar and acceptable to both the agencies and Congress.

H. Benefit-Cost Analysis

The best developed, quantitative framework is benefit-cost analysis (Prest and Turvey 1966, and Aldine annuals). It asks for a full specification of the social effects of a proposed action, quantification of these, and then a comparison of them using some common metric, generally dollars, so that the net social effect can be estimated. One of the most controversial aspects of its application is putting an explicit dollar value on human life, or rather on prolonging life (Linnerooth 1979); another is the social rate of discount (Baumol 1970).

Some economists advocate this framework as the sole basis for making decisions. Every effect ought to be encompassed, even though some are better quantified and evaluated. In theory effects as nebulous as redistribution of income or extinction of some species can be quantified and evaluated, but in practice

there is no hope of doing so in a way that would be widely accepted.

While benefit-cost analysis is not the only basis for decision making, it is an important input. The scientific facts are invariably incomplete, but they indicate what is known, what is false, and what are the best current conjectures. Although incomplete, benefit-cost analysis provides an important input to decision making since it stresses what is known and measurable.

I. Other Methods

Myriad other frameworks have been proposed or used. These eight frameworks are the principal ones and little is gained by explicit consideration of others. Current frameworks are conditioned by the desire to avoid problems in public hearings or Congressional oversight and to withstand legal challenge. Many of the agencies are embattled, with challenges in the media or in court; they have too little resources to carry out the functions that are legally mandated. Thus, their efforts are shaped by pragmatic concerns. When required by statute or executive order, they will estimate compliance costs, inflationary impacts, or significance of risk; however, there is a notable reluctance to add additional material, both because of the additional effort and the possibility of inviting further legal challenge. The current frameworks are worth studying because they reflect current legal, political, and economic pressures.

III Implementation of Frameworks

In applying these frameworks to particular examples, a series of issues arise. A few are settled by the asumptions of a framework, but almost all require painstaking research and policy analysis.

A. Required Information and Analysis

The frameworks differ markedly with respect to the amount of information and analysis required, from market regulation to formal benefit-cost analysis. Often important information is not available or is exorbitantly expensive to collate and analyze. What methods should be used for quantifying risk and how much confidence can be placed in each (Lave and Seskin 1977, 1979)?

A related difficulty is that agencies are often not purposive in the information they develop. Data are not available on a timely

basis or there is a concentration of resources on questions that researchers want to pursue, rather than on those related to the agency's mission. A careful specification of the decision analysis framework would reveal what data are required and help improve the quality of agency decision-making.

B. Quantification of Risk

The frameworks from risk-risk through formal benefit-cost analysis require quantification of risk (Hoel 1974, Crump 1979, Crandall and Lave 1981, ILRG 1979, BEIR 1972). Some authorities have asserted that quantification can encompass many fields (Lave 1979). Much examination has been done of the confidence that can be placed in various aspects of risk quantification. Unfortunately, the underlying theoretical structure and methods differ among applications and so generalization is difficult, e.g., accident risks versus carcinogens.

C. Priority Setting

Each agency must decide which issues to ignore, and, of those it will attend to, the order of priority. Frameworks such as cost-effectiveness and the regulatory budget naturally produce a priority ordering and cut-off for action. Others, such as benefit-cost and risk-risk analysis produce outputs that can be used for setting priorities. Frameworks such as no-risk and market regulation determine which should be regulated but give no hint of priorities.

Complicating the various frameworks is the set of issues not encompassed within their analysis. Society places higher priority on protecting children than on adults; cancer is considered to be worse than accidental death. These considerations are used to set priorities in practice. They must be meshed with priority setting within each framework.

D. Uncertainty

Information and analysis are never complete and definitive. Uncertainty is often handled by ignoring it; a slightly conservative value is picked from a probability distribution or those aspects of the problem we do not understand are ignored.

Both choosing a single value and ignoring aspects of the problem are unsatisfactory. They lead to unwarranted confidence in tne

outcome of the analysis, do not promote the needed research and data collection, and lead to policy recommendations that make little sense. The alternative is a careful modeling of uncertainty and explicit treatment within the analysis and decisionmaking.

E. How Safe is Safe Enough?

Regulation requires setting some standard or goal. How much safety does society desire in view of the cost (Fischhoff et al 1978)? Nearly every framework addresses this issue, e.g., no-risk proscribes any unnecessary risk. More generally, the safety level can be set at any desired level within each framework by manipulating parameters such as the value of life. Thus, Congress or the regulatory agency must set the critical parameter on the basis of its perception of society's goals.

F. Implementation of Regulations

Regulations are currently implemented by ad hoc processes of negotiation and inspection that have fines, shutdown, or criminal penalties. The current system does not work very well (Mills 1978, Mills and White 1978, Ruff 1979, and Zeckhauser and Nichols 1978). Economists have proposed the public use of private interest (Schultze 1977), the use of economic incentives that redirect self-interest toward achieving what is in the social interest.

Economic incentives, such as effluent fees and marketable discharge rights focus on economic efficiency, with less concern for other factors. Considerations of property rights and due process of law often play critical roles in the implementation of health and safety regulation. Exploration is needed of the properties of each proposed method, particularly as it calls for modification of existing administrative and legal structures. Complicated frameworks and methods of implementation require many resources, are difficult to explain, hard to administer, and more vulnerable to legal challenge. Simplicity is often not merely a virtue; complicated frameworks will not work.

G. Economic Efficiency

Each of the frameworks and methods of implementation has implications for economic efficiency. We need to measure the deviation from Pareto optimality of each proposal, as well as what

is lost. Furthermore, static efficiency must be supplemented by examination of dynamic efficiency. Much of the discussion of the "dead hand" of regulation refers to problems with efficiency over time. For example, environmental regulations have allegedly slowed productivity and innovation, thus imposing high long term costs.

H. Equity

Each of the frameworks and methods of implementation has implications for equity, both at present and for future generations. While there is no general consensus on the desired amount of income redistribution or the desired distribution of consumption, equity plays an important role in regulatory decision making. Ad hoc decision making examines the implications for children, the old, the poor, minorities, and other identifiable groups. In each case some decision is reached in which equity considerations played an important role, either because of legitimate distributional concerns or as a mask for more self-interested goals.

IV. Statutes Governing Regulatory Agencies

The federal regulatory agencies listed in section I operate under a variety of diff[illegible] statutes. In some cases, such as the Delaney Clause, C[illegible]s has given the agencies quite specific instructions; in other cases, such as that for the Occupational Safety and Health Administration, the statute is ambiguous. In the latter case, there is more to be learned from the recent decisions of each agency than from a careful examination of the statute. We review each of the statutes in this section and then examine examples in the next section.

A. Consumer Product Safety Commission

The Consumer Product Safety Commission (CPSC) attempts to insure that products marketed for consumer use do not cause injury or disease. Options open to the commission include information dissemination, labeling, and outright banning of constitutents or entire products. CPSC was created by the Consumer Product Safety (CPS) Act of 1972 and given the mission of administering such previous acts as the Federal Hazardous Substances Act. CPSC was instructed "to protect the public against unreasonable risks of injury associated with consumer products."

FDA, EPA, NHTSA, and other agencies also have responsibility for safety aspects of consumer products. In some cases, Congress explicitly resolved the conflicts by allocating jurisdiction, e.g., NHTSA, not CPSC, has authority over automobiles; FDA has jurisdiction over products it regulates. However, in many cases there is overlap with possible contradictory regulations due to the different nature of the statutes (e.g., EPA versus CPSC).

To ban a product under section 8 of the CPS Act, the commission must find that: "(1) a consumer product is being or will be distributed in commerce and such consumer product presents an unreasonable risk of injury; and (2) no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury associated with such product ...". The Act does not define "unreasonable risk of injury." Although the Commission has attempted to examine and roughly balance the benefits and costs of a proposed action, there is no formal requirement to do so in the statute. However, under section 9, the Commission is required to make findings concerning: "(A) The degree and nature of the risk or injury the rule is designed to eliminate or reduce; (B) the approximate number of consumer products, or types of classes thereof, subject to such rules; (C) the need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need; and (D) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety." Finally, the Commission must find "that the promulgation of the rule is in the public interest..".

This language could be used to justify requiring a formal benefit cost analysis or simply a recitation of a descriptive listing of effects. The magnitude of its task and general circumstances helped CPSC to become controversial from the beginning. It suffered several important reversals in the courts, while its successes have tended to follow regulations promulgated by other agencies.

B. Occupational Safety and Health Administration[2]

After prolonged debate, Congress enacted the Occupational Safety and Health Act to protect workers against both accidents and occupational disease. Administered by the Department of Labor, the act is intended "to assure so far as possible every working man and woman in the nation safe and healthful working conditions...". The general duty of each employer is to "... furnish each of his employees employment and a place of employment which is free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees...".

The language of the statute was subject to intense debate and carefully crafted; yet there are contradictions. The agency is to

> set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

OSHA interpreted the statute to require the agency to err on the side of caution when there was uncertainty. The latest scientific evidence was interpreted to mean data, but not include quantitative analysis of risk. Accordingly, OSHA proposed a generic carcinogen standard in which carcinogens would either be banned from the workplace or exposure minimized to the extent permitted by current tecnology.

This general policy was used to decide a specific exposure level for benzene in the workplace. Since the technology exists to lower exposure to 1 ppm in industrial settings, and since benzene is a carcinogen at concentrations of several hundred ppm, OSHA revised the standard from 10 ppm to 1 ppm.

The Fifth Circuit Court of Appeals set aside the standard on the grounds that costs and benefits must be at least roughly comparable, which they were not in this case. The Supreme Court set aside the standard in a complicated set of opinions, with three justices subscribing to a main opinion and two others writing concurring opinions. (Industrial Union Dept. AFL-CIO v. American Petroleum Institute, 1980.) The Court held that OSHA had failed to show that there was an appreciable risk at the old standard and thus there were grounds for tightening the standard. The Court explicitly decided not to rule on the lower court's contention that benefits and costs must be roughly commensurate. A ruling on this contention may emerge during the present term when the court considers OSHA's cotton dust standard.

It is clear in many cases that OSHA's standards have imposed major costs on some industries, including threatening the viability of many companies. This fact has lessened the enthusiasm of both OSHA and the Courts to set standards as stringent as appear to be called for in the Act. OSHA has not yet come out with rules that take account of the benzene decision. No definitive rules are likely to emerge before the Supreme Court's decision on cotton dust.

C. Environmental Protection Agency

EPA operates under a series of quite different statutes, ranging from the Clean Air Act to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The former requires that EPA set a primary air quality standard that protects the public health, presumably (according to legislative intent) the health of even the most sensitive members of the population. Benefit-cost analysis or even considering cost is forbidden. Under FIFRA, EPA is required to conduct a balancing of the benefits and costs of each substance in deciding which to license and what uses are permissible.

Largely because the Clean Air Act is uncompromising, EPA has experienced severe difficulties in implementing it. As shown below, EPA has considered the costs of meeting each standard and attempted to get some estimates of the health implications of various standards.

The Water Quality Act is similarly uncompromising in setting a goal of "zero discharge" by 1984. It calls for technology based standards, such as "best available technology (BAT)." Again, EPA clearly attempts to estimate the costs of various standards and to do at least a rough balancing of benefits and costs in setting standards.

EPA regulation of exposure of the general population to ionizing radiation from the nuclear fuel cycle is governed by a combination of technology based standards and cost-effectiveness analysis. An overall exposure goal is set on the basis of negligible harm to the public. Standards for individual facilities are then set by cost-effectiveness analysis, attempting to trade off emissions and control costs in each aspect of the operation so that the most cost effective way of meeting the standard is found. Finally, there is the general rule of "as low as reasonably achievable" (ALARA) or its variant, "as low as practicable" (ALAP), which attempt to reduce emissions still further as costs or technology change so as to make it possible to achieve a lower standard.

The Toxic Substances Control Act (TSCA) is similar to FIFRA in demanding quantification of benefits and costs and a balancing. Indeed, no other criteria would be reasonable since chemicals designed to kill pests almost certainly pose some risks to humans. A no-risk approach would require banning pesticides as well as toxic chemicals. Instead the statute calls for a balancing. EPA has had an extremely difficult time implementing these acts, especially TSCA, because of the difficulties of quantifying risk and estimating costs.

D. Food and Drug Administration[3]

The FDA Act of 1906 declared adulterated any food that contained "any added poisonous or other added deleterious ingredient which may render such article injurious to health."

1938 Act: "(B)ut in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."

1938 Act, Section 406: FDA should set tolerances for certain "necessary" or "unavailable" added constituents at levels necessary to protect the public health.

1954 Pesticides Residues Act regulated pesticide residuals.

1958 food additives amendment, includes Delaney Clause.

1960 color additives amendments.

There are major differences among the statutes concerning food additives, food contaminants, drugs, and cosmetics. Since food additives are under the control of the manufacturer, the statute requires evidence the additives are safe. In particular, the Delaney Clause prohibits the addition of substances to food which are carcinogens. The prohibition is without respect to the level of risk or the benefit the additive may convey.

Food contaminants, such as rodent droppings and biological contaminants are not under the complete control of the processor. Thus, FDA establishes a tolerance level that attempts to balance the cost and availability of food with potential damage to health and aesthetic considerations.

Virtually all drugs have undesirable side effects. Thus, the decision to license a drug is a decision that the real or imagined benefits of a drug outweigh the undesired effects, taking account of alternative drugs that might fulfill the same purpose. However, not until the past two decades has FDA been empowered to examine the efficacy of a drug as well as its undesired effects. Now, FDA demands evidence on both efficacy and side effects in order to reach a judgment balancing the two in deciding whether to license a drug.

Cosmetics are similar to food additives in that they are under the complete control of the manufacturer. Thus, FDA demands a strict standard of no harm from cosmetics.

FDA also regulates medical appliances; the framework is similar to that for drugs.

V. Recent Federal Regulatory Decisions

As the previous section illustrates, Congress has given only the most general instructions to many agencies regarding concrete goals. We present a series of examples to: (a) explore the actions actually taken by each agency; (b) show the implications of the alternative frameworks, and; (c) explore the most sensitive areas.

Setting quantitative safety goals requires analysis that quantifies risk as well as a quantitative goal. The following examples focus on the former. If quantification is not possible, the scheme fails. The acceptability of each agency's action must be ascertained under each case. We selected major cases since most analyses are perfunctory and pass with little comment. In virtually all of these cases, it was clear that this issue would be subject to intense scrutiny and controversy.

We hasten to point out that quantitative analysis and quantitative safety goals are used in a number of areas. The Federal Aviation Administration is most explicit in its full benefit-cost analsis, but other agencies routinely estimate quantitative risk and have quantitative safety goals. Finding acceptable quantitative safety goals is a secondary problem, given that one can quantify risk. This is not to say that finding quantitative goals is easy or uncontroversial, but goals are a second order problem from an agency's viewpoint. Setting goals is precisely the problem for Congress. When an agency has done satisfactory quantitative risk analysis, either Congress will intervene to set quantitative goals or will implicitly accept the agency's criteria after some oversight.

A. Application to Food Additives

Many ingested substances, even such common ones as water and salt, are benign in small quantities and toxic in large quantities. Individuals differ in susceptibility to any substance due to age, sex, current health state, genetic factors, and exposure to other substances. It is literally impossible to protect everyone with a uniform set of regulations because of allergies, inborn errors of metabolism, and differing consumption patterns. Rules designed to keep most people healthy would lead to serious disease in a minority. Thus, the FDA must decide whom it seeks to protect, what warnings to require, and who will not be protected and will have to exercise discretion in choosing food.

Food regulation is far from automatic or mechanical. While the basic statute prohibits adulterated food or food that would cause

harm, categories such as "natural foods," additives which have been used for decades, and new additives are treated differently; furthermore, objectives such as the quantity and cost of food and appearance are considered. The FDA has become embroiled in controversy concerning contaminated cranberries, artificial sweeteners, filth from pests, and growth stimulants given to animals. In spite of the inherent simplicity of the Delaney Clause with its no risk framework, the FDA has had to make many complicated judgments trading off safety for other considerations. The complexities of the problem and current system are illustrated in the following four cases.

Sodium Nitrite

Sodium nitrite is a salt used for preserving meats; it changes the color and flavor and inhibits the growth of Clostridium botulinum, a bacterium causing botulism. Nitrite has been used for thousands of years and careful application has prevented any deaths from botulism in commercially cured meats in the United States for decades. The characteristic color and flavor of cured meats is due to nitrite. Without it, bacon would be gray and taste like salt pork. Banning nitrite may well mean the demise of hot dogs, ham, corned beef, pastrami, and other cured meats -- or at least the elimination of cured meats of current color and flavor.

Unfortunately, nitrite combines with amines and amides to form nitrosamines, which are potent carcinogens. Some nitrosamines are produced during storage, some in cooking, and some by human digestion. In addition, there is cloudy evidence that nitrite itself might be a carcinogen.

Regulation of nitrite raises both health and aesthetic issues. Banning nitrite would increase the number of botulism deaths; continuing to add it to cured meats would increase the number of cancers. Banning nitrite would eliminate many cured meats that Americans desire, require much greater care in transporting and refrigerating cured meats, and lead to a product that Americans regard as inferior in taste and appearance, and much less convenient. No substitute exists for nitrite.

Such direct contradictions require sorting out and balancing opposing effects. We need to know the effect on cancer incidence of banning nitrite along with the effect on the incidence of botulism; we must estimate consumer demands for cured meats with current flavor, appearance and convenience. While quantitative estimates of each aspect can be produced, none are worthy of confidence.

Nitrosamines are highly carcinogenic in rats and other animals. Evidence for humans is nearly impossible to obtain, since much of the nitrosamines are produced within the body. Thus, estimating

the effect of nitrosamines on cancer incidence requires a triple jump: from high doses given to laboratory animals to low doses; from laboratory animals to humans; and finally internal dose must be estimated for both laboratory animals and humans. Although uncertainty about the estimate is large, only about ten cancers per year in the United States are estimated to arise from the nitrosopyrrolidine in cooked bacon.

The carcinogenicity of nitrite itself is the focus of a major controversy. A large bioassay found a significant increase in carcinogenicity, but rereading the slides has cast doubt on the original conclusion. In any case, nitrosamines would be esimated to be a more significant threat than nitrite.

Clostidium botulinum is a widely dispersed, anaerobic bacterium present in nearly all meat. Under warm, airtight conditions, the spores will generate, producing toxins that cause botulism. Some strains can grow at temperatures as low as 38 degrees Fahrenheit. Cured meats are handled casually now, with canned hams or meat sandwiches left unrefrigerated; at temperatures of 80-100 degrees F., the bacteria can grow quickly. The concentration of nitrite required to give cured meat its distinctive color and taste is much smaller than that required to protect against botulism.

Nitrite added to cured meat is a small proportion of the amount we consume. Leafy vegetables contain nitrite and we ingest large amounts of nitrate which is converted to nitrite in our bodies. According to one estimate, only about 3 percent of nitrite in the body comes from cured meats.

The question facing FDA is whether to prohibit nitrite as an additive to cured meat. Initial evidence that nitrite is a carcinogen has been contradicted; however, nitrosamines are still believed to be carcinogenic. FDA hesitated to ban nitrite both because of the risk of botulism and the predictable reactions of consumers and producers. It proposed that nitrite levels in meat be kept at the lowest level that would provide protection against botulism, but that use be phased out over a number of years, if satisfactory substitutes were found.

DES As a Growth Stimulant for Steers

Diethylstilbestrol (DES) is a synthetic estrogen used as a drug for humans and, until recently, as a growth stimulant for steers. After nearly a decade of controversy, the FDA banned the use of DES as a growth stimulant for meat producing animals on the grounds that residual amounts of DES could sometimes be detected in the liver of such animals and that even these minute amounts might pose a risk to humans.

Estrogens are used in the treatment of conditions such as gonadal dysgenesis and postmenopausal osteoporosis in women and prostate cancer in men. DES is used as a "morning after" drug to prevent pregnancy and was used, unsuccessfully, to prevent miscarriage. Large doses of DES were shown to cause birth defects, and probably cause cancer in the fetus.

From the late 1940s through the early 1970s, large doses of DES were given to pregnant women believed to be in danger of miscarriage. Almost all of the daughters exposed in utero developed some genital abnormality, such as ridges in the vagina or cervix. Several hundred of the millions of women at risk developed clear cell adenocarcinoma, a potent cancer resulting in death in about 20 percent of the cases. This disease was virtually unknown in young women and had a low incidence rate in general.

Some genital disorders were found in the sons exposed in utero, but there is no evidence of cancer in these males or in the mothers. However, there remains the possibility of cancer after a long latency period. The effects in human are confirmed by animal bioassays. In addition to genital abnormalities, DES produces such teratogenic effects as heart valve defects.

DES was discontinued as a preventive treatment for miscarriage because it was found ineffective. Getting cooperation in doing a clinical trial was extremely difficult.

The use of DES was so widespread that careful records were not kept. In many cases, it is uncertain whether a particular pregnancy was supported with DES, much less what dose was given. However, it seems safe to conclude that virtually all DES daughters who received a total dose of 5 to 15 grams had genital abnormalities, although generally these could be detected only with microscopic examination. There is evidence that these abnormalities disappear over time. The incidence of clear cell adenocarcinoma is so small that it is difficult to conclude its precise cause or dose-response relationship.

Although DES is a synthetic hormone, the properties discussed are shared by normal hormones. Estrogens cause both cancer and birth defects. Pregnant women have estrogen in their bodies during pregnancy and ingest estrogens and hormone active substances in much greater concentrations than DES or its metabolites. There is evidence that the body produces fewer hormones in response to ingesting them so as to keep the levels of hormones in the blood within a normal range. Thus, it is possible, indeed likely, that ingesting minute amounts of DES has no effect on birth defects or cancer.

Steers exposed to DES gain weight faster (15-19 percent) and metabolize their food more efficiently. The weight gain is similar to that of a bull, but without the behavioral difficulties or less desirable flavor. The cost of banning DES was estimated

to increase beef prices about 9 percent during the first year, a cost of about $4 billion; other estimates range as low as $500 million per year.

If DES ingested in minute amounts causes neither birth defects nor cancer, the FDA ban is incorrect, needlessly costing the public up to $4 billion per year. If the dose-response relationships are described by linear, non-threshold curves, then a slight increase in cancers and teratogenic effects would occur from continuing to use DES as a growth stimulant. However, various estimates of cancer indicate the incidence might be as high as 10 per year or only one every several years, depending on the precise calculation. Estimated birth defects might be as high as several hundred per year, although these would presumably be microscopic and would disappear over time.

Aflatoxin

The product of a mold growing on grains and nuts, aflatoxin is a potent carcinogen in rats and other laboratory animals and is implicated in the incidence of liver cancer in Africa and Asia. Since aflatoxin is a contaminant, there is no possibility of banning it. The current tolerance level is 20 parts per billion, but FDA has proposed lowering it to 15 ppb. Since there are no beneficial effects, the question is simply one of how much society should spend to lower the exposure to aflatoxin, which would presumably lower the incidence of liver cancer.

The molds Aspirgillus flavus/parasiticus grow on grains and nuts under warm, moist conditions, especially when the kernel has been mechanically damaged, as by insects or other molds and bacteria. Aflatoxin is transmitted to meat, milk and eggs through contaminated food. The Southeastern United States has aflatoxin problems, along with countries in Africa and Asia. In the latter regions, there is a close association between the incidence of liver cancer and the amount of aflatoxin in the diet. On the basis of current exposure levels, the data from Africa and Asia imply that aflatoxin causes 20 to 67 liver cancer deaths per 100,000 people in the Southeast each year.

The data used in epidemiological studies are subject to many problems. The difficulties are confounded by the very different susceptibilities of rats and mice. In addition, liver cancer rates are lowest in the United States in the Southeast where there is the greatest exposure to aflatoxin. However, assuming the epidemiological data are correct, and the linear, no threshold curve applies, one would estimate that between 75 and 252 people get liver cancer each year from aflatoxin. Cutting aflatoxin levels by 50 percent would presumably save 38 to 126 people per year.

Saccharin

Perhaps the most controversial food additive has been saccharin. This nonnutritive sweetener was discovered almost a century ago, but has been suspected of being a carcinogen for much of this period. A vast number of animal bioassays have been performed, with generally contradictory results until recently. Recent experiments have taken great pains to eliminate contaminants and have found that saccharin is a weak carcinogen in rats. Three recent epidemiological studies have failed to find a close association. They might be interpreted either as showing that saccharin is not a human carcinogen or that it is a weak carcinogen, as indicated in the animal bioassays.

Assuming saccharin is a carcinogen, data from the animal bioassays can be used to estimate the incidence of bladder cancers in humans. The weak nature of the carcinogen makes estimation of human effects especially uncertain. Various plausible models give estimates that differ by as much as a factor of ten million. If the linear, no threshold model is used, saccharin might be responsible for as many as several thousand cancers per year.

FDA acted on the basis of the animal bioassays to ban saccharin as a food additive in 1977. The agency was quickly overruled by Congress, which canceled the ban and imposed a regulatory moratorium of 18 months in order to allow the National Academy of Sciences to study the issue. While the Academy reported that saccharin was probably a weak carcinogen, it did not come to a recommendation about banning it. The moratorium expired in May 1979 and there is no evidence that would have led the FDA to have changed its ruling that saccharin is a carcinogen; however, the FDA has failed to act.

With the earlier banning of cyclamate, saccharin is the only nonnutritive sweetener allowed in the United States. the National Academy of Sciences found no conclusive evidence that using saccharin helps in weight control. The basic conflict within the committee concerned whether consumer desires for a nonnutritive sweetener justified exposing people to a carcinogen. Many committee members felt that either uninformed consumers or children would be subject to risk and that society must protect them, even at the cost of denying saccharin to informed consumers who were aware of the risk.

Application of the Eight Frameworks

Application of the eight frameworks to these food additives or contaminants is summarized in Table 1. Under present regulation,

Table 1. Application of Decision Frameworks

	Nitrite	DES	Aflatoxin	Saccharin
Market Regulation	No Action	No Action	No Action	No Action
No Risk	Ban	Ban	As low as possible (ALAP)	Ban
Technology Based	Ban	Ban	ALAP	Ban
Risk-risk	Permitted-low amounts	Not applicable	Not applicable	No demonstrated health benefit
Risk vs. benefits	Permitted no-excess	Permitted careful use	Fairly stringent	Don't regulate
Cost-effectiveness	No agency attention	No agency attention	More attention and control	No agency attention
Regulatory Budget	No agency attention	No agency attention	More attention and control	No agency attention
Benefit-cost	Permitted no excess	Permitted careful use	More stringent than present	Don't regulate

FDA has banned DES, but has suspended action on nitrite and saccharin, and has proposed a lowering of the tolerance level for aflatoxin, based on the instruments available for detection. Initial action to ban saccharin was overridden by Congress while initial action to ban nitrite was overridden by the Secretary of Health, Education, and Welfare. Although these are four difficult cases, it is clear that the current framework is unsatisfactory. The FDA has been reversed on two of its decisions, is faced with large scale violatons of the DES ban, and appears to be dealing with aflatoxin by focusing on instruments to detect it rather than dealing with the issue of desired contamination level.

Market regulation would leave the FDA with no action on food additives, save possibly for labeling and information dissemination.

A no-risk criterion would call for banning the three additives and setting the tolerance level for aflatoxin as low as possible, which would presumably mean prohibiting the growing of corn in the Southeast. This framework leads to clear cut answers, but these answers are not perceived by the public to be acceptable. The implications of a no risk framework give some indication why FDA has such a difficult time carrying out its responsibilities.

A technology based standard would examine the extent to which current technology can lower risks. For the three additives, best available technology would presumably mean banning them. For aflatoxin, the combination of detection technology and farming practices could lower concentrations below current levels.

The risk-risk framework permits other health effects to be considered. This framework is applicable only to nitrite, where there is an approximate balancing between risks due to cancer and risks due to botulism.

The risk-benefit framework permits consideration of nonhealth effects, such as the costs and availability of food, taste, appearance, and convenience. Since the risk-risk framework showed there to be a balancing betweeen botulism and cancer, allowing consideration of taste, appearance, and convenience increases the desirability of retaining nitrite. However, no excess would be permitted above that required to protect against botulism. Permitting DES has the effect of increasing the supply of meat and lowering its cost. These effects appear substantial, especially in view of the uncertain health effects of DES. The framework implies use, but with care to minimize DES remaining in marketed meat. Regulating aflatoxin is largely a question of how much society is willing to spend to lower exposure. Little evidence has been developed to indicate the cost of various tolerance levels, although the resulting cancer incidence can be estimated with major uncertainties. The present standard appears to be approximately correct. The issue for saccharin is simply whether people desire a nonnutritive sweetener enough to be willing to

take on the risks. The evidence from current behavior is that saccharin is still used in spite of the warnings and publicity.

Cost-effectiveness requires that a class of alternatives be defined. If one considered all FDA activities, it is likely that FDA would devote more effort to regulating drugs and to biological contamination. Within these four substances, attention would center on aflatoxin. The number of lives that could be saved and the cost of saving them appears smallest for aflatoxin, at least when consumer preferences are considered in the costs of banning saccharin.

The regulatory budget is one method of implementing cost-effectiveness analysis for food additives and contaminants. Thus the answer is quite similar.

A full blown benefit-cost analysis has not been done. However, one might value premature death at $300,000 to $500,000 and complete the calculation. If this range of values for health effects, or even values several times as high are used, costs exceed benefits for banning nitrite, DES, and saccharin. So little is known about the costs of reducing aflatoxin that it is impossible to estimate the desired tolerance level. However, one can pose the precise question: If reducing aflatoxin exposure in half costs less than $19 to $63 million per year, then it is worthwhile to do so.

The table makes evident the problems with the no-risk framework. Attempts to use it to guide regulatory decisions are certain to keep the agency in hot water and get its decisions reversed. If there is a decision that health effects cannot be traded off against cost, convenience, and appearance, then the risk-risk framework is a more rational one than the no-risk framework. But its failure to consider nonhealth effects makes it unacceptable. The table indicates how similar are the conclusions from applying any of the four frameworks while allowing consideration of nonhealth effects. Which of these should be chosen depends not on the outcome, but rather on whether the questions posed by the framework are phrased so as to highlight the most important issues and so that they appear familiar to Congress and the agencies. Risk-benefit analysis appears to do this, but is so vague that it is not really a framework. Benefit-cost analysis poses questions, such as the tradeoff between costs and health, in a fashion which noneconomists find unacceptable. The regulatory budget has the considerable advantage of posing the issues nicely in ways familiar to Congress and the agencies.

B. Photochemical Oxidants*

The Clean Air Act Amendments of 1970 required EPA to set primary air quality standards that protected the health of even the most

sensitive members of the population. The 0.08 part per million level established for photochemical oxidants in the 1971 standard was based on studies that seemed to show increases in asthma attacks and eye irritation down to perhaps 0.15 part per million. EPA was required to review this standard in 1979. Since few studies had been done between 1971 and 1979, EPA was forced to reexamine the studies used to set the earlier standard. Difficulties in measuring total oxidants led to setting the standard for ozone alone and a close look at the studies led to a looser standard. In the midst of intense controversy, EPA changed the standard from the 0.08 part per million level (total oxidants) to 0.12 part per million (ozone alone). Initially, EPA proposed to loosen the standard to 0.10 part per million, but decided to relax it further in view of the criticism of the health studies on which it was based and the cost of controlling oxidants. Even so, EPA has been challenged in court, both by environmentalists wanting a more stringent standard and an industry group contending the standard is more stringent than can be justified.

Ozone is a pulmonary irritant that affects respiratory mucous membranes, lung tissues, and respiratory functions.[5] A series of laboratory experiments indicates respiratory effects at concentrations of about 0.30 part per million and higher, although reactions are sensitive to the presence of other pollutants and to activity level. Epidemiological studies suggest reactions such as eye irritation, increased risk of asthma attacks, and respiratory symptoms at lower concentrations, down perhaps to 0.20 part per million.

An analysis by the Council on Wage and Price Stability concluded that the standard should be in the range of 0.16 to 0.20 part per million.[6] The Council estimated that the incremental costs associated with achieving standards in the 0.08 to 0.14 part per million range would be extraordinarily large and argued that the health benefits associated with such standards were nonexistent, or at least very small.[7] Thus, a benefit-cost framework would call for a standard in the 0.16 to 0.20 part per million range.

EPA made its case by finding that the Clean Air Act Amendments of 1970 specifically prohibited it from using a benefit-cost framework; EPA was instructed to protect the health of the population, including (by implication) the most sensitive members. The Agency sought to estimate a threshold at which health effects occurred by a procedure that asked health experts for their subjective probabilities of the occurence of various health effects for range of concentrations. EPA first asserted that it used these judgments in setting the standard, and then denied they had played a role.[8] The experts were concerned about too great a reliance being placed on these data, since the encoding procedure had been casual in a number of cases.[9]

Amidst intense pressure from environmentalists, administration economists, and business, EPA set the standard at 0.12 part per million. The Agency had loosened the standard from 0.08 part per

million and measured only ozone, but would loosen it no further. As might have been predicted, EPA was immediately sued by both sides, with arguments from one side that it had lowered the standard too much and, from the other, that the standard was still too stringent.

Given this review of the case and the description of EPA's decision, the eight decision frameworks can be applied and compared with EPA's decision. The market regulation framework makes no sense for air pollutants. Oxidants are due to millions of individual sources with no one source being sufficiently important to make a noticeable contribution. No one motorist is motivated to lower his fuel economy and the performance of his car in order to reduce emissions. Yet the vast majority of people agree that emissions should be lowered. This is not a problem that the market can handle, at least not without government intervention to set up effluent fees or marketable discharge rights.

EPA set its standards under a no-risk framework. However, this is a case where no-risk does not have an easy interpretation. Probably no standard within the range of 0.08 to 0.20 part per million could be said to be absolutely protective of the most sensitive member of the population; certainly, there is no assurance that 0.12 ppm is as protective as 0.08. In formulating the standard, EPA must have given some consideration to factors other than risk to health; if not, why would it have relaxed the standard without evidence that 0.12 part per million was safe?

Risk-risk analysis is not applicable.

COWPS argued against the 0.10 part per million proposed standard on the grounds that the cost of curtailing each health effect would be extraordinarily large, presumably much larger than it would cost to lower health effects in other parts of EPA's program.[10] A crude look a the cost-effectiveness framework would indicate that EPA's oxidant standard is too stringent. Comparing the cost of preventing a health effect under the oxidant and toxic substances shows that the former is not cost effective. Cost-effectiveness would presumably shift attention from oxidants to toxic substances in the environment, especially pesticides and disposal of toxic wastes.

COWPS argued that a benefit-cost framework would call for a standard in the 0.16 to 0.20 part per million range. Although both cost and benefits estimates are subject to major uncertainty, the COWPS conclusion is probably correct because costs of control increase rapidly within this range, while similar arguments on the benefits side seem tenuous.

In retrospect, the qualitative nature of EPA's revision of the oxidant standard seems obvious. The laboratory and epidemiological studies conducted since 1971 failed to confirm the fears associated with promulgating the first standard. Since many

additional cities began to experience problems with photochemical oxidants during this period and the costs of control were recognized to be extremely high, EPA proposed a token relaxation of the standard (from 0.08 to 0.10 part per million), but was forced to go further. EPA's analysis of health effects was unsatisfactory. The agency appeared to be grasping for straws by using hastily done, inherently suspicious techniques. However, the no-risk statute enabled EPA to resist a more significant loosening of the standard. Clearly, EPA took account of the costs of meeting various standards, but it stopped far short of using a benefit-cost framework, or even a cost-effectiveness framework.

C. Other Toxic Substances

Many other toxic substances are in the environment. People are exposed to them through water or food. Examples include mercury, PCBs, and kepone in fish; lead in paint; pesticide residuals in food; and radionuclides in air, water, and food generally. In some cases, EPA or FDA have performed rough analyses that are unworthy of much confidence; other analyses have been helpful.

The most care and attention has been given to the effects of ionizing radiation. Radionuclides escaping to the environment have been identified and measured with some care.[11] Exposures to these radioactive substances, both directly and indirectly through food, have been estimated, with care taken to identify the various types of radiation, target organs, and biological effectiveness of each type of radiation for each organ.[12] Complicating the analysis is reconcentration of radionuclides in the food chain.

Estimating the health effects of low level exposure to ionizing radiation is similar to inferring the effects of low level exposure to any toxic substance. Acute effects at high doses are known for laboratory animals, less precisely for humans. Chronic effects due to somewhat lower doses are known in less detail.

However, the doses of ionizing radiation received by the general population, or even by people occupationally exposed to radiation, are so low that no direct evidence of effect can be found.[13] Instead, scientists must extrapolate from effects observed at higher doses. There is evidence that a linear dose-response relationship is approximately correct for radiation, although there is intense controversy over whether a best estimate would be that effects are lower than predicted by the linear model at low doses.[14] Radiation is simpler than toxic chemicals to analyze because there is a single type of effect (ionizing radiation). Toxic substances and their metabolites have a host of effects, since they have impact on different organs in different ways.

The resources devoted to learning the effects of radiation and then estimating low level effects are large, especially compared

to the resources devoted to any other environmental challenge. The analyses of radiation present an archetype of how quantitative analyses such as cost-effectiveness and benefit-cost can be done, of the uncertainties involved, and of how the analysis can be used in setting standards.

Vast experience has been accumulated in estimating the risks of environmental exposures to toxic substances. Since some of the statutes have required frameworks akin to benefit-cost analysis, the difficulties of estimating dose-response relationships have been faced along with attempts to estimate costs and benefits. Where Congress has mandated a no-risk framework, needless controversy has been generated by the impossibility of setting the required standard within an industrial society. Although uncertainties do and will always remain, it is possible to estimate the risks of toxic substances in the environment. The application of decision frameworks more general than no-risk helps improve regulatory decisions.

D. Health and Medical Care

As the costs of medical care have escalated and the government took on a larger role in financing them, pressures for evaluation of the efficacy of various preventive and therapeutic procedures have increased. Attempting to infer whether a particular action has a particular effect is exceedingly difficult without the ability to experiment. Confounding factors are so important as to raise questions about the ability to infer causation or to estimate the magnitude of the response.[15] While this problem is common to many areas, ethical reasons for not giving each patient less than the best care make it endemic in health. A randomized clinical trial, where patients are randomly assigned among two or more competing treatments, is possible only when the participating physicians, study sponsors, and the medical community at large feel that the competing treatments promise approximately the same benefit to each patient. Thus, if physicians are convinced that one treatment dominates, they are precluded from testing their belief and from estimating the magnitude of the benefit. This means that the vast majority of medical practices have never been tested and will never be tested, even though there is good reason to suspect, based on previous experience, that a large proportion are not efficacious or are even harmful.[16]

Our cultural heritage is typified by films from the 1930s where any medical problem could be cured if only the victim could get the assistance of the Mayo Clinic. This general belief is reinforced by the miracles of medical intervention; broken bones are mended, eyesight corrected, infection cured, and hearts transplanted. However, rates of morbidity and mortality have little relationship to the quality and quantity of personal health services. Life expectancy is not greatest in the country with the

most advanced biomedical research or even in the country with the greatest per capita expenditures on medical care. Instead, as a growing part of the health care community has come gradually to conclude, general health, morbidity rates, and life expentancy are influenced more by genetic heritage, exercise habits, diet, and such environmental factors as stress than by personal health services.[17] While this general skepticism about the value of personal health services is of no direct relevance in evaluating a particular program, it does condition evaluation in two ways. The first is a general skepticism about the merit of "miracle drugs" or "miracle treatments." These are likely to have more side effects than anticipated and prove to be less effective than their discoverers claim. Indeed, the major benefit is likely to come from a "placebo" effect. The second is a heightened responsibility to carry out evaluations, even where a new technique appears to be efficacious on the basis of a small number of uncontrolled case studies.

With the nationalization of health services after World War II, Great Britain put stringent budget limitations on health services.[18] This caused the National Health Service to resist many new expensive or unproven techniques in favor of expanding simple, proven ones. Budget pressures also caused the administration of randomized clinical trials in order to assure an expensive new technique was effective before introducing it. In spite of the cost and time required, A.L. Cochrane cites the value of clinical trials, arguing that purely observational data, such as case studies, offer little information because of the confounding factors.[19] Randomized clinical trials have been done all over the world.[20] They have provided quantitative estimates of the efficacy of the treatment studied, including the costs and quantitative degree of improvement. Going from these data to a benefit-cost analysis is straightforward, although the additional assumptions are certain to increase controversy.

Bunker et al. examine the efficacy of past and present surgical procedures.[21] Unlike Cochrane's studies, the Bunker studies focus on the qualitative question of whether the surgical procedure helps. While one must grant that the focus is on unfortunate procedures, the reader carries away a general sense of skepticism about surgical procedures in general. For most of the procedures examined by Bunker et al., the issue is efficacy. However, several chapters consider a series of disease treatments that do prove effective, although at vast differences in the cost per additional year of life expectancy. For example, Bendixen describes a range of cases involving intensive care, from barbiturate overdose (95 percent survival, young patients, four days of hospitalization at $600 per day) where life expectancy is prolonged at $84 per year to hepato-renal failure in chronic alcoholics (20 percent survival, short life expectancy among those surviving, 30 days hospitalization at $1,200 per day) where life expectancy is prolonged at a cost of $180,000 per year.[22] The two extremes in Bendixen's study are defined by patients with drug abuse; both crises result from self-inflicted damage. (The

assumed increase in life expentancy for the barbituate overdose patient may be too high if the individual is determined to attempt suicide again.)

A major goal of the Bunker et al. studies is to remove the mystery from the use of quantitative evaluation and decision techniques in medical care. They show that these techniques are extremely helpful and not terribly difficult to apply. Thus, there is no doubt that quantitative evaluation techniques can be and are being applied to personal health services. Ethical considerations mean that some well established techniques will never be evaluated and that some new techniques are likely to be adopted without evaluation. However, there are no good ethical or financial reasons for not evaluating the vast majority of new treatments. Several reviews of the literature using these quantitative techniques show that a vast number of studies are now being done and published.[23]

Preventive health measures have a long history of formal evaluation. Yet, if anything, they are more difficult to evaluate than therapeutic services. There is a large literature evaluating inoculations, screening, and asymptomatic exams.[24] In addition, a literature is accumulating on attempts to change health habits and to educate people about how to achieve better health.[25]

Much of the literature in the past half decade goes beyond the usual evaluation of efficacy to do a benefit-cost analysis or at least to estimate the cost of prolonging life or avoiding an untoward event. Many of the analyses are self-serving in the sense that the qualitative outcome was known in advance; the benefit-cost analysis resulted from an attempt to buttress a position. Thus, quantitative analysis has been used to argue that preventive care, inoculations, or various research programs generally ought to receive more resources.[26] The use of quantitative analysis is rare in many programs for children where more is spent than would be justified by a benefit-cost analysis (a notable exception is screening for PKU).[27]

E. Transport Safety

Many of the difficulties arising in the analysis of health also arise in the analysis of accidents. Identifying the immediate and contributory causes is controversial, as is attempting to deduce what actions might lower the accident rate or the severity of their consequences. Perhaps the major difference is that a highway accident is associated with a highway, while one cannot trace a lung cancer back to any individual activity, location, or exposure. Even if they are not the immediate cause, the use of psychoactive drugs, fatigue, negligence, and ignorance contribute to accidents. It is tempting to seek easy solutions by changing the design or construction of some product, such as the

automobile, rather than attempting to deal with the more important factors of personal behavior. Vehicle design or mechanical failures are responsible for only a small fraction of accidents.[28]

The number of serious accidents and deaths occurring in transportation is public information and is widely disseminated.[29] Individual accidents, especially those involving the deaths of more than one person, are widely publicized. Publicity about specific accidents, especially air crashes, combines with annual statistics to create public pressure for regulatory actions to make transportation safer. The safety of each of the major modes of transportation is regulated by a specific agency charged with improving safety. Two agencies, the Federal Aviation Administration and the National Highway Traffic Safety Administration, have been especially active in preparing quantitative analyses of new designs, safety features, and operating procedures that would enhance safety.[30] Each agency prepares an analysis of the extent to which risks would be lowered and property damage and injury averted, as well as the estimated costs of a proposed new regulation. While controversy is inevitable, these two agencies have established firmly a tradition of analysis of proposed regulations.

Air Transport. For example, the Federal Aviation Administration report ASP-78-5 is an analysis of frangible approach lighting systems at airports.[31] The report identifies the principal benefit of these easily broken lighting poles to be an enhancement of safety when the pole is struck by an aircraft. Secondary benefits include lower maintenance and less energy use.

Potential accident reduction is estimated by tabulating recent experience by air carriers and general aviation to determine which accidents were due to collision with a rigid light pole. Health outcomes are tabulated in categories of death and serious or minor injury. The value to society of preventing injury was taken from an analysis of actual settlements, $300,000 for death, $45,000 for serious injury, and $6,000 for minor injury. The dollar values for the two injury categories, particularly serious injury, seem underestimated, since some injuries involve long hospitalizations and permanent disability. Damage to aircraft is estimated on the basis of replacing the aircraft with a comparable used aircraft or repairing the damage. Maintenance savings are estimated via the reduction in manhours at the current wage rates. Energy savings are valued at $.05 per kilowatt-hour.

The number of accidents caused by or aggravated by collision with lighting standards was divided by the total number of operations during this period to get the average risk per operation. The total damage sustained in the accidents, injury plus aircraft damage, was tabulated and divided by the number of operations to get the average loss per operation due to collision with rigid light standards.

The benefits of various proposals are estimated via the expected number of operations at these airports multiplied by the cost reduction due to safe operations. These present discounted costs are $14.59 per operation for air carriers and $.22 per operation for general aviation. The report finds that 397 lighting systems are candidates for replacement at a total cost of $77.7 million. Of these, 272 with a total cost of $48.4 million have benefits greater than costs.

The report is technically well done in terms of carrying out the benefit-cost analysis. It is to be praised for attempting an analysis for each candidate runway, rather than attempting to compare the total benefits of the program to its total costs. However, the report does not go so far as to rank candidate runways by their benefit-cost ratio in order to determine where the Federal Aviation Administration ought to concentrate its initial efforts. One might quarrel with the parameter values used to estimate the social cost of injury, but there is a reasonable basis for the estimated parameters. A major weakness is the estimated reduction in accidents stemming from frangible lighting systems. However, it is difficult to imagine how better estimates could be achieved from available data. The report is to be commended, but the uncertainties and estimated dispersion about the estimates should have been discussed explicitly, rather than allowing the reader to infer that the estimates were not precise.

The eight decision frameworks can be applied to setting a standard for frangible light poles. Market regulation would call for the FAA to present this analysis to airport managers and allow them to make teir own decisions. The FAA is currently responsible for air safety and a change in legislation might be required to allow airports to make their own decision. A no-risk framework would call for frangible standards at all airports, with a large increase in expenditures. While the FAA could probably fund this program, it could not fund the implementation of all programs which would reduce risk in commercial and civil aviation. The risk-risk framework could be applied here, since constructing and erecting the new light poles would be expected to result in occupational injuries and disease. While it is conceptually possible to estimate the increase in occupational injuries, the increase is likely to be small. Technology based standards would lead the FAA to replace all light poles. As with the no-risk framework, the FAA would not be able to obtain sufficient funds to implement best available technology throughout aviation. Risk-benefit would probably compare the risk per hour of flying with the risk of other activities. Since the risk is somewhat higher, this activity would probably be deemed to need improvement and so the lighting standards would be required, presumably without differentiating between large and small airports.

The cost effectiveness and regulatory budget frameworks would lead to a different solution only if the FAA budget were so constrained that it could not implement all standards whose benefits exceeded their costs, The FAA has acted in a disciplined, responsible

fashion and both the Department of Transportation and Congress have learned to trust their analyses.

If one uses political (i.e., Congressional) acceptability as an indicator of social preferences, then this is a case where applying a framework other than benefit-cost analysis would have led to a less desirable solution. Certainly, there were controversies associated with the assumed value placed on preventing an accidental death, and with airports which did not receive the new light poles. However, the quality of the analysis prevailed.

Auto Safety: Passive Seat Belts. About 50,000 people are killed on highways each year, making highway accidents the most common cause of death of young adults. The NHTSA was set up to lower this slaughter.[32] One key part of the solution is restraining occupants during a crash. Seat belts are extraordinarily effective; it is estimated that the number of fatalities and serious injuries would be lowered 50 percent if all occupants wore three-point belts.[33] In practice only about 10 percent of occupants wear their belts. Thus, a potentially highly effective safety device is almost totally useless in practice.

NHTSA attempted to compel people to buckle up in 1974 and early 1975 model automobiles by requiring an interlock device, which would keep the automobile from being driven unless all occupants had buckled their belts. However, the combination of mechanical problems and public resentment led Congress to forbid NHTSA to continue requiring the device. Since 1975, NHTSA has been searching for a way of protecting occupants without requiring a belt to be buckled or similar action. This concern resulted in a standard calling for cars to be designed so that occupants would receive no more than minor injuries should their automobile crash into a solid barrier at 30 mph, without their having to buckle their seat belts or take other protective action.[34] This requirement was scheduled to be phased in from model years 1982 to 1984, beginning with the large cars.

Two current safety systems are capable of meeting the standard. The first is an air bag system, where bags in the steering wheel and dash board inflate rapidly in case of a collision, holding the occupant in the seat. The other is a passive seat belt that automatically operates without passenger action. Difficulties with air bags include their expense; the lack of protection for side crashes, multiple collisions, or rollovers; danger to young children; premature deployment; and damage from being activated by vandals. Moreover, air bags are less effective if a lap seat belt is not worn.[35] The air bag's principal advantages are that they allow occupants to be completely unencumbered by belts and permit a bench front seat. Of the two devices, air bags are more expensive, provide less protection, and are more costly to repair after an accident. Passive seat belts have all the disadvantages of seat belts, except that they are automatically activated. Some people object to being confined; NHTSA estimates that 33 percent

of occupants may disable their passive belts in order to avoid being confined.[36]

A major issue is the extent to which individuals are or should be capable of making their own safety decisions. Public and government reaction has been ambiguous. By requiring safety equipment for automobiles, NHTSA is assuming that buyers are not able to make correct decisions with regard to their own safety. However, failing to require people to wear the required seat belts is an admission either that the regulation could not be enforced or that it should not be made. This schizophrenia about whether people are responsible leads to costly decisions. If people are not responsible, seat belts ought to be required and their wearing should be mandatory. If people are responsible, they can make their own decisions about wearing seat belts and safety equipment should not be required.

Major controversy erupted between the Department of Transportation and the automobile companies about the number of lives that would be saved by air bags or passive belts. The government first estimated that 30,000 people would be saved each year, then 15,000 and then 9,000.[37] The automobile companies were more skeptical, although they gradually raised their estimates over time. A series of social experiments has reduced the range of uncertainty. A fleet of General Motors car was equipped with air bags and then studied for crash protection. Volkswagen equipped some cars with passive belts and these cars have been studied. Sufficient experience has been accumulated so that there is general agreement about the number of fatalities (6,000 to 9,000 per year) and serious injuries (about 36,000 per year) that would be averted by air bags, air bags and lap belts, or passive belts (that have not been disconnected).

Quantitative analysis has not resolved the issue of whether air bags, passive seat belts, or the wearing of standard belts should be required, but it has provided estimates of the benefits stemming from each of these policies and of the costs of each. The ultimate decision requires much more than quantitative analysis. However, it is evident that the analysis has managed to rule out many proposed solutions and clarify the implications of others.

The eight decision frameworks can be applied to passive seat belts. Market regulation would call for offering these devices as optional features, disseminating information to consumers, and letting them make their own decisions. Since only a small proportion of buyers elected either the passive seat belts or air bags in available models, it seems likely that few buyers would elect them in the future. The result would be little or no decrease in the number of severe or fatal highway accidents. Society appears to have made a decision that the number of highway deaths and severe injuries is too large to be tolerated. Thus, the market solution is not recognized as commensurate with social goals. However, the failure of automobile occupants to fasten

their current seat belts, and the fact that perhaps 1/3 of owners of automobiles with passive seat belts disconnect them, means that the new standard will be less than totally effective in achieving social goals. Even though the market solution is apparently not socially acceptable, it cannot be dismissed lightly.

The no-risk framework would require the air bags in combination with lap seat belts, since they appear to be most effective. However, even more effective in reducing injuries would be lowering speed limits, prohibiting people from driving while drunk or fatigued, and taking away the licenses of accident prone drivers. This solution has not been attempted.

The risk-risk framework adds little, since the increase in occupational injuries from making the passive restraint devices would be small.

Technology based standards would require these devices as best available technology. There are a host of other devices, including designing an automobile to be crash resistant, which would add to safety dramatically. These would, of course, increase the cost of an automobile. NHTSA has not required best available technology.

Risk-benefit analysis would probably call for the passive restraints on the grounds that riding in an automobile is more dangerous per hour than other activities. Indeed, it would presumably call for the redesign of the automobile until it was as safe as other activities, even though this would increase the price of a car to the point of denying it to many current owners.

Cost-effectiveness analysis would call for passive restraints. To be exact, it would call for passive belts since they are more cost effective than air bags. As long as they are not disconnected, they save lives at approximately the cost of other NHTSA regulations. This analysis would probably not take account of consumer preferences, and might not consider the number of devices that would be disconnected.

The regulatory budget would probably parallel the outcome under cost-effectiveness analysis, with the same difficulties.

A benefit-cost analysis would probably lead to the same outcome: requiring the passive restraints. The analysis should account for the number of devices that would be disconnected, which would lower benefits. More difficult would be considering people's feelings about being required to pay for and use these devices when they desired current seat belts or no encumbrance. Society can desire a reduction in highway deaths but reject a particular safety device, as for example, the interlock. The social dilemma is whether the reduction in death and serious injuries from automobile accidents justifies the increased price of cars, requiring people to accept air bags or passive belts, and denying automobile ownership to those who cannot afford the increase in

vehicle cost. While benefit-cost analysis does not meld all these factors into summary numbers, it does stress consideration of all these effects.

F. Consumer Products

The Consumer Product Safety Commission was created to regulate accident and disease risks from products purchased and used by consumers.[38] Recognizing that some degree of risk was inherent in all products, Congress created a statute that requires CPSC to balance risks and benefits in setting standards. Thus, analyses have been done using a risk-benefit framework, with only rough attempts to quantify costs and benefits, monetize them, and complete a benefit-cost analysis.

The requirement for analysis and balancing did not prevent the agency from proposing an ill-advised standard for swimming pool slides, but it did enable the manufacturer to get the standard vacated.[39] Other analyses helped persuade manufacturers of baby cribs to alter the spacing of crib bars so that an infant's head could not be trapped between them. Nothing as formal as benefit-cost analysis is needed to make the case for cribs since the costs of altering the design of cribs is virtually zero; the only issue is whether widely spaced bars present enough of a risk that redesign is required. Crib design is probably a case where market regulation would be sufficient. Giving the public information about the threat of widely spaced bars could be expected to shift purchases, particularly since the effect of redesign on price is likely to be trivial. Even those who do not care about the risk would eventually be protected because better informed consumers would not purchase unsafe cribs, reducing their market and profitability to the point where they would no longer be manufactured. In addition, governmental identification of the risk would be a valuable aid for the parents of an infant injured or killed in a poorly designed crib; they could expect to collect damages in a suit against the retailer and manufacturer. This threat of substantial awards would provide even more incentive for manufacturers to change their design.

A set of proposed standards for lawn mower safety is another example of the use of quantitative analysis. The Council on Wage and Price Stability analyzed these standards and challenged them, finding simplistic the CPSC analysis that, under one set of assumptions, benefits would exceed costs. The primary benefit of the COWPS analysis is to examine each of the proposed design changes and to estimate the benefits and costs of each. The analysis shows that some of the changes are cost-effective, while others are absurd. The separation of standards showed that virtually all of the increase in consumer safety could be achieved for a small fraction of the cost of the entire package.[40]

To date, few of the analyses done by CPSC have been of sufficient quality to support good decisions. While there are difficulties in estimating costs and benefits, there is no reason that the analyses could not have been improved, as shown by the Council on Wage and Price Stability study. In at least one case -- the regulation on flame resistant children's sleepwear -- the rush to find a solution led to a policy (adding TRIS to flammable fabrics) that probably imposed greater risks than were present before the regulation.

G. Impact Statements -- The Misuse of Analysis

The overselling of the value of analysis is evident in various types of impact statements required by the President and Congress. To determine the effects of the new legislation or agency regulations on some social goal, and to ensure that Congress and the agency recognize these effects, the President and Congress have mandated environmental and inflationary impact statements. While the intent of these requirements may have been noble, there can be little doubt that few beneficial results have followed. The principal effect has been to slow the passage of new legislation, the enactment of agency decisions, and the commencement of private sector projects. Since the requirements for these various impact statements were never rigorously defined nor was their role in decision making specified, their effect has been confined largely to stopping a project until a satisfactory (usually defined by the courts) statement has been prepared.[1] Generally, the resulting impact statements are so voluminous that no one considers or even reads them, much less attempts to modify decisions on the basis of their findings. This is surely one of those cases of overload where additional data are not examined and thus have no role in decision making. If some future impact statement is to affect decision making, other than to slow it, the nature of the analysis must be carefully defined, along with the role the resulting information is to have in making decisions. Merely preparing something that is vaguely relevant provides no assurance that it will prove useful. Analyses must be carefully specified and tailored to the needs of decision makers. If not, they become millstones about the necks of people trying to make decisions; they contribute nothing and slow the process.

VI Conclusion

In a wide variety of contexts, the quantitative analysis of risk and the setting of quantitative safety goals are feasible and, if done in an appropriate framework, desirable. Although Congress has occasionally specified the framework that an agency must use to set a safety goal, more generally agencies have considerable

discretion in this regard. Our discussion has indicated how considerations as diverse as technological risk, hazardous materials, and toxic substances can be--and have been--incorporated into the analysis.

The choice of a framework for analysis is of fundamental importance. Major issues involved in selecting an appropriate framework include: (a) the required amount of data collection, analysis, and value judgments called for by the framework; (b) the possibility of quantifying the risks involved; (c) the manner in which the framework aids in setting priorities; (d) the residual level of uncertainty remaining after analysis; and (e) the general costs of the regulatory process. The choice of a framework may be legislatively prescribed (e.g., no risk or risk benefit) or up to the agency.

In those cases where a very narrow framework, such as no-risk, has been mandated by Congress, considerable difficulties have resulted, in spite of the inherent simplicity of the framework (e.g.: Delaney clause). Qualitative goals such as technology-based standards (e.g., ALARA, ALAP, Best Available Technology) set safety levels implicitly. In so doing, however, they either ignore important tradeoffs that accompany technological choices, or these are considered in an ad hoc manner for which the framework makes no allowance.

Frameworks that require quantification of risk can encompass many fields. In this survey, we have indicated numerous instances where a framework that involves such quantification was applied in a situation in which the safety concerns are similar to those facing the NRC. Although there have been cases where the analysis was poorly conceived and executed, safety levels have been quantified by many agencies and used in their regulation. It is also apparent that recent court rulings have been moving in the direction of greater judicial expectation of quantitative rather than qualitative analysis in health and safety regulation. Perhaps the greatest difficulty has not been the ability to analyze and quantify risk, but rather the lack of clearly drawn general safety goals from Congress. Either directly or through agency oversight, Congress must clarify the goals and framework appropriate for each agency in order to improve the quality of regulation.

FOOTNOTES

1. For an excellent review, see R. A. Merrill, Federal Regulation of Cancer-Causing Chemicals, Chapter III, Administrative Conference, 1980.

2. Merrill, Chapter IV, provides an excellent review. The major statutes are:
Clean Air Act, 42 USC Sec 1857 et seq. (1970); with amendments in P.L. 91-604, 84 Stat 1676 (1970).
Federal Water Pollution Control Act, 33 USC Sec. 1251 et seq. (1972).
Toxic Substances Control Act. P.L. 94-469 (1976).
Federal Insecticide, Fungicide, and Rodenticide Act, 61 Stat. 163 (1947); with major amendments in P.L. 92-516 (1978).

3. For a review, see M. Hinich and R. Staelin, "Regulation of the US Food Industry," in Study on Federal Regulation, Appendix to Volume 6. US Senate Committee on Government Affairs, 1978.

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This report was prepared in support of NRC's project to develop a safety goal.

Each agency regulating health or safety must set a safety goal, implicitly or explicitly. In some cases Congress has given specific guidance to work toward zero risk or to balance risks and benefits; more generally, Congress has given immense discretion to the agencies.

Eight frameworks for regulating health and safety are described: (1) market regulation, (2) no-risk, (3) risk-risk, (4) technology based standards, (5) risk-benefit, (6) cost effectiveness, (7) regulatory budget, and (8) benefit-cost analysis. All frameworks except (3) and (7) are currently used. Important issues in deciding which framework to select include: (a) the required amount of data collection, analysis and value judgments for each, (b) whether risk can be quantified in each case, (c) how each framework affects priority setting, (d) the residual level of uncertainty after analysis, (e) safety goals, and (f) the general costs of regulating. The report examines the legislation and case studies of the major health and safety agencies: CPSC, OSHA, EPA, and FDA.

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