Eight Frameworks for Regulation


The frameworks used to guide analysis and the decisions made regarding proposed health and safety regulations are inextricably linked. For example, if an agency is required by law to ban any substance shown to be a carcinogen, little or nothing is gained by an elaborate analysis of the economic and other implications of alternative decisions. The decision framework establishes priorities among issues and changes the way both regulators and nongovernmental decisionmakers view health and safety issues. Choosing a decision framework and using it consistently is perhaps the most important device for influencing the billions of decisions governing health and safety that are outside the control of federal regulators. Failure to appreciate the importance of the decision framework is the root of much of the criticism of social regulation. Legislation such as the Toxic Substances Control Act; the Federal Insecticide, Fungicide, and Rodenticide Act; and the Consumer Product Safety Act requires analysis of benefits, costs, and risks in formulating a regulation. Unfortunately subject areas such as carcinogenicity lack a firm scientific foundation for an analysis of this kind, and agencies often lack resources to carry out analysis for those areas having a scientific foundation. Legislation such as the Delaney Clause is highly specific in requiring a ban, but occasionally


2. The so-called Delaney Clause resulted from hearings held by Congressman James Delaney of New York and is found in the Food, Drug, and Cosmetic Act of 1938 (12 Stat. 1786). It states in part that "no additive shall be deemed to be safe if it is found... to induce cancer in man or animal."

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this action is so counter to public desires that the agency is condemned for carrying out the legislation, for example, for banning saccharin.

Decision Frameworks

Six frameworks for making regulatory decisions are currently being used and two have been proposed. The frameworks range, roughly, from those requiring the least theory, data, and analysis and offering the least flexibility to those at the opposite pole; they include market regulation, no-risk, technology-based standards, risk-risk (proposed), risk-benefit, cost-effectiveness, regulatory budget (proposed), and benefit-cost.

Market Regulation

Economic theory has formalized the 200-year-old insight of Adam Smith that competitive markets are efficient. In particular (under a set of stringent assumptions including complete information, no transaction costs, rational consumers and producers, no economies of scale in production, and no externalities), a competitive market produces an efficient (or Pareto optimal) equilibrium in the sense that no one can be made better off without making at least one person worse off. This efficiency principle also holds for situations involving risk, such as hazardous products or jobs, although still more stringent assumptions are needed.

Each person in such an economy presumably would decide what is best for him by looking at the array of available products and jobs. Since risk is an undesirable attribute, all risky products and jobs having no compensating attributes would be eliminated, and individuals would scrutinize those risky products and jobs that offered higher pay or some other

3. Arranging the frameworks is not so simple. For example, risk-benefit analysis requires as much information as benefit-cost analysis, although it is less formal. While more than a single dimension is involved, the ordering is roughly accurate. See the bibliography for additional references.


advantage to determine which should be taken. Under the restrictive assumptions, government regulation would be unnecessary.

Clearly the U.S. economy does not satisfy the host of restrictive assumptions; both buyers and sellers can often influence price, many effects are transmitted outside the marketplace, and often buyers and sellers are woefully ignorant of the health and safety implications of a product. Market equilibrium is inefficient and a case can be made for government intervention. Some economists caution Americans to eschew perfection, arguing that they would be better off in the long run by tolerating these relatively minor evils instead of erecting a huge, self-defeating regulatory structure. Regulation requires resources, but more important, it is virtually impossible to regulate so that incentives are not distorted, and this often leads to even greater inefficiency than in the unregulated market—for example, transportation regulation, particularly of airlines and trains. Many economists argue that regulation is justified only when serious violations of the assumptions occur, and then only if the regulation can be relatively efficient. An outstanding controversy concerns whether the current U.S. economy is essentially competitive and the consumers well informed. One side claims that the economy has hardly a hint of competition and that most consumers and workers are ignorant. The other side sees intense competition, even within such oligopolistic industries as automobiles and airlines. Each side can muster persuasive examples, although general proof is impossible. Society has tended to sway with the winds of intellectual discourse, with gusts of regulation and then deregulation, as in transportation, for example. There is general agreement, however, that the economy is basically governed by the free market and that some regulation is necessary. Successful regulators are pragmatic. Doctrinaire positions concerning government control or laissez-faire are interpreted within the context of each case, with the ultimate outcome dependent on the nature of price control, consumer and worker ignorance, and magnitude of risk.


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Whether to license auto mechanics or to regulate sodium nitrite is decided by consideration of the specific facts and risks rather than by the doctrinaire view that government should or should not regulate risky situations.

In summary, the decision to use the market to regulate risk puts faith in consumer information and judgments. It sees the costs of bureaucracy constraining private decisions as larger than costs arising from market imperfections and advises accepting current imperfections rather than creating a regulatory morass.

No-Risk

The philosophy behind the Delaney Clause of the Food, Drug, and Cosmetic Act, and food additive amendments generally, is that the public should be exposed to no additional or unnecessary risk. Carcinogens cannot be added to foods or remain as residuals in meat since this might increase the risk of cancer; according to the Clean Air Act Amendments of 1970, air pollution levels must be sufficiently low to protect the population from adverse effects, presumably even the most sensitive members.

This approach has great appeal as rhetoric. To argue that carcinogens ought to be permitted in the food supply is to argue that society must allow higher than necessary risks of cancer. Why should any unnecessary exposure be tolerated, even if the risk appears to be small?

The no-risk framework has the advantage of requiring little data and analysis and precludes agonizing about the decision to be made. According to the Delaney Clause, the only question is whether a food additive has been shown to be a carcinogen in humans or animals. Thus data (on the quality, variety, and price of food) concerning the consequences of banning may not be considered. The Delaney Clause has a simple, straightforward answer to a complicated question: ban a substance if there is evidence of carcinogenicity. Frameworks other than market regulation require answers to a set of complicated questions: What level of risks are acceptable? What benefits would serve to offset the risks? Can animal bioassays be relied on to demonstrate human carcinogenicity?

Can the potency of a substance for humans be demonstrated under current exposure levels? If one requires simple answers to these questions or distrusts the complicated answers given by experts, no-risk offers an appealing solution.

Unfortunately the answers are too simple. Virtually all "natural" foods contain trace elements of carcinogens, including biological contaminants and pesticides. The Food and Drug Administration treats natural foods differently than food additives; apparently it is less troublesome to die from a cancer induced by a natural food than from one induced by a food additive. Does anyone seriously propose to ban all foods with trace levels of carcinogens? Does it make sense to treat those with trace amounts in the same way as those with large amounts of potent carcinogens?

In practice the Food and Drug Administration considers, at least indirectly, the potency of each substance and the effects on the food supply. As shown in chapter 4, the agency agonizes over decisions concerning carcinogens when banning would reduce the food supply or merely deprive Americans of some cherished food. Any attempt to impose consistency runs into the impossibility of eliminating risks generally and carcinogens particularly. It is less obvious, however, that they could not be eliminated from a narrow class of substances such as food additives.

If society were concerned solely or even principally with the safety of food, the no-risk approach would be an appropriate guide for regulation, but society is concerned with many other issues as well. People eat foods they know to be harmful to their health and they indulge in a range of habits indicating that health is neither their sole objective nor even a very important one. For example, in addition to overeating and not eating wholesome foods in a balanced diet, people smoke cigarettes, live in cities with polluted air, and work in occupations they know pose risks of accidents and chronic disease. Attempting to legislate safety by banning food additives that lower cost, enhance flavor and appearance, or increase convenience is like attempting to legislate morality: the rhetorical appeal is evident, but regulation can hope to affect only a tiny proportion of the relevant risk, and at rapidly increasing cost.

The three principal objections to this framework are the current misallocation of resources, the closing of the door to future solutions, and the inconsistency in government policy. In addition this framework cannot distinguish between a toxin that is extremely weak and to which few people are exposed and a potent carcinogen to which nearly the entire population is exposed. Insofar as there are many carcinogens and it is costly to ban at least some of them, this framework does not help to develop priorities—which substance should be treated first—or guidelines—what level of safety ought to be sought where banning is infeasible? Instead, it sends regulators scurrying off to devote much of their attention to relatively benign substances by giving all toxins equal priority. Thus the framework is a pernicious guide to regulators confronted with complicated problems.

Although Congress has written the no-risk framework into legislation, it is a straw man unworthy of serious consideration. Even the attempt to maintain the facade is increasingly recognized by the regulatory agencies to be impossible. For example, the Food and Drug Administration has attempted to define a "negligible" risk level; any risk below a level of one in one million lifetimes would be considered to be zero for regulatory purposes. The Environmental Protection Agency has taken an even more hostile view of the no-risk framework:

A requirement that the risk from atmospheric carcinogens emissions be reduced to zero would produce massive social dislocations, given the pervasive-ness of at least minimal levels of carcinogenic emissions in key American industries. Since few such industries would soon operate in compliance with zero-emission standards, closure would be the only legal alternative. Among the important activities affected would be the generation of electricity from either coal-burning or nuclear energy; the manufacturing of steel; the mining, smelting, or refining of virtually any mineral (e.g., copper, iron, lead, zinc, and limestone); the manufacture of synthetic organic chemicals; and the refining, storage, or dispensing of any petroleum product. That Congress had no clear intention of mandating such results seems self-evident."


Technology-Based Standards

Recognizing the difficulty of attempting to estimate the health and safety effects of a proposed standard (much less the problem of quantifying these effects), a number of agencies have placed their reliance on engineering judgments. 17 The best available control technology has been required extensively by the Environmental Protection Agency in regulating air and water pollution. This framework has the simplicity of requiring the estimation of neither benefits nor costs. The data and analysis required are for identifying a hazard and then for making the engineering judgment as to the best available control technology. This framework requires a second set of information for determining the best available control technology in addition to the carcinogenicity data required for the no-risk framework.

In practice, however, there is never a best technology but only successively more expensive and stringent technologies. For example, the effectiveness of an electrostatic precipitator in removing suspended particles from air is proportional to the collector plate area; effectiveness can be increased by increasing the area. In practice, engineering judgment defines best available control technology as a finite collector plate area, even though further increases in plate area would improve (minutely) the effectiveness of collection. At some point additional abatement is unwarranted because social costs exceed social benefits; but even then technology is available that would abate emissions further. In practice, best available control technology embodies implicit assumptions about the benefits and costs of further abatement.

The crucial issue in implementing this framework at present is the financial burden each industry can bear. As long as an industry is not in danger of bankruptcy, a technology that lowered emissions would be considered acceptable. Sufficient uncertainty exists about what cost level would endanger an industry that regulators rarely impose standards that come close to doing so.

In summary, the primary advantage of technology-based standards is that they require no formal evidence on costs or benefits; the only data required are those necessary for good engineering judgments. The resulting standard, however, will depend on regulators' perceptions of industry profitability. If an area is populated by an industry teetering on the brink of bankruptcy, best available control technology will be weak and few emissions will be abated. If the industry is profitable, it will require large expenditures. There is more than a theoretical possibility that the first regulation in an industry would press it to the limit of its ability to afford regulation, leaving no financial resources to handle later regulations that might be far more important. Rather than being a framework for lowering risk or even for using engineering judgments, technology-based standards is a framework for regulating economic activity through imposing costs arbitrarily among industries until all are at the same minimal level of profit.

Risk-Risk: Direct

Even if maximum protection were desired, the Delaney Clause would be a poor framework because it requires banning carcinogens. Some toxic substances, such as food additives and fungicides, prevent contamination of food, and thus it is desirable to weigh one risk against another, as recognized by the Food and Drug Administration and the Department of Agriculture in the proposed risk-risk analysis. 18 Balancing the toxicity of a substance against the enhanced protection it brings can be done from either of two perspectives. The narrow perspective is that of balancing the risk to the consumer of the additive against the direct health benefits. Sodium nitrite may be a carcinogen, but it protects against botulism; the risk of cancer must be balanced against that of botulism. The broad perspective takes account of both producers and consumers as shown below.

Since the risk-risk framework allows beneficial health effects to be considered along with adverse health effects, it is more flexible than no-risk. It and the remaining frameworks are qualitatively different from no-risk in that they require quantification of risk and at least partial estimation of benefits. If quantification were impossible, this framework could not be implemented because there would be no method for balancing unmatched risks (for example, chronic respiratory disease versus broken legs). Quantification is particularly difficult for the effects of toxic substances; thus this and the remaining frameworks are subject to the caution of those who contend that potency cannot be estimated from animal bioassays, or at least that potency for humans at low doses cannot be


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inferred reliably.\textsuperscript{19} The ability to estimate human risks will be treated in chapter 3.

All frameworks except the first two allow the possibility of labeling or other action short of banning.\textsuperscript{18} This gives wider choice to individuals, permitting them different life-styles. Insofar as choice and diversity are important, alternatives to banning are important.

While the risk-risk framework provides somewhat greater flexibility, it still precludes consideration of nonhealth effects. Conceptually it is a small step since it merely includes both the health risks and health benefits of a proposal. In practice it appears to be a major improvement over the no-risk framework—where it is applicable. Cases such as sodium nitrite where the risk-risk framework is inapplicable are the exception. Few substances offer a direct health benefit to the consumer other than drugs, products for which the Food and Drug Administration already uses this framework. The framework is of limited interest because it is of such limited applicability.

Risk-Risk: Indirect

The advantage of the risk-risk framework over the no-risk framework is that it permits wider analysis of risks. One way of stating the objective is that society desires to minimize the adverse health effects associated with a given food such as bacon. Thus society would permit nitrite in bacon if the improvement in the health of consumers from bottulon protection exceeded the decrements in health from the risk of cancer. Yet it is evident that the direct risk-risk framework takes only the first step of considering the health of the person consuming the food. People are also associated with the production and distribution of food; society desires to minimize the adverse health effects associated with producing as well as consuming bacon (for a fixed level of production). Workers would not

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\textsuperscript{20} See NAS, Food Safety Policy, pp. 4–17, 8–1; and Oliver E. Williamson, "Public Policy on Searcett: The Decision Process Approach and its Alternatives," in Robert Cram and Lester B. Lave, eds., The Scientific Basis of Health, Safety, and Environment Regulation.

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contenence a regulation that offered consumers a small amount of protection at the cost of a large increase in risk to workers.

Since every human activity is risky, a regulation that requires more man-hours to produce a unit of food would increase the exposure and presumably the occupational risk of workers. The indirect risk-risk framework includes occupational risks associated with each additive or contaminant (see the appendix for some methods that might be used to estimate these occupational risks).

One qualification to this approach is that consumers generally are unaware of food risks, while workers are likely to have better information and receive a wage premium to take occupational risks. Furthermore, there is some selectivity of workers for a particular job, at least limited flexibility to change jobs or even to quit if the risks are too high, and some ability to remain alert when risks are highest.\textsuperscript{21}

The indirect risk-risk framework is an important generalization since it allows consideration of implied health risks to workers. The difficulty is estimating health risks. As a first step in the analysis, assume that the same quantity of a regulated product would be produced as has been produced before. The immediate effect on workers might be estimated by assuming that the average rates of accidents and occupational disease in an industry would apply to the additional effort required by the proposed regulation. For example, additional feed grains to fatten steers because diethylstilbestrol is banned in particular, if banning it required a 10 percent increase in corn production, accidents and occupational disease among corn farmers would be estimated to increase by 10 percent. There are a series of ripple effects, however. The additional farming will require more seed, fertilizer, machinery, and fuel; these in turn will require more steel, coal, and so forth, each of which will involve occupational accidents and disease. Some preliminary notions for quantifying such ripple effects are discussed in the appendix.

Risk-Benefit

Unlike the risk-benefit framework, the three previous ones do not allow consideration of nonhealth effects. The folly of refusing to consider these effects is illustrated by examining one's own choices. For example, most people are willing to risk the minute chance of biological contaminations...
tion rather than to be bothered with boiling drinking water. They are willing to undertake additional risks in order to get rewards such as additional income and recreational stimulation. For example, there is a risk premium in the pay of workers in hazardous occupations to attract them in the face of the higher risks. These premiums can be extremely high, as for test pilots, steeplejacks, and divers working deep in the ocean. If the effect of a regulation is to lower risk minutely at the cost of a vast increase in price, a lessening of choice or convenience, harm to the environment, or a sacrifice in social goals generally, society should not be satisfied. The frameworks previously mentioned suffer from their lack of recognition of other social goals such as the ecosystem, endangered species, and individual freedoms.

Under the risk-benefit framework, regulators would be enjoined to balance the general benefits of a proposed regulation against its general risks. This framework is intended to be somewhat vague, with all effects being enumerated, but with full quantification and valuation being left to the general wisdom of the regulators. The framework may account for cost, convenience, and even preferences in an attempt to balance benefits against risks. A vast array of frameworks can come under the risk-benefit heading, from balancing health risks against health benefits (like the risk-risk indirect framework) to consideration of all risks, costs, and benefits. The framework has an immediate appeal to congressmen and regulators since it is a general 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.

The intellectual difficulty with this framework is its lack of precise definition. Are only health risks to be considered, or are risks to the present and future environment (air, water, houseworks, snail darters, and tundra) relevant? If they are not, the framework is no more complete than the previous one, and if they are, how can the risks to houseworks be added to those to the health of our great grandchildren and of current workers? Similarly, there is no guidance about how to quantify benefits: what is the value of an increase in the supply of food or electricity?

This is the most general and flexible framework, but one despairs at its implementation. Is it more than an injunction that decisionmakers ought to think broadly about the risks and benefits of their decisions? Insofar as decisionmakers are suspicious of quantification or do not believe that it can be done with confidence, this framework serves to broaden their consideration, but it still relies on their intuitive judgments. While it is desirable to broaden the scope of matters to be considered, the failure to define what is irrelevant has lengthened hearings and complicated the record. The risk-benefit framework makes no pretense at being an automatic decisionmaking tool. It forces regulators to consider a broad set of costs and outcomes; they cannot abdicate their responsibility by examining only a narrow set of effects or appealing to some arbitrary criterion as they can under the no-risk framework. The risk-benefit framework, however, has produced decisions and justifications that seem arbitrary and inexplicable; it has been a step forward, but it is too unsatisfactory to be more than a transitional step.

Cost-Effectiveness

Many organizations, private and public, find themselves attempting to increase output even though their current budget is fixed. The intellectual contribution in defining this problem and developing rules to solve it have come from the Department of Defense. Although cost-effectiveness is often thought erroneously to refer to getting some specific project done at lowest cost, the concept is much broader, referring to accomplishing some general objective at lowest cost. President Eisenhower's secretary of defense, Charles Wilson, described the goal succinctly as an attempt to "get the most bang for the buck."

How can a goal be achieved within a fixed budget? For example, the goal of the National Cancer Institute is to lower the cancer death rate. It might achieve this goal by devoting resources to basic research, clinical trials testing new treatment techniques, public education, prevention by lowering the amounts of carcinogens in the environment, early detection of cancer, or the provision of more treatment. How should the fixed
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budget can lead to bad decisions, and there is no internal mechanism for showing the errors in these decisions and the changes in goals or budget that are necessary.

Regulatory Budget

Cost-effectiveness is a good framework if the relevant costs are being measured in the analysis. Unfortunately when the only costs considered are those of the regulatory agency, the framework will misallocate resources because only one subset of the total costs of the regulation to the entire economy is being considered. The agencies have little or no reason to consider the costs that their regulations impose on others unless the costs are so high that industry bankruptcy is a relevant possibility. The agencies are instructed to protect the environment, consumers, or workers without any apparent limits on their ability to impose costs on others. That the resulting regulations are not universally perceived as desirable can be judged from the comments of the affected companies and the fact that the federal government has often exempted itself from the regulations or has been slow in implementing them.

An idea originating in the Council of Economic Advisers under Charles Schultz was to give each regulatory agency an implementation budget in the form of a limit on the total annual costs that its regulations could impose. For example, the Environmental Protection Agency might be given an implementation budget of $10 billion a year, which would mean that the costs of implementing its air, water, solid waste, radiation, and pesticide regulations could not exceed $10 billion in that year. Each agency would develop an implementation budget request, just as it currently develops its operating budget request. The administration would coordinate and impose priorities on the agencies, and then Congress would react to these requests, modifying them as necessary.

The regulatory budget is one method of implementing cost-effectiveness analysis. The goals needed for the framework are stated in the legislation for each agency, supplemented by whatever informal instructions

arise from hearings, appropriations, Office of Management and Budget directives, or presidential intervention. The internal and implementation budgets would be considered and approved by Congress, based on each agency's data on effectiveness. A major advantage of the framework is that it would elicit from the agencies a clearer indication of their priorities and would enable Congress to make more intelligent decisions regarding social values.

The principal difficulties with the framework are in estimating the costs and effects of each regulation. Where a control device must be added to a smokestack, there is debate about the cost of the device and about its expected lifetime, maintenance, and reliability. For a new piece of technology, these difficulties might perhaps introduce a factor-of-two difference in estimated costs. When the regulation will require a change in process or result in banning a substance, the costs become much more uncertain. If there is a factor-of-five-or-more difference between reasonable high and low estimates of implementation costs, the regulatory budget cannot provide a helpful constraint.

Discipline might be exerted by the use of ex post reviews of previous cost estimates and the resulting experience. Even for regulations that have been implemented, however, it is difficult to estimate the additional costs due to the regulation. In addition, several years would elapse before sufficient experience accumulated to estimate costs retrospectively; disciplining the agency for bad cost estimates during a previous administration would make little sense.

Excluding uncertain or indirect costs (while estimating only direct costs or those that can be confidently quantified) would give a terrible set of incentives to the regulatory agency. For example, banning a substance would minimize direct costs, even though it might impose very substantial indirect costs. Similarly, counting only current costs would lead the agency to design a regulation to impose costs in the future.

Estimating the accomplishments or benefits of a regulation is even more difficult, but this problem is common to all the frameworks from risk-risk to benefit-cost analysis. Good estimates of costs are required for the frameworks encompassed by cost-effectiveness and benefit-cost. There is no easy way to improve the quality of the cost and effectiveness estimates. They will necessarily be uncertain, and agencies will choose estimates from the end of the range that can be justified. This framework cannot be seen as a mechanical way of laying to rest the difficult ques-

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tions of setting regulations, but it might serve to present more complete information in a useful framework to the correct decisionmakers.

A good deal of work remains to be done in exploring this framework. Seemingly subtle issues affect the outcome of the analysis. For example, the budget constraint can be stated for all regulatory agencies, for each division or program, or for "discretionary" funds. If trade-offs are made only within narrow programs, the overall result is unlikely to be satisfactory. For example, should the Food and Drug Administration be making trade-offs among food additives or among all activities under its purview that could enhance health? If the Food and Drug Administration were permitted to allocate time and funds among all activities, it might focus on cigarette smoking and ignore food additives. Some groups feel strongly about food additives and would protest a lack of regulatory attention to this area, even if the resources saved more lives by decreasing cigarette consumption.

How would the regulatory budget be determined? Agencies would request large budgets and be opposed by those who must pay implementation costs. The major advantage of this framework is precisely that it puts these issues of social values and of agency efficiency into a forum that facilitates their discussion and resolution and forces Congress to make these judgments. The resulting hearings will raise many relevant issues.

Academics see the advantages of coherent, well thought out intellectual frameworks. For example, there is a misallocation of resources if some agency assumes, implicitly or explicitly, that the cost to society of premature death is greater than that assumed by another agency. Congressmen express shock at the notion that such a value exists. The political process presents an incremental approach, where a set of social values emerges from dozens of laws and decisions, much like the development of common law. Decisionmakers feel more confident in answering these questions for particular cases than in giving abstract uniform answers.

While the regulatory budget is admirably matched to current American political institutions; the result is unlikely to be an intellectually coherent framework.

Benefit-Cost

This framework is similar to the general balancing of risks against benefits; the principal difference is that it is more quantitative and formal.
In addition to enumerating the various benefits of the regulation and then subjectively balancing benefits against costs, this framework would require quantification of the extent to which the benefits and costs vary with the level of regulation, and then would require each of these effects to be translated into dollars.

There are many controversial aspects to its application, including putting an explicit value on prolonging a life, quantifying other benefits, deciding the rate at which effects in the future are discounted to make them equivalent to current effects, and redistributing income. Valuing benefits, or even deciding what is a benefit, runs into the diversity of cultural backgrounds, personal goals, fears, and time horizons. These difficulties are explored in chapters 4 and 5. Benefit-cost analysis is the most general and quantitative of the frameworks, and thus elicits the most information and requires the most analysis.  

Benefit-cost analysis is a sufficiently broad framework to be adapted to consider virtually any aspect of a regulation or public decision. The implications for those who gain or lose can be folded into the analysis. None of the objections to the framework have the effect of showing an inherent bias or blind spot in the analysis.

In practice, however, the picture is quite different. Benefit-cost analysis is often viewed, correctly, as a tool for defending the status quo. It is rarely used to consider who benefits or pays, and it focuses on the present, giving short shrift to even the near-term future with no importance for events more than a few decades in the future. Adjustment costs are often estimated to be higher than would be observed, reflecting a prejudice that the current situation must be the best one (when adjustment costs are not considered, the analysis is biased toward change). Finally, a number of simplifying assumptions are made that bias the analysis against change.

In a world where data are costly to gather and analyze and are rarely conclusive, one must be content with uncertainty and with making educated guesses. The most important material should be considered first, leaving data and issues of lesser importance for future analysis, if warranted. This framework is especially good at interpreting economic data; economic issues have tended to be of first-order importance and thus the framework has raised the significant issues. The more important non-economic concerns are and the more remote the relationship to economic variables is, the less helpful this framework will be.

For example, when benefit-cost analysis is used within a profit-making corporation to enlighten an investment decision, economic issues are of central concern. In considering government investments in inland waterways, economic considerations are predominant, although a host of other issues must be considered. In considering whether the United States should purchase oil from a particular nation in the Middle East, economic considerations are dominated by political and more general ethical considerations. In moving from a corporate decision concerning an investment to purchasing oil from a particular nation, the relative importance of economic issues declines. The benefit-cost framework ceases to be comprehensive and loses any claim to being the sole factor in making the decision. Instead, it becomes a framework for raising issues, organizing information, and deriving quantification where possible.

Benefit-cost analysis is not the best framework for examining distributional questions since it offers no way of quantifying the desirability of transferring income from one individual to another. While it might be decided that a project has a beneficial redistribution of income, the net benefit cannot be quantified. Some ethicists (for example, the utilitarians) were able to deal with this issue theoretically by defining an optimal distribution of income: in practice these questions are hotly debated and decisions are specific to situations. None of the frameworks can be expected to handle this set of questions well.

A Comparison of Frameworks

The eight frameworks stretch from simple solutions (let the market do it or accept no unnecessary risk) to elaborate ones (identify all effects and value them in dollars). The range of problems is even greater, stretching from purely scientific ones (is nitrite a carcinogen?) to purely value judgments (since so few people buckle their belts, should passive seat belts...
be required, even though they are more expensive and less effective than
current belts?). Only by appreciating the complexity of problems and
frameworks can there be an intelligent analysis of how to improve stan-
dard settings.

The issues of simplicity and the amount of data collection and analysis
required are illustrated by proceeding from the no-risk to the benefit-cost
framework. Flexibility in finding solutions and a broader purview of the
issues are being purchased at the cost of collecting and analyzing more
data and grappling with myriad problems, some of which have no solu-
tion. For example, how does society value a cancer today as against one
occurring in twenty years? As against one occurring in 300 years? How is
a risk of death of one in one million to be weighed against the risk of a
broken leg of one in ten?

Four criteria might be used to compare frameworks:

The first is comprehensiveness. Are all the relevant issues encompassed
within the framework? No-risk considers only carcinogenesis (or
other health attributes); risk-risk considers all health consequences either
to the consumer (direct) or more generally (indirect). Cost-effectiveness
and the regulatory budget require examination of costs as well as health,
buts they can be considered only within the goals of the agency. Benefit-
cost and risk-benefit are the most encompassing, although even they are
not used in practice to address equity questions.

The second criterion is the intellectual foundation required of each
framework. One can be most certain about the foundation for the simple
frameworks, but drawing in additional considerations requires more
knowledge, assumptions, and value judgments. The wider coverage comes
at a price. In some cases there is insufficient knowledge to be able to
quantify or even explore these other considerations; if so, there is no
alternative to a simple framework or an ad hoc decision.

The third criterion is the resources required to implement the frame-
work. The more complicated frameworks require exploration of further
aspects of the problem, which in turn requires more data collection
and analysis. Generally the resources available to analyze alternative
regulations constitute a small proportion of those available for drafting
and defending the regulations, and a minuscule proportion of the cost of
carrying out the regulation. If additional analysis can result in even a tiny
improvement in the quality of the regulation, the reduction in implemen-
tation and other costs should more than pay for the effort.

The fourth criterion is felicitousness. The world is complicated; it
changes so rapidly that an agency rarely gets to second-order priority

issues. The most important issues must be treated first, and they must be
raised in easily comprehended fashion. If the issues are posed in a con-
 fused or obscure manner, the decision is likely to be made on an ad hoc
basis. The felicitousness of the framework is more important than its
comprehensiveness.

None of these frameworks is sufficiently complete and sound to serve
as an automatic way of making decisions. The current Delaney Clause
framework would appear to be the most concrete; even it, however, be-
comes mired in controversy over proving carcinogenicity—for example,
the Newberne study regarding nitrite. 28

The other frameworks have the more difficult task of quantifying risk
and of attempting to quantify other aspects of the issue (for example, the
value of greater choice). In all cases judgment is required to examine the
suitability of the quantification, the factors that could not be quantified,
and the valuation of the aspects that were quantified. These issues are far
too complicated for a mechanical decisionmaking framework to be ap-
propriate—for example, one of pursuing a project if and only if estimated
benefits exceed costs.

The real question is the extent to which each of these frameworks can
prove helpful in informing the decisionmaker. Must all effects be quanti-
fied accurately and all valuations be agreed upon before benefit-cost
analysis is helpful? 29 If complete quantification is not possible or if there
are difficulties in estimating risk, is it better to slip back to a less demand-
ing framework, possibly back to the no-risk framework? 30 The answer
depends on both the amount of uncertainty and the extent to which the
general nature of the uncertainty is known. No analysis of health and
safety regulations has managed to quantify all aspects of the issue, and it
is evident that no future analysis can be expected to be complete. If this
lack of completeness is deemed fatal, there is no point in considering
benefit-cost analysis further.

28. Paul M. Newberne, "Dietary Nitrite in the Rat." See also Newberne, "Nitrite
Promotes Lymphoma Incidence in Rats, pp. 1079-81; Council on Agricultural Sci-
cence and Technology, "Comments on the Newberne Report on the Effect of Dietary
Nitrite in the Rat."; Food Safety and Quality, Hearings, pp. 1-28, 176-80, 231-34,
236-38, 356-64. Cmptroller General of the United States, Does Nitric Cause
Cancer? Concerns about Validity of FDA-Sponsored Study Delay Answer.

29. See, for example, Howard Radis, Decision Analysis: Introductory Lectures on
Choice under Uncertainty.

30. For a discussion of the point see Richard Zeckhauser and Albert Nichols,
"The Occupational Safety and Health Administration: An Overview," app., pp. 161-
248, and National Academy of Sciences, Decision Making for Regulating Chemicals
in the Environment.
CHAPTER THREE

Problems in Estimating the Consequences of Regulation

The twin purposes of analyzing social regulation are, first, to separate scientific issues from values or political consensus-building and, second, to trace out the implications of proposed actions. The former is important because scientific facts are the hard reality that condition political solutions; for example, not even a unanimous vote would stop gravity or change pi to 3.0. Ignoring scientific facts is attempting to govern by dreaming. Tracing out the implications of alternative policies allows poor policies to be identified and discarded.

A more subtle consequence of the use of an analytic framework is the prevention of an instant decision. The more contemplative approach requires the decisionmaker to step back from the problem, muster facts, identify alternatives, and examine consequences. The eight frameworks discussed in chapter 2 differ in the extent to which they serve these ends. Market regulation, no-risk, and technology-based alternatives are not analytic frameworks. Market regulation leaves the decision to consumers and producers and their individual frameworks and possible methods of analysis. No-risk provides an automatic reaction to a single piece of information concerning the existence of a risk; a single scientific fact is required and others are ignored along with any contemplation of alternatives or consequences. Similarly, technology-based standards attend to only one scientific fact (is there a viable technology that can reduce emissions or attain some other physical goal?); alternative proposals and consequences are ignored.

The previous chapter suggested some of the implications of using each framework to guide regulatory decision-making. These implications provide major criteria for evaluating the frameworks. The other major criterion is the ease of implementing each framework, from conceptual difficulties to time and professional resources required for each. The most