APPENDIX E

Final Guidance for Preparation of Regulatory Impact Analyses, 1990–91 *Regulatory Program*

sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately.

5. *Alternative methods of ensuring compliance.* Compliance alternatives include the appropriate entity (local, State, or Federal) enforcing compliance, whether compliance is enforced by on-site inspection or periodic reporting, and structuring compliance penalties so that they provide the most appropriate incentives.

6. *Informational measures.* Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be made mandatory or left voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hot-lines, or public interest broadcast announcements). If intervention is necessary to address a market failure arising from inadequate information, informational remedies will generally be the preferred approaches. As an alternative to a mandatory standard, a regulatory measure to improve the availability of information has the advantage of being a more market-oriented approach. Thus, providing consumers information about concealed characteristics of consumer products gives consumers a greater choice than banning these products (for example, consumers are likely to benefit more from information on energy efficiency than from a prohibition on sale of appliances or automobiles falling below a specified standard of energy efficiency).

Except for prohibiting indisputably false statements (whose banning can be presumed beneficial), specific informational measures must be evaluated in terms of their benefits and costs. Paradoxically, the current state of knowledge does not generally permit the benefits and costs of informational remedies to be measured very accurately. Nonetheless, it is essential to consider carefully the costs and benefits of alternative informational measures, even if they cannot be quantified very precisely. Some effects of informational measures can easily be overlooked. For example, the costs of a mandatory disclosure requirement for a consumer product include not only the obvious cost of gathering and communicating the required information, but also the loss of any net benefits of information displaced by the mandated information, the cost of any inaccurate consumer interpretation of the mandated information, and any inefficiencies arising from the incentive that mandatory disclosure of a particular characteristic gives to producers to overinvest in improving that specific characteristic of their products.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, as will often be the case, the least intrusive alternative, sufficient to accomplish the regulatory objective, should be chosen. For example, it will often be sufficient for government to establish a standardized testing and rating system without mandating its use, because firms that score well according to the system will have ample incentive to publicize the fact.

7. *More market-oriented approaches.* In general, alternatives that provide for more market-oriented approaches, with the use of economic incentives replacing command-and-control requirements, should be explored. Market-oriented alternatives that may be considered include fees, subsidies, penalties, marketable rights or offsets, changes in liabilities or property rights, and required bonds, insurance or warranties (in many instances, implementing these alternatives will require legislation).

III. ANALYSIS OF BENEFITS AND COSTS

A. General Principles

The preliminary analysis called for by Sections I and II should have narrowed the number of alternatives to be considered by quantitative benefit-cost analysis to a workable number. Ordinarily, one of the alternatives will be to promulgate no regulation at all, and this alternative will commonly serve as the base from which increments in benefits and costs are calculated for the other alternatives. Even if alternatives such as no regulation are not permissible statutorily, it is often desirable to evaluate the benefits and costs of such alternatives to determine if statutory change would be desirable. Departments and agencies bear a similar burden when they perform environmental impact statements in which alternatives that lie outside their statutory authority must be considered.

In some cases, the desirability of specific alternatives outside the scope of the agency's regulatory authority may be determined by use of basic economic concepts in light of the principles enumerated in Section I. In other instances, however, only a quantitative benefit-cost analysis can resolve the question, and such alternatives will need to be included in the analysis of this section. In addition, alternative forms of agency regulation will need to be evaluated by quantitative benefit-cost analysis.

1. *Evaluation of Alternatives.* Except where prohibited by law, the primary criterion for choice among alternatives is expected net benefit (benefits minus costs). Other criteria may sometimes produce equivalent results, but they must be used with care to avoid

the potentially serious pitfalls to be explained in Part B of this section and in Section IV. Both benefits and costs should be expressed in discounted constant dollars. Appropriate discounting procedures are discussed in the following section.

The distinction between benefits and costs in benefit-cost analysis is somewhat arbitrary, since a positive benefit may be considered a negative cost, and vice versa, without affecting the net benefit (benefits minus costs) decision criterion. This implies that the considerations applicable to benefit estimates also apply to costs and vice versa. The different issues are considered separately under benefits or costs in Sections B and C below according to where they most often arise.

If the proposed regulation is composed of a number of distinct provisions, it is important to evaluate the benefits and costs of the different provisions separately. The interaction effects between separate provisions (such that the existence of one provision affects the benefits or costs arising from another provision) may complicate the analysis but does not eliminate the need to examine provisions separately. In such a case, the desirability of a specific provision may be appraised by determining the net benefits of the proposed regulation with and without the provision in question. Where the number of provisions is large and interaction effects are pervasive, it is obviously impractical to analyze all possible combinations of provisions in this way. Some judgment must be used to select the most significant or suspect provisions for such analysis.

2. *Discounting.* The monetary values of benefits and costs occurring in different years should be discounted to their present values so that they are comparable. This is not the same as correcting for inflation. An inflation adjustment is made with a price index, whereas discounting to present value is done with a discount rate. Benefits and costs expressed in constant (i.e., unaffected by inflation) dollars must further be discounted to present values before benefits and costs in different years can be added together to determine overall net benefits. As an equivalent alternative to discounting nonmonetized benefits, the RIA may use the discount rate to annualize (amortize) costs over a period that corresponds to the occurrence of the benefits. Regardless of the discounting procedure selected, the RIA must contain a schedule indicating when the benefits and costs occur.

Discounting takes account of the fact that resources (goods or services) in a given year are worth more than identical resources in a later year. The underlying reason for this is that resources can be invested so as to return more resources later. Partly because of this productivity of investment, individuals value consumption in earlier years higher than consumption in later years.

Modern analysis of discounting for public programs stresses the distinction between two rates of return:

- The *before-tax* rate, also known as the opportunity cost of capital. This is the real rate of return to marginal private investments. Estimates of the opportunity cost of capital in the U.S. economy vary substantially. The 10 percent discount rate specified by OMB Circular A–94 for use in evaluating government programs is intended to represent the opportunity cost of capital.
- The *after-tax* rate, also known as the consumption rate of interest. This represents the rate at which consumers would be willing to exchange present for future consumption, that is, the rate at which consumers must be compensated for postponing their consumption. As with the opportunity cost of capital, alternative estimates of the consumption rate of interest vary significantly. A rate of 4 percent is reasonably representative of the range of alternative estimates and consistent with a 10 percent before-tax rate of return.

The basic concept underlying the academic literature on public-sector discounting is that economic welfare is ultimately determined by consumption and only indirectly by investment. Therefore, the value of investment must be measured by the value of the subsequent increase in consumption it permits. Any effect that a government program has on investment must be converted to an equivalent time-stream of consumption before being discounted. In practice, this results in a complex procedure that uses the before-tax and after-tax discount rates, a "shadow price of capital," and the impacts of benefits and costs on investment. It is recommended that agencies continue to use the well-understood procedure of discounting by a single rate (as specified by OMB Circular A–94) and, when appropriate, perform additional analysis using the more complex shadow-price-of-capital methodology.

There are two circumstances when it is important to perform sensitivity analysis using the shadow price of capital approach:

(a) Where the costs of the regulation are almost entirely current costs borne by consumers. In such circumstances, a low rate close to 4 percent is called for. (This assumes, as is normally the case, that the benefits are all in the form of disposable income or other benefits directly to individuals.)

(b) Where some of the costs are capital costs financed out of saving *and* there is a long period between the time when most costs are incurred and the time when most benefits accrue. In general, the

smaller the fraction of costs that are capital costs financed out of saving and the *longer* the time period between costs and benefits, the greater the likelihood that the shadow price of capital approach will be correct.

It is conceptually incorrect to adjust the discount rate as a device to account for the uncertainty of expected future benefits and costs. This procedure will virtually never lead to a correct adjustment of benefits and costs. Therefore, risk and uncertainty should be dealt with according to the principles in Section 3 below and not by changing the discount rate.

3. *Treatment of Risk and Uncertainty.* Where uncertainties exist about important parameters affecting the expected benefits or costs of an alternative under consideration, it is essential to carry out a *sensitivity analysis* to determine the effect on net benefits of plausible variations in the value of the parameters. One form of sensitivity analysis involves calculation of the "switch-point" value of the parameter under examination, that is, the value of the parameter at the break-even point at which the net-benefit decision criterion switches over from favoring one alternative to favoring another. When this break-even point of the parameter value is determined, the analysis may then consider the probability that the true parameter value is above or below the break-even value. For example, if the major uncertainty about a proposed regulation were its cost, the analysis could calculate how high the cost would need to be in order to reduce the net benefit of the proposal to zero. If it is judged to be highly unlikely that the actual cost would be that high or higher, it may be concluded that the choice of the proposed alternative is not sensitive to uncertainties about its cost.

A primary objective of sensitivity analysis is to identify where additional analysis may be most needed. If the choice of a specific regulatory action is sensitive to alternative parameter values that are about equally likely to be true, more research to better determine the true parameter value could be very valuable.

Wherever parameter estimates are uncertain, for either benefits or costs, expected-value estimates should be presented. Hypothetical best-case or worst-case estimates may be presented as alternatives for sensitivity analysis. Where possible, information about the probability distribution of the parameter estimate should be presented.

A common situation that arises in estimating both benefits and costs is that a number of different studies may exist which together provide a range of different estimates for a particular parameter. In general, it is not appropriate to use the midpoint of the range of extreme values provided by the studies. Such a technique ignores the information provided by all studies except those providing the extreme values, which may be the least reliable. The preferred approach to deriving an expected-value estimate of a particular parameter in this situation would be to derive it as a weighted average of the estimates of the individual studies, with the weight of each estimate being based on the reliability (in the best judgment of the agency) of the study that produced it.

Where expected future benefits or costs are uncertain, their value to those who receive them may be different from their value if they were certain. (Often, but not always, a certain future benefit is worth more to people than an uncertain future benefit with the same expected value.) As noted in the previous section, it is incorrect to adjust the discount rate as a device to account for the riskiness of future benefits or costs. Any allowance for risk should be made by adjusting the monetary values (for the year in which they occur) of the uncertain benefits and costs so that they are expressed in terms of their "certainty-equivalents."

For an uncertain benefit in future year X, the certainty-equivalent is the number of certain dollars in year X that the uncertain benefit is worth to its recipient. For example, suppose that a particular regulation reduces the probability of fire in a particular type of facility. As part of a benefit-cost analysis for this regulation, the dollar value of the expected reduction in fire loss would be calculated. The owners of the protected facilities place a higher dollar value on the risk of a fire than the expected dollar value of the loss. This is demonstrated by their willingness-to-pay for fire insurance. Therefore, their relative net cost (the percentage difference between insurance premiums and insurance company claim payments) for fire insurance can be used to increase the expected dollar value of the reduction in fire loss to its certainty-equivalent value.

In the example of the preceding paragraph, the adjustment for risk would involve an increase in the value of the benefit, whereas uncertainty of a benefit is normally thought to reduce its certainty-equivalent value. The reason is that even though this benefit by itself is uncertain, it acts to reduce the overall level of risk that would prevail in the absence of the regulation. This illustrates the important principle that what matters is not the variability or riskiness of a regulation's net benefits by themselves but the regulation's effect on risk and uncertainty overall.

While an adjustment to account for risk may be called for in the fire-risk example given, a similar adjustment for the value of reductions in fatalities and injuries would not be appropriate. Assuming that

the values of fatalities and injuries have been derived by the willingness-to-pay methodology recommended in Section B.2 below, they would already represent the certainty-equivalent value of the uncertain risk. This is because the estimated dollar values represent the certain dollar amounts that individuals would sacrifice to reduce these risks.

Probably, in most cases, it will not be advisable to adjust for risk and uncertainty. As a theoretical matter, no adjustment for risk is necessary wherever the net benefits are widely dispersed among many individuals and are not correlated with disposable income. And in cases where this does not apply, risk may be relatively unimportant or may already be taken into account by use of the willingness-to-pay methodology. In other cases, there may be no practical way to quantify the value of changes in risk.

4. *Assumptions.* Where benefit or cost estimates are heavily dependent on certain assumptions, it is essential to make these assumptions explicit and, where alternative assumptions are plausible, to carry out sensitivity analyses based on plausible alternative assumptions. If the decision criterion proves to be sensitive to alternative plausible assumptions, this may necessitate further research to develop more evidence on which of the alternative assumptions is the most appropriate. Because the adoption of a particular estimation methodology sometimes implies major hidden assumptions, it is important to analyze estimation methodologies carefully to make hidden assumptions explicit.

5. *International Trade Effects.* In calculating the benefits and costs of a proposed regulatory action, generally no explicit distinction needs to be made between domestic and foreign resources. If, for example, compliance with a proposed regulation requires the purchase of specific equipment, the opportunity cost of that equipment is ordinarily best represented by its domestic cost in dollars, regardless of whether the equipment is produced domestically or imported. The relative value of domestic and foreign resources is correctly represented by their respective dollar values, as long as the foreign exchange value of the dollar is determined by a free exchange market. Nonetheless, an awareness of the role of international trade may be quite useful for assessing the benefits and costs of a proposed regulatory action. For example, the existence of foreign competition usually makes the demand curve facing a domestic industry more elastic than it would be otherwise. Elasticities of demand and supply frequently can significantly affect the magnitude of the benefits or costs of a regulation.

A regulation that discriminates unjustifiably against foreign exporters is a form of economic protectionism. The economic loss to the U.S. due to the fact that protectionism is economically inefficient will be reflected in the net benefit estimate of any properly conducted benefit-cost analysis. However, a benefit-cost analysis will generally not be able to measure the potential U.S. loss from the threat of future retaliation by foreign governments. Therefore, special attention should be given to any possibility that a regulation would unjustifiably discriminate between domestic and foreign producers and consumers—both discrimination against foreigners and discrimination in favor of foreigners.

The fact that a regulation has a differential effect on foreigners as compared to Americans does not necessarily constitute discrimination. If, for example, an automobile safety standard could be complied with less expensively by large cars than by small cars, such a standard would be more favorable to American car producers, who produce relatively more large cars compared to the fleet mix of foreign producers. Nonetheless, such a differential effect would not be discriminatory if the difference in compliance cost between large and small cars was necessary to achieve legitimate regulatory objectives in the most efficient way.

If a regulation has an adverse differential effect on foreign producers or consumers relative to domestic producers and consumers that is not necessary to realize regulatory goals efficiently, then a discriminatory effect on foreign trade exists. The RIA should identify any substantial differential effect on international trade and explain why it is necessary to achieve legitimate regulatory goals in the most efficient way. One means for reducing the likelihood of international discrimination would be for a U.S. product standard for an internationally traded good to be based on an international standard, wherever an international standard exists and is compatible with the health, safety, or environmental needs of the U.S. International harmonization can be beneficial for regulations directly setting standards for internationally traded goods or services. For example, it would be appropriate to consider international harmonization in setting safety standards for automobiles. There is no similar advantage to international harmonization where a regulation does not directly affect the quality of an internationally traded good or service, even if it indirectly affects its costs (e.g., environmental controls for automobile plants).

6. *Distributional Effects.* Those who bear the costs of a regulation and those who enjoy its benefits often are not the same persons. Benefits and costs of regulation may also be distributed unevenly over time, perhaps spanning several generations. There is no generally accepted way to monetize potential

distributional effects. Attempts to incorporate distributional concerns in benefit-cost analysis require the establishment of unequal weights for different groups in society. Because positive economics treats equally the willingness-to-pay of all individuals, any alternative weighting would undermine the objective character of the analysis. Policymakers may wish, however, to take account of the distributional effects of various regulatory alternatives. Therefore, where there are potentially important differences between those who stand to gain and those who stand to lose under alternative regulatory options, the RIA should identify these groups and indicate the nature of the differential effects. The RIA should also present information on the streams of benefits and costs over time as well as present value estimates, particularly where intergenerational effects are concerned.

B. Benefit Estimates

The RIA should state the beneficial effects of the proposed regulatory change and its principal alternatives. In each case, there should be an explanation of the mechanism by which the proposed action is expected to yield the anticipated benefits. An attempt should be made to quantify all potential real incremental benefits to society in monetary terms to the maximum extent possible. A schedule of monetized benefits should be included that would show the type of benefit and when it would accrue; the numbers in this table should be expressed in constant, undiscounted dollars. Any expected incremental benefits that cannot be monetized should be explained.

The RIA should identify and explain in detail the data or studies on which benefit estimates are based. Where benefit estimates are derived from a statistical study, the RIA must provide sufficient information so that an independent observer can determine the representativeness of the sample, whether it was extrapolated from properly in developing aggregate estimates, and whether the results are statistically significant.

For regulations addressing health and safety risks, the calculation of potential benefits should derive from the agency's estimate of the mean expected value of the reduction in risk attributable to the standard. Estimates of the prevailing level of risk and of the reduction in risk to be anticipated from a proposed standard should be unbiased expected-value estimates rather than hypothetical worst-case estimates. Extreme safety or health results should be weighted (along with intermediate results) by the probability of their occurrence to estimate the expected result implied by the available evidence. In addition, to the extent possible, the distribution of probabilities for various possible results should be presented separately, so as to allow for an explicit margin of safety, where required, in final decisions. If a margin of safety is to be provided, the proper place for it is the final stage of the decision-making process, not by adjusting the risk or benefit estimates in a conservative direction at the information-gathering or analytical stages of the process. Conservative estimates should be presented as alternatives to best estimates for sensitivity analysis but should not substitute for them.

It is important to guard against double-counting of benefits. For example, if a regulation improved the quality of the environment in a community, the value of real estate in the community might rise, reflecting the greater attractiveness of living in the improved environment. It would ordinarily be incorrect to include the rise in property values among the benefits of the regulation. Ordinarily, the value of environmental benefits (e.g., reduced health risks, scenic improvements) will already be included among the benefits. The rise in property values reflects the capitalized value of these improvements. Therefore, to count as benefits both the value of the environmental improvements and the corresponding increase in property values is to count the same benefits twice. Only where a direct estimate of the benefits has not been included would it be appropriate to include the increase in property values among the benefits.

1. *General Considerations.* The concept of "opportunity cost" is the appropriate construct for valuing both benfits and costs. The principle of "willingness-to-pay" captures the notion of opportunity cost by providing an aggregate measure of what individuals are willing to forgo so as to enjoy a particular benefit. Market transactions provide the richest database for estimating benefits based on willingness-to-pay, so long as the goods and services affected by a potential regulation are traded in markets. Estimation problems arise in a variety of instances, of course, where prices or market transactions are difficult to monitor. Markets may not even exist in some instances, forcing regulatory analysts to develop appropriate proxies that simulate market exchange. Indeed, the analytical process of deriving benefit estimates by simulating markets may suggest alternative regulatory strategies that create such markets.

Willingness to pay always provides the preferred measure of benefits. Estimates of willingness-to-pay based on observable and replicable behavior deserve the greatest level of confidence. Considerably less confidence should be conferred on benefit estimates that are neither derived from market transactions nor based on behavior that is observable or replicable. Of course, innovative benefit estimation method-

ologies may be necessary in some cases, and should be encouraged. However, reliance upon such methods intensifies the need for quality control to ensure that estimates derived conform as closely as possible to what would be observed if markets existed.

2. *Principles for Valuing Directly Observable Benefits.* Ordinarily, goods and services are to be valued at their market prices. However, in some instances, the market value of a good or service may not reflect its true value to society. If a regulatory alternative involves changes in such a good or service, its monetary value for purposes of benefit-cost analysis should be derived using an estimate of its true value to society (often called its "shadow price"). For example, suppose a particular air pollutant damages crops. One of the benefits of controlling that pollutant will be the value of the crop saved as a result of the controls. If the price of that crop is held above the free-market equilibrium price by a government price-support program it will overstate the value of the benefit of controlling the pollutant if the crop saved were valued at the market price established by the support program. The social value of the benefit should be calculated using a shadow price for crops subject to price supports. The estimated shadow price should reflect the value to society of marginal uses of the crop (e.g., the world price if the marginal use is for exports). If the marginal use is to add to very large surplus stockpiles, the shadow price would be the value of the last units released from storage minus storage cost. Therefore, where stockpiles are large and growing, the shadow price is likely to be low and could well be negative.

3. *Principles for Valuing Benefits that are Indirectly Traded in Markets.* In some important instances, a benefit corresponds to a good or service that is indirectly traded in the marketplace. Important examples include reductions in the health-and-safety risks, the use-value of environmental amenities and scenic vistas, and savings in time. To estimate the monetary value of such an indirectly traded good, the willingness-to-pay valuation methodology is still conceptually superior, because the amount that people are willing to pay for a good or service is the best measure of its value to them. As noted in Sections 4 and 5 immediately following, alternative methods may be used where there are practical obstacles to the accurate application of direct willingness-to-pay methodologies.

A variety of methods have been developed for estimating indirect benefits. Generally, these methods apply statistical techniques to distill from observable market transactions the portion of willingness-to-pay that can be attributed to the benefit in question. Examples include estimates of the value of environmental amenities derived from travel-cost studies, hedonic price models that measure differences or changes in the value of land, and statistical studies of occupational-risk premiums in wage rates.

Contingent-valuation methods have become increasingly popular for estimating indirect benefits, but they suffer from the fact that survey instruments have a limited capacity to simulate real-world market behavior. Benefit estimates derived from contingent-valuation studies thus have a greater burden of analytical care to ensure that they represent in an unbiased manner what actually occurs in the marketplace.

4. *Principles and Methods for Valuing Benefits that are Not Traded Directly or Indirectly in Markets.* Some types of goods, such as the social benefit of preserving environmental amenities apart from their use and direct enjoyment by people, are not traded directly or indirectly in markets. The practical obstacles to accurate measurement are similar to (but generally more severe than) those arising with respect to indirect benefits, principally because there are not market transactions to provide data for willingness-to-pay estimates.

Contingent-valuation methods provide the only analytical approaches currently available for estimating the benefits of such untraded goods. The absence of observable and replicable behavior with respect to the benefit in question, combined with the difficulties of avoiding bias in contingent-valuation studies, argues for great care and circumspection in the use of such methods. This means, for example, that estimates of willingness-to-pay must incorporate the variety of alternative means individuals have of expressing value for untraded goods. Moreover, analyses must faithfully capture individuals' budget constraints, which restrict their willingness-to-pay for untraded as well as traded goods and services. Benefit analyses derived from contingent valuation and similar methods thus require considerable analytic rigor in design and careful execution. Absent such efforts, analyses based heavily on the benefits of untraded goods and services ordinarily would fail the test of a satisfactory RIA.

5. *Methods for Valuing Health and Safety Benefits.* For health and safety benefits, a distinction should be made between risks of nonfatal illness or injury and fatality risks.

(a) *Nonfatal illness and injury.* Although the willingness-to-pay approach is conceptually superior, the current state of empirical research in the area is not sufficiently advanced to assure that estimates derived by this method are necessarily superior to direct-cost valuations of reductions in risks of nonfatal illness or injury. Any injury-value estimate from a willingness-

to-pay study is necessarily an average over a specific combination of injuries of varying severity. If the average injury severity in such a study is greatly different from that for the regulatory action under study, then the study's estimated injury value may not be appropriate for evaluating that action. Accordingly, the agency should use whichever approach it considers most appropriate for the decision at hand. The primary components of the direct-cost approach are medical costs and the value of lost production. Possibly important costs that may be omitted by the use of the direct-cost approach are the value of pain and suffering and the value of time lost from leisure and other activities that are not economically directly productive.

(b) *Fatality.* Reductions in fatality risks are best monetized according to the willingness-to-pay approach. The value of changes in fatality risk is sometimes expressed in terms of the "value of life." This is something of a misnomer since the value of a life really refers to the sum of many small reductions in fatality risk. For example, if the annual risk of death is reduced by one in a million for each of two million people, that represents two "statistical lives" saved per year (two million × one millionth = two). If the annual risk of death is reduced by one in 10 million for each of 20 million people, that also represents two statistical lives saved. The conclusion that the fatality risk reductions in these two cases are equivalent implies an assumption. The implicit assumption—that equal increments in risk are valued equally—allows different risk increments to be added together and compared directly. As a different example, suppose there are two alternative reductions in the annual risk faced by an individual:

A: from $.10 \times 10^{-5}$ to $.09 \times 10^{-5} = .01 \times 10^{-5}$
B: from 1.00×10^{-5} to $.99 \times 10^{-5} = .01 \times 10^{-5}$

Since in both cases the reduction in annual risk is the same ($.01 \times 10^{-5}$), the value of A and B should be considered the same.

The assumption that equal increments in fatality risk are of equal value is a legitimate one, so long as the level of fatality risk is below 10^{-4} annually. There is evidence that the willingness-to-pay value for increments in fatality risk does not change significantly over a wide range of risk exposure below 10^{-4} annually.

For levels of annual risk exposure of 10^{-4} and above it cannot be assumed that equal increments of risk are valued equally. At these higher risk levels, it is particularly important to distinguish between situations of voluntary risk assumption and those of involuntary risk. Where the high risk is involuntary, it is appropriate to value reductions in risk from that high level more highly than equal risk reductions at lower risk levels. In general, the greater the risk that an individual bears, the higher will be the value the individual places on marginal changes in risk. On the other hand, where a high risk is chosen voluntarily those assuming the risk tend to be persons who place a relatively low value on averting safety risks. Empirical studies of risk premiums in high-risk occupations suggest that reductions in voluntarily assumed high risks should be valued less than equal risk reductions at ordinary risk levels.

Estimates of the value of fatality risks refer only to changes in an uncertain risk of death. They have no application to the certain prevention of the death of an identifiable individual.

6. *Alternative Methodological Frameworks for Estimating Health and Safety Benefits.* Several alternative ways of incorporating fatality risks into the framework of benefit-cost analysis may be appropriate. These may involve either explicit or implicit valuation of fatality risks.

One acceptable explicit valuation approach would be for the agency to select a single value for reductions in fatality risk at ordinary risk levels (below 10^{-4} annually) and use this value consistently for evaluating all its programs that affect ordinary fatality risks. Another acceptable explicit valuation approach would be to use a range of values for reductions in fatality risk and apply sensitivity analysis as with other parameters that have alternative plausible values. The range of alternative values should be a reasonable one, not one that includes the most extreme upper and lower values of fatality risk reduction that have been estimated. Extreme values are more appropriate for instances of extraordinarily high risks (above 10^{-4} annually), with the extreme low values being appropriate where voluntary assumption of high risk leads to self-selection and the extreme high values being appropriate where the high risk is involuntarily assumed.

Where the analysis uses a range of alternative values for reductions in fatality risk, it may be useful to calculate break-even values, as in other sensitivity analyses. This requires calculating the borderline value of reductions in fatality risk at which the net benefit decision criterion would switch over from favoring one alternative to favoring another (i.e., the value of fatality risk at which the net benefits of the two alternatives are equal). This method will frequently be infeasible because of its computational demands or because alternatives are continuous rather than discrete (e.g., alternative stringencies for exposure levels), but where appropriate, it is a useful supplement to the sensitivity analysis.

An implicit valuation approach could entail calculations of the cost per unit of reduction in fatality risk (cost per "statistical life saved"), with costs defined as costs minus monetized benefits. This must be used with care since there is a serious potential pitfall: It is *not* correct to choose between two mutually exclusive alternatives by selecting the alternative with lowest cost per statistical life saved. The alternative with higher cost per life saved may nonetheless be the alternative with the higher net benefit to society.

The way to avoid this pitfall while retaining the implicit valuation approach is to make all calculations of cost per life saved in terms of increments between alternatives. Alternatives should be arrayed in order of their total reduction in expected fatalities and the incremental cost per life saved calculated between each adjacent pair of alternatives. In contrast to explicit valuation approaches, this avoids the necessity of specifying in advance a value for reductions in fatality risks. However, a range of values will be implied by the final selection of an alternative. This range should be consistent with estimated values of reductions in fatality risks calculated according to the willingness-to-pay methodology.

Another way of expressing reductions in fatality risks is in terms of life-years saved. For example, if a regulation protected individuals whose average remaining life expectancy was 40 years, then a risk reduction of one fatality would be expressed as 40 life-years saved. Such a refinement may be desirable for regulations that disproportionately protect young people (e.g., motor vehicle safety regulations) or elderly people (e.g., regulations controlling carcinogens). To derive the value of a life-year saved from an estimate of the value of life, first determine the average remaining life expectancy of the sample population in the study from which the estimate was drawn. Assuming that the average age of the sample population is known, the average remaining life expectancy may be derived from actuarial tables giving life expectancy in relation to age. Using standard compound interest tables, the value of a life-year saved can then be determined as the estimated value of life annualized over a period equal to the number of years of remaining average life expectancy.

C. Cost Estimates

1. *General Considerations.* The opportunity cost of an alternative is the value of the benefits foregone as a consequence of that alternative. For example, the opportunity cost of banning a product (e.g., a drug, food additive, or hazardous chemical) is the foregone net benefit of that product. It is measured by changes in producers' and consumers' surpluses. (Producers' surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the distance between the price and the supply curve for that unit. Consumers' surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the distance between the price and the demand curve for that unit.) As another example, even if a resource required by regulation does not have to be paid for because it is already owned by the regulated firm, nonetheless, the use of that resource to meet the regulatory requirement has an opportunity cost equal to the net benefit it would have provided in the absence of the requirement. Any such foregone benefits for an alternative should be monetized wherever possible and either added to the costs or subtracted from the benefits of that alternative. Any costs that are averted as a result of an alternative should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

All costs calculated should be incremental, that is, they should represent changes in costs that would occur if the regulatory alternative is chosen compared to costs in the base case (ordinarily no regulation or the existing regulation). Future costs that would be incurred even if the regulation is not promulgated, as well as costs that have already been incurred (sunk costs), are not part of incremental costs. If marginal cost is not constant for any component of costs, incremental costs should be calculated as the area under the marginal cost curve over the relevant range.

Costs include private-sector compliance costs, government administrative costs, and costs of reallocating workers displaced as a result of the regulation. Costs that are not monetary outlays must be included and should be attributed a monetary value wherever possible. Such costs may include the value (opportunity cost) of benefits foregone, losses in consumers' or producers' surpluses, discomfort or inconvenience, and loss of time. A schedule of monetized costs should be included that would show the type of cost and when it would occur; the numbers in this table should be expressed in constant, undiscounted dollars. Any expected incremental costs that cannot be monetized should be explained. An important type of cost that often cannot be quantified is a slowing in the rate of innovation or of adoption of new technology. For example, regulations requiring a costly and time-consuming approval process for new products or new facilities may have such costs, as may regulations setting much more stringent standards for new facilities than existing ones.

APPENDIX F

Section on Risk Management Budgeting in the Fiscal Year 1992 *Budget* Document

IX.C. REFORMING REGULATION AND MANAGING RISK-REDUCTION SENSIBLY

Protecting and enhancing human health and welfare has always been an essential purpose of Government at all levels. The Federal Government both funds programs and imposes regulations to reduce risks to health and safety. Federal involvement in these areas has expanded enormously since World War II. There have been benefits, but also costs.

This section of the budget describes:

- The Administration's approach to regulatory reform.
- Problems associated with managing risk-reduction sensibly.
- Concepts for managing, and budgeting for, risk reduction.
- A 1991 Risk Management Budgeting Initiative to affect development of the 1993 budget and the regulatory agenda

THE ADMINISTRATION'S APPROACH TO REGULATORY REFORM

The Administration is committed to the prudent use of Federal regulation to achieve social benefits where these are not provided by the marketplace. This commitment is based on the principles of Executive Order Nos. 12291 and 12498 which require that Federal regulation be based on adequate information; that the benefits of Federal regulations exceed their costs; and that regulatory agencies develop an annual regulatory plan so that Congress and the public may know what regulations are likely in the coming year.

OMB's Office of Information and Regulatory Affairs (OIRA), working with the President's Council on Competitiveness, reviewed in 1990 over 2,100 rules—to ensure that necessary and cost-effective Federal regulations were promulgated and that the principles of Executive Order No. 12291 were applied. OMB also reviewed more than 3,000 agency information collection requests—to ensure they imposed minimal burdens, had practical utility, and were not duplicative. These reviews led to significant improvements.

The Administration has, in addition, reaffirmed the principle of Executive Order No. 12612, "Federalism," that decisionmaking be left to State and local governments wherever possible. Many policy decisions are best left to those levels of government closest to the constituencies the decisions will affect.

In conducting its reviews, OIRA emphasized benefit cost analysis and the use of performance standards that establish regulatory goals, letting the regulated community devise the most efficient method of meeting the standards. Performance standards govern outcomes and results rather than inputs and methods.

Where possible, the Administration has also encouraged the tailoring of regulatory programs and information collections to reduce their burdens on small business. Small business often lacks the capacity easily to absorb the costs related to regulatory programs.

PROBLEMS ASSOCIATED WITH RISK MANAGEMENT

There is risk in everything—in nature, in individual behavior, in the behavior of others. Table C–1 shows risks related to certain common events and activities.

- Out of every one million people in the United States exposed to the following risks, 196,000 die from all forms of cancer, 13,400 from motor vehicle accidents, 7,700 from home accidents, 960 from fires, and 17 from venomous bites and stings.
- Heart disease claims one of every four Americans, and much of this risk could be classified as both behavioral (smoking, diet) and natural (genetic predisposition, aging).
- Accidents involving motor vehicles claim one life in every 75; fatality risk is, of course, dramatically influenced by individ-

Table C–1. SELECTED RISKS TO LIFE

Cause of Death	Mortality Risk[1] per million persons exposed	Average Risk per exposed individual
Smoking (1 pack/day)[2,4]	252,000	1 in 4.0
Heart Disease[8]	230,000	1 in 4.3
Cancer (all causes)[4,7]	196,000	1 in 5.1
Motor vehicle accidents[10]	13,400	1 in 75
Passenger cars	7,350	1 in 140
Passenger cars, restraints used	4,816	1 in 210
Passenger cars, restraints not used	8,757	1 in 110
Home accidents[4]	7,700	1 in 130
Homicide[5]	7,000	1 in 140
White females, 15–24 years[3]	400	1 in 2,500
White males, 15–24 years[3]	1,100	1 in 910
Black females, 15–24 years[3]	1,700	1 in 590
Black males, 15–24 years[3]	10,100	1 in 100
Drowning[6]	2,520	1 in 400
Cancer from exposure to medical X-rays[7]	1,400	1 in 710
Fires[6]	960	1 in 1,050
Cancer due to cosmic radiation from living at 5,280 feet instead of sea level[7]	560	1 in 1,800
Cancer from aflatoxin in 4 tablespoons of peanut butter per day[4,7]	560	1 in 1,800
Electrocution[6]	371	1 in 2,700
Cancer from radon in drinking water at 1.5 picocuries per liter[4]	259	1 in 3,900
Commercial aircraft accidents (one round trip per year)[9]	51	1 in 19,600
Cancer from chloroform in drinking water at EPA limit of 0.1 milligram per liter[4]	42	1 in 24,000
Lightning[6]	35	1 in 28,500
Bites and stings by venomous animals and insects[6]	17	1 in 58,800

[1] Based on a 70 year average lifetime.
[2] Includes cancer and heart disease.
[3] Based on 10 years within age category.
[4] Richard Wilson and Edmund Crouch, "Risk Assessment and Comparisons: An Introduction," Science, vol. 236 (April 17, 1987), pp. 267–270.
[5] Don Colburn, "The Risky Lives of Young Black Men," *Washington Post Health*, December 18/25, 1990, p. 7.
[6] Richard Wilson and Edmund Crouch, *Risk-Benefit Analysis*, (Cambridge: Ballinger, 1982), Table 7–2.
[7] *Ibid.*, Table 7–5.
[8] Estimated from Vital Statistics of the United States.
[9] Derived from Department of Transportation, *National Transportation Statistics*, 1989
[10] Derived by DOT from Fatal Accident Reporting System (FARS).

ual behavior—miles driven, driver care, use of alcohol, use of seat belts and vehicle weight.

- The risk of death from homicide (about 1 in 140) is distributed unevenly across the population—for the 15–24 age group, for example, about 1 in 2,500 for white females, but almost 1 in 100 for black males (25 times greater).

Risks also vary by an individual's age and the duration of individual exposure. Whereas cancer and heart disease are highly correlated with old age, accidents are the leading cause of death up to the age of 44. Risky activities (e.g., automobile travel) may result in immediate death or serious injury, while other behavioral choices (e.g., smoking) involve long-term exposures that may lead to chronic ill-

Cost Effectiveness of Federal Intervention

Table C–2 shows the risks and costs associated with selected Federal regulations.[1] As can be seen, the cost-effectiveness (in constant 1990 dollars) of regulatory actions varies over more than eight orders of magnitude—from about $100,000 per premature death prevented (for certain automotive safety features) to more than $5 trillion per premature death prevented (for regulating wood preserving chemicals as hazardous wastes). This range shows clearly that society's resources for reducing risk are being poorly allocated. On average, spending $2 million dollars on highway safety saves at least one life in just a few years. However, the same amount spent regulating cancer risks posed by wood preserving chemicals prevents one cancer case every 2.9 million years.

Table C–2 also shows that:

- Department of Transportation agencies (i.e., the Federal Aviation Administration and the National Highway Traffic Safety Administration) apply relatively consistent standards to determine whether benefits warrant costs. Most significant OSHA safety standards are similarly cost effective. But EPA regulations and OSHA health standards often entail very large costs for every premature death prevented.
- Programs intended to prevent deaths caused by injury are generally more cost-effective than programs aimed at reducing the mortality risk of environmental and occupational cancer. The cost of regulations aimed at reducing transportation injury risks have consistently remained under $2 million per death averted. However, many regulations targeted at occupational, environmental and dietary cancer risks have been extraordinarily costly.
- Many cancer risks from environmental exposures (excluding smoking and diet) are very small relative to other threats to human health. Nevertheless, about half of the significant regulations listed in Table C–2 (and a much larger percentage of the most expensive Federal regulatory actions) are aimed at reducing these same small cancer risks.

[1] All cost-effectiveness ratios provided are in constant 1990 dollars. These estimates can be compared to what can be discerned from individual behavior. A recent survey of this literature found estimates ranging from $1.6 million to $8.5 million. The authors placed more confidence in the estimates at the lower end of this range. *See* Ann Fisher, Lauraine G. Chestnut, and Daniel M. Violette, "The Value of Reducing Risks of Death: A Note on the New Evidence," *Journal of Policy Analysis and Management*, vol. 8, no. 1 (1989), pp. 88–100.

Table C–2. RISKS AND COST-EFFECTIVENESS OF SELECTED REGULATIONS

Regulation [1]	Year Issued	Health or Safety?	Agency	Baseline Mortality Risk per Million Exposed	Cost per Premature Death Averted ($Millions 1990)
Unvented Space Heater Ban	1980	S	CPSC	1,890	0.1
Aircraft Cabin Fire Protection Standard	1985	S	FAA	5	0.1
Auto Passive Restraint/Seat Belt Standards	1984	S	NHTSA	6,370	0.1
Steering Column Protection Standard [2]	1967	S	NHTSA	385	0.1
Underground Construction Standards [3]	1989	S	OSHA–S	38,700	0.1
Trihalomethane Drinking Water Standards	1979	H	EPA	420	0.2
Aircraft Seat Cushion Flammability Standard	1984	S	FAA	11	0.4
Alcohol and Drug Control Standards [3]	1985	H	FRA	81	0.4
Auto Fuel-System Integrity Standard	1975	S	NHTSA	343	0.4
Standards for Servicing Auto Wheel Rims [3]	1984	S	OSHA–S	630	0.4
Aircraft Floor Emergency Lighting Standard	1984	S	FAA	2	0.6
Concrete & Masonry Construction Standards [3]	1988	S	OSHA–S	630	0.6
Crane Suspended Personnel Platform Standard [3]	1988	S	OSHA–S	81,000	0.7
Passive Restraints for Trucks & Buses (Proposed)	1989	S	NHTSA	6,370	0.7
Side-Impact Standards for Autos (Dynamic)	1990	S	NHTSA	NA	0.8
Children's Sleepwear Flammability Ban [4]	1973	S	CPSC	29	0.8
Auto Side Door Support Standards	1970	S	NHTSA	2,520	0.8
Low-Altitude Windshear Equipment & Training Standards	1988	S	FAA	NA	1.3
Electrical Equipment Standards (Metal Mines)	1970	S	MSHA	NA	1.4
Trenching and Excavation Standards [3]	1989	S	OSHA–S	14,310	1.5
Traffic Alert and Collision Avoidance (TCAS) Systems	1988	S	FAA	NA	1.5
Hazard Communication Standard [3]	1983	S	OSHA–S	1,800	1.6
Side-Impact Stds for Trucks, Buses and MPVs (Proposed)	1989	S	NHTSA	NA	2.2
Grain Dust Explosion Prevention Standards [3]	1987	S	OSHA–S	9,450	2.8
Rear Lap/Shoulder Belts for Autos	1989	S	NHTSA	NA	3.2
Standards for Radionuclides in Uranium Mines [3]	1984	H	EPA	6,300	3.4
Benzene NESHAP (Original: Fugitive Emissions)	1984	H	EPA	1,470	3.4
Ethylene Dibromide Drinking Water Standard	1991	H	EPA	NA	5.7
Benzene NESHAP (Revised: Coke By-Products) [3]	1988	H	EPA	NA	6.1
Asbestos Occupational Exposure Limit [3]	1972	H	OSHA–H	3,015	8.3
Benzene Occupational Exposure Limit [3]	1987	H	OSHA–H	39,600	8.9
Electrical Equipment Standards (Coal Mines) [3]	1970	S	MSHA	NA	9.2
Arsenic Emission Standards for Glass Plants	1986	H	EPA	2,660	13.5
Ethylene Oxide Occupational Exposure Limit [3]	1984	H	OSHA–H	1,980	20.5
Arsenic/Copper NESHAP	1986	H	EPA	63,000	23.0
Haz Waste Listing for Petroleum Refining Sludge	1990	H	EPA	210	27.6
Cover/Move Uranium Mill Tailings (Inactive Sites)	1983	H	EPA	30,100	31.7
Benzene NESHAP (Revised: Transfer Operations)	1990	H	EPA	NA	32.9
Cover/Move Uranium Mill Tailings (Active Sites)	1983	H	EPA	30,100	45.0
Acrylonitrile Occupational Exposure Limit [3]	1978	H	OSHA–H	42,300	51.5
Coke Ovens Occupational Exposure Limit [3]	1976	H	OSHA–H	7,200	63.5
Lockout/Tagout [3]	1989	S	OSHA–S	4	70.9
Asbestos Occupational Exposure Limit [3]	1986	H	OSHA–H	3,015	74.0
Arsenic Occupational Exposure Limit [3]	1978	H	OSHA–H	14,800	106.9
Asbestos Ban	1989	H	EPA	NA	110.7
Diethylstilbestrol (DES) Cattlefeed Ban	1979	H	FDA	22	124.8
Benzene NESHAP (Revised: Waste Operations)	1990	H	EPA	NA	168.2
1,2-Dichloropropane Drinking Water Standard	1991	H	EPA	NA	653.0
Haz Waste Land Disposal Ban (1st 3rd)	1988	H	EPA	2	4,190.4
Municipal Solid Waste Landfill Standards (Proposed)	1988	H	EPA	<1	19,107.0
Formaldehyde Occupational Exposure Limit [3]	1987	H	OSHA–H	31	86,201.8
Atrazine/Alachlor Drinking Water Standard	1991	H	EPA	NA	92,069.7
Haz Waste Listing for Wood Preserving Chemicals	1990	H	EPA	<1	5,700,000.0

[1] 70-year lifetime exposure assumed unless otherwise specified.

[2] 50-year lifetime exposure.

[3] 45-year lifetime exposure.

[4] 12-year exposure period.

NA=Not available.

Agency Abbreviations.—CPSC: Consumer Product Safety Commission; MSHA: Mine Safety and Health Administration; EPA: Environmental Protection Agency; NHTSA: National Highway Traffic Safety Administration; FAA: Federal Aviation Administration; FRA: Federal Railroad Administration; FDA: Food and Drug Administration; OSHA–H: Occupational Safety and Health Administration, Health Standards; OSHA–S: Occupational Safety and Health Administration, Safety Standards.

The Context of Risk Management

Progress has been made in reducing health and safety risks. Life expectancy has increased from approximately 45 years at the turn of the century to the present 71 years for men and 78 years for women. Government helped with this, through immunization and public health programs. But longer lives have also resulted in more instances of chronic disease, such as cancer and heart disease, which now account for almost 60 percent of deaths.

Significant percentages of cancer and heart disease are attributable to such self-induced risks as smoking, alcohol abuse and poor diet. In fact, smoking is responsible for one in every six deaths in America—390,000 deaths per year (87 percent of lung cancer deaths, 30 percent of all cancer deaths and 21 percent of heart disease deaths). Alcohol abuse was responsible for half of the 47,000 highway deaths in 1988 and 40 percent of drownings. It is a major cause of cirrhosis, the ninth leading cause of death in the United States; it has also been linked to violence, homicide and suicide.

Indeed, Secretary of Health and Human Services Sullivan has pointed out that control of fewer than ten risk factors could prevent between 40 and 70 percent of all premature deaths, a third of all cases of acute disability and two-thirds of all cases of chronic disability. Most of these risk factors are within the control of the average citizen—stop smoking, wear seat belts, increase exercise, improve eating habits, end drug or alcohol abuse, seek early prenatal care and necessary medical examinations and immunizations.

The individual's perception of risk to health and safety depends on a variety of factors including the individual's confidence in private and public institutions. Those with confidence in America's institutions tend to rely on those institutions to implement general injunctions to reduce risks. Those who lack such confidence tend to want Government to regulate potential risks, assuming "worst case" scenarios for both risk and institutional behavior. The problem of perception is further complicated by what is often a lack of agreement among scientists and "experts."

Federal Budgetary Programs

The Federal Government now funds a variety of programs to reduce risks to health and safety. While many of these programs produce important benefits—Corps of Engineers flood control programs and Department of Transportation air safety programs—they are also costly. The budget requests $18.4 billion in 1992 for major health and safety risk-reduction programs, $91.4 billion over the 5-year period 1992–96 (see Table C–3).

Federal Regulatory Programs

Federal health and safety regulation has similarly resulted in significant benefits. Federal control of emissions to air and water and of the safe disposal of wastes can yield substantial environmental and health benefits. EPA's cost-effective rule phasing down the use of lead in gasoline has resulted in a marked decline in the ambient air levels of lead in U.S. cities. Similarly, Federal regulation of auto safety over the last 20 years has yielded important reductions in the annual toll of deaths and injuries on the Nation's highways.

The costs of regulation are, however, enormous—estimated as high as $185 billion annually in direct costs on the private sector and State and local governments—nearly $1700 for every taxpayer. Federal regulation is also intrusive. The Code of Federal Regulations contains well over 100,000 pages. In 1990, over 1200 new rules were added, and 1990 amendments to the Clean Air Act, alone, will require scores of new rules over the next several years.

REDUCING THE MOST RISK FOR THE BUCK

The standards for determining Government spending and regulatory program priorities are haphazard, leading to great disparities in benefits in relation to costs. To remedy this problem, the Administration is advancing a new initiative: Risk Management Budgeting—careful risk assessment and analysis of programmatic alternatives. Risk Management Budgeting should enable decision makers to reallocate scarce resources to produce both lower risks and lower costs.

Table C–3. **EXAMPLES OF FEDERAL HEALTH AND SAFETY PROGRAMS**[1]

(Budget authority; in millions of dollars)

	1992	1992–96
Department of Agriculture:		
Rural Water and Disposal Grants	225	1,125
Food Safety Inspection Service	425	2,124
Forest Service Firefighting	302	1,511
Environmental Protection Agency:		
Superfund	1,750	8,750
Sewage Grants	1,900	3,700
Air	505	3,523
Water	413	2,067
Hazardous Waste	334	1,672
Pesticides[2]	140	664
Department of Energy:		
Environmental Restoration		
Civilian	523	2,708
Defense	3,705	22,619
Uranium Enrichment Cleanup	124	799
Department of Commerce:		
National Weather Service	499	2,033
Corps of Engineers:		
Flood Control	1,000	5,200
Department of Labor:		
OSHA	302	1,511
Mine Safety	186	931
Department of Transportation:		
Highway Safety	437	1,886
Aviation Safety	598	2,448
Rail, Boating, Other Safety	771	3,155
Department of Defense:		
Environmental Restoration (Non-nuclear)	1,253	7,354
Department of Health and Human Services:		
Food and Drug Administration[2]	770	3,902
Medicare and Medicaid Survey and Certification	881	4,692
Centers for Disease Control	1,397	6,985
Total	18,440	91,359

[1] Selected programs $100 million or more annual budget authority.

[2] Obligations (includes user fees).

Risk Management Budgeting

Risk.—Risk is the individual likelihood (e.g., one accident in over nine million airline flights) of harm (e.g., airplane crash) from some level of exposure (e.g., 110 million airline flights 1975–85) to a hazard (e.g., windshear at airports). Risk and exposure are combined to determine how much harm (e.g., 12 crashes and 400 lives lost) is caused. The term "risk" is also used to represent the sum of all individual risks, particularly when developing population estimates.

Risk-reduction Analysis.—Risk Management Budgeting requires the establishment of common units of measurement that enable risk reduction benefits and costs to be compared across a range of options and incremental funding levels within a program. This will allow the allocation of resources to achieve the greatest net benefits. Initially, Risk Manage-

ment Budgeting will be applied to resource allocation within individual programs. In subsequent years, as many programs employ the technique, it will be possible to allocate resources across programs. Thus, benefit estimation requires the establishment of uniform government-wide standards for performing risk assessments.

Cost estimates should include the opportunity cost of the resources required by a given program (or program alternative) including both private and Federal budget costs. The opportunity cost of an alternative is the value of the benefits foregone due to the selection of that alternative.

Some programs address activities and events that may lead to immediate death (e.g., automobile safety), while others seek to reduce chronic or latent illness (e.g., reduced air pollution or the fostering of low-fat diets). The measure used in Table C–2 is cost per premature death avoided (adjusted for some of these differences, but not all).

Some suggest analysis should use "life-years" instead of "lives," since the public generally places a higher value on reducing risks faced by children than on increasing longevity *per se*. Others suggest it should also take into account ancillary benefits (for example, the commercial and private benefits of an improved highway system, in addition to reduced highway fatalities brought about by the system).

Good analysis must also avoid upper-bound estimates or "worst-case" scenarios; these mislead policy makers and the public and exaggerate the amount of risk reduction that can be achieved; they also create a systemic bias in favor of programs and policies that would eliminate exaggerated risk, while neglecting high risks elsewhere.

For example, the first five regulatory actions listed in Table C–2 have identical cost-effectiveness ratios of $100,000 per premature death avoided. However, the baseline mortality risk varies from five premature deaths per million persons exposed to almost 40,000—a factor of more than 7,000. Focusing exclusively on risk would have led decision makers to ignore the relatively low hazards from aircraft cabin fires, even though they were relatively inexpensive to remedy. Similarly, many of the regulations in Table C–2 have relatively large baseline risks that are very expensive to remedy—hence, their cost-effectiveness ratios are quite unfavorable.

If individual or population risk alone is used in setting program priorities, there is no guarantee that the programs selected are reducing risk sensibly. Large individual or population risks, that are very expensive to reduce, may not be cost-effective. Only by considering both the benefits and the costs of risk reduction can sensible decisions be made.

1991 RISK MANAGEMENT BUDGETING INITIATIVE

The 11 pilot programs selected for Risk Management Budgeting in 1991 span the interests of Government—from nuclear waste cleanups at the Department of Defense and the Department of Energy to regulation of clinical laboratories by the Department of Health and Human Services. Each program was evaluated for Risk Management Budgeting potential, as well as agency interest in applying Risk Management Budgeting to a particular program.

These pilot programs have been chosen because they:

- are aimed at mitigating health and safety risks;
- have substantial resource requirements over the next five years;
- are amenable to risk budgeting analysis in program priority settings; and
- are minimally quantifiable.

Budgetary Programs

There follow descriptions of four budgetary programs which will be subjected to Risk Management Budgeting in developing the 1993 budget. Agencies will, in consultation with OMB, complete the assessments during 1991.

Department of Energy (DOE).—Environmental Restoration and Waste Management is one of the fastest growing programs in DOE ($4.2 billion requested in the Budget for 1992). DOE has nearly 100 sites located in 31 States and territories containing various waste types (including radioactive, hazardous mixed, and

sanitary wastes). Some of these date from World War II. DOE is developing a methodology for better setting cleanup priorities in order to maximize risk reduction across its many sites and, by 1993, will be ready to use this methodology more effectively in formulating future budget requests.

Department Defense (DOD).—The DOD Environmental Restoration Program is currently addressing the cleanup requirements of over 17,000 sites, with $1.3 billion requested in the budget in 1992. DOD is testing, a "Defense Priority Model" designed to use site-specific environmental data and other factors (including the proximity of hazardous wastes to human populations) to develop preliminary rankings of risk. The purpose is to assist decision makers in determining funding priorities for remedial actions among DOD sites requiring clean-up. The DOD model was developed in consultation with EPA and the States, and is being evaluated for technical validity by the National Academy of Sciences.

Defense/Energy.—While the safety record of the U.S. nuclear weapons stockpile has been impressive to date, the recent report of the "Drell Panel" raised health and safety concerns about current and future nuclear warheads and missile systems, primarily with respect to the risk of accidentally dispersing plutonium into the environment. DOD has budgeted funds to address some of these concerns, and, in conjunction with the Department of Energy, is studying whether additional steps should be taken. Existing analyses seem to focus primarily on the tradeoffs between the safety and military capabilities of weapons systems, rather than on the tradeoffs between safety and costs. Risk Management Budgeting would be used as a means of determining whether to augment the existing nuclear weapons safety program, and, if so, which risks to address first. It would provide a focused assessment of the actual gains in safety that can be made, and at what cost. Also, to the extent that more data on nuclear safety is required to provide an adequate benefit-cost analysis, Risk Management Budgeting would clarify which experiments are the most cost-effective to conduct.

Department of Health and Human Services (HHS) Immunizations.—Although over 95 percent of all children entering school have received their immunizations, low immunization levels among low-income urban infants and toddlers have been a factor in the rising number of measles cases (33 percent more in 1990 than in 1989). The budget includes an infant immunization initiative intended to evaluate the potential effectiveness of linking continued participation in low-income assistance programs (Women, Infants, and Children, Medicaid, Aid to Families with Dependent Children) with documented immunization of young children. Risk Management Budgeting can be an effective tool in reducing both health risks and future budget exposure.

Regulatory Programs

OMB will in 1991 undertake Risk Management Budgeting with respect to the following seven regulatory programs.

Food Safety.—The Department of Agriculture (USDA) is responsible for the safety of meat and poultry, and operates a universal inspection system intended to achieve such safety. The Food and Drug Administration (FDA) regulates foods not regulated by USDA based on a number of concerns, including pesticide residue tolerances set by the Environmental Protection Agency (EPA).

Two of these agencies are currently addressing certain of these risks though new regulatory initiatives—USDA regarding meat and poultry inspection, and EPA regarding pesticide regulation. Risk Management Budgeting will estimate food risks and the costs of the risk reduction so as to provide a useful benchmark for evaluating these initiatives and ensure that Federal expenditures obtain the highest possible return on investment.

Seafood Safety.—Industry, consumer groups, and several Congressional committees have all called for legislation to expand the existing mandatory seafood inspection program operated jointly by the Food and Drug Administration (FDA) and the Commerce Department's National Oceanic and Atmospheric Administration (NOAA). The National Academy of Sciences' (NAS) Institute of Medicine released in January 1991 the first comprehensive evaluation of the health effects of fishery products available to the consumer. The NAS concluded that (1) most health risks associated with seafood originate in the envi-

ronment and should be dealt with by control of harvest or at the point of capture and (2) that, although inspection at the processing level is important to maintain safety of seafood, there is little evidence that increased inspection activities at this level would effectively reduce the incidence of foodborne disease.[1]

A joint Food and Drug Administration (FDA)/Center for Disease Control (CDC) risk assessment shows that the risk of acute foodborne disease from eating fish (excluding raw shellfish) is 1 in 2 million; from chicken, 1 in 25,000; and from raw shellfish alone, 1 in 1,400.[2] FDA's risk assessment thus supports the first conclusion of the NAS report: the health problem associated with seafood lies primarily with raw shellfish, and regulators should try to solve that problem in the water—before shellfish are harvested.

To address the shellfish risk, the budget increases spending for Federal seafood regulation by $23 million and proposes new Federal authorities that will help FDA, NOAA and State regulators prevent shellfish from contaminated waters from reaching the marketplace. Of the $23 million, $9 million will be recovered through user fees charged to seafood processors to cover the costs of incremental increases in inspections (in accordance with Administration policy to charge fees for Federal services that provide a private benefit to industry over and above any benefit to public health or safety). The budget also includes an additional $7.5 million in FDA (a 22 percent increase over 1991) and $6.5 million in NOAA (a 37 percent increase over 1991) to support FDA and NOAA research, consumer education efforts, and cooperation with States to improve seafood safety overall.

Seafood regulation should be based on science and epidemiology. It thus offers an important opportunity to test Risk Management Budgeting. Risk Management Budgeting should assist FDA, NOAA and the States in designing a regulatory and inspection system that maximizes risk reduction at minimum cost.

Occupational Exposure to Cadmium.—Cadmium is a heavy metal which appears in different forms in the workplace, some more toxic than others. Studies show a correlation between adverse health effects and high-level exposure, but these associations are much more uncertain at exposure levels commonly found in the workplace. Compounding the uncertainty of low-dose risk estimates is the fact that epidemiological studies show a synergistic (but unquantified) effect between cadmium exposure and smoking.

The Occupational Safety and Health Administration (OSHA) issued a proposed rule in February 1990 which would reduce the permissible exposure limit (PEL) to cadmium from the present 100 or 200 micrograms per cubic meter of air ($\mu g/m^3$), depending on its form, to 1 or 5 ($\mu g/m^3$). (Major industrial nations generally limit cadmium exposure to 50 ($\mu g/m^3$); none has set a limit below 20 ($\mu g/m^3$).) According to the latest *Regulatory Agenda*, OSHA plans to issue a final rule on cadmium exposure by September 1991.

OSHA has estimated that achieving the 1 ($\mu g/m^3$) PEL would prevent 14 excess cancer deaths and 13–189 kidney dysfunction cases a year at a cost of about $160 million per year; and compliance with the 5 ($\mu g/m^3$) PEL would prevent four excess cancer deaths and 11–41 excess kidney dysfunction cases per year at a cost of $57 million per year. Since estimates of both health effects may be exaggerated (particularly in light of observed synergism between smoking and cadmium inhalation), the Risk Management Budgeting effort will carefully review OSHA's risk assessment.

1988 Clinical Laboratory Improvement Amendments (CLIA 88) Implementing Rules.—The Health Care Financing Administration (HCFA) is responsible for surveying and certifying all Medicare participating clinical laboratories (hospital-based and independent) and interstate commerce laboratories, but not physician office laboratories. CLIA 88 was enacted to enhance the quality of laboratory services by extending Federal oversight to Medicare physician office laboratories (POLs) and establishing new quality assurance standards for cytology. CLIA 88 requires the Depart-

[1] Committee on Evaluation of the Safety of Fishery Products, *Seafood Safety*, National Academy of Sciences, National Academy Press, Washington, D.C., 1991.

[2] Center for Food Safety and Nutrition, Food and Drug Administration, manuscript in preparation, 1990. These risk calculations are based on a single, 4 oz. serving.

ment of Health and Human Services (HHS) to promulgate rules outlining these standards for July 1991 implementation.

In May 1990, HHS published a proposed rule describing the standards. Most of the 60,000 comments received by the close of the comment period in September 1990 expressed concern regarding the effects of the rule on health care cost containment, access, and quality. While HCFA failed to provide a regulatory impact analysis, comments indicated that the rule would cost the private sector billions of dollars and have uncertain benefits. HCFA estimates user fees covering enforcement alone would cost $540 million. The Risk Management Budgeting effort will assist HHS and HCFA to access risks associated with physician office laboratories and design cost effective standards for them.

Corrective Action for Certain Hazardous Waste Treatment, Storage and Disposal Facilities.—Current regulations promulgated under the Resource Conservation and Recovery Act (RCRA) give the Environmental Protection Agency (EPA) authority to require "corrective action" only at Regulated Units (RUs) that have received hazardous waste since July 1982. Solid Waste Management Units (SWMUs) that have not received wastes since that date are not subject to these requirements. However, legislation enacted in 1984 directs EPA to develop a program to deal with these units as appropriate. In July 1990, EPA published a proposed rule that would require "corrective actions" at virtually any facility with a SWMU that has releases to the environment.

EPA has estimated that this rule would impose net present value social costs of $10–60 billion (other estimates are higher); $3–18 billion of these costs would be borne by the Federal government. (DOE estimates the cost of cleaning up its own facilities will exceed $100 billion.)

Human health and environmental benefits expected to be obtained through these actions have not been estimated, making it difficult for policy makers to determine a cost-effective regulatory strategy. EPA is now engaged in an effort to develop an improved analysis of both benefits and costs before policy makers select a course of action. Risk Management Budgeting will help to assure cost effective regulations of SWMU's and proper stewardship of scarce Federal budget authority.

Department of Labor (DOL).—Certain OSHA Regulations are more effective than others in reducing occupational illnesses and injuries. Risk Management Budgeting will enable OSHA to identify the most successful regulatory approaches. Currently, OSHA's regulatory planning is largely reactive. As a result, OSHA often regulates high-profile, low-risk hazards, while leaving low-profile, high-risk hazards unregulated. Risk Management Budgeting will help OSHA develop an analytical approach to ranking workplace hazards for the Administration's 1992 regulatory agenda—according to magnitude, preventability, and potential benefit of regulations.

Department of Transportation (DOT).—Motor vehicle accidents are responsible for about 45,000 fatalities and 3.2 million injuries annually. The Department of Transportation is now in the process of examining its highway safety programs to determine their relative cost effectiveness. Included will be projects that prevent crashes, such as evaluation of heavy truck antilock brake technology, as well as those that protect individuals if a crash were to occur. In addition, the Department is attempting to improve its risk analysis capability with the development of a National Advanced Driving Simulator. The Simulator, when completed, will be the most advanced of its kind in the world, and will significantly enhance the capabilities of the Department and safety experts to evaluate risk reduction strategies in highway safety. Risk Management Budgeting will assist DOT in designing its future regulation to target the highest risks and then regulate to reduce these risks in the most cost effective manner.

APPENDIX G

"Principles of Regulatory Review for Biotechnology"
(Council on Competitiveness, Aug. 1990)

THE VICE PRESIDENT'S OFFICE

Office of the Press Secretary

FOR IMMEDIATE RELEASE AUGUST 14, 1990

PRINCIPLES OF REGULATORY REVIEW FOR BIOTECHNOLOGY

Vice President Quayle announced today that President Bush has approved the four Principles of Regulatory Review of Biotechnology, developed by the President's Council of Competitiveness.

The principles were developed in response to the President's request that the Council Competitiveness institute a review of regulatory issues. They will ensure that the benefits outweigh the costs of government-imposed burdens on biotechnology -- already a $1 billion industry with great potential for new drugs, pesticides, environmental clean-up technology, and agricultural products.

These four risk-based principles shall guide Federal agencies that oversee biotechnology research, product testing, and approval as the agencies develop and implement biotechnology regulations:

Principles of Regulatory Review of Biotechnology

Federal regulation of biotechnology is a critical determinant of how long it will take, and how much it will cost, to bring a product to market. In general, the Federal government shall seek to eliminate unnecessary regulatory burdens for all phases of developing new biotechnology products -- laboratory and field experiments, development of the product, and eventual sale and use.

In general, existing regulatory structures provide an adequate framework for regulation of biotechnology. Lead responsibility for oversight in each type of biotechnology application shall continue to be guided by the Coordinated Framework for Regulation of Biotechnology (51 FR 23302). Consistent with the Coordinated Framework, the following principles shall guide the Federal agencies in writing and implementing biotechnology regulations:

Federal government regulatory oversight should focus on the characteristics and risks of the biotechnology product -- not the process by which it is created.

Products developed through biotechnology processes do not per se pose risks to human health and the environment; risk depends instead on the characteristics and use of individual products. Biotechnology products that pose little or no risk should not be subject to unnecessary regulatory review during testing and commercialization. This allows agencies to concentrate resources in areas that may pose substantial risks and leaves relatively unfettered the development of biotechnology products posing little or no risk.

For biotechnology products that require review, regulatory review should be designed to minimize regulatory burden while assuring protection of public health and welfare.

Expedited review procedures should be adopted for products likely to pose lesser risk. The jurisdiction of the several regulatory agencies should be clarified to avoid unnecessary confusion and delay and agencies should use the same standards and apply them consistently. This is especially important where a product could be regulated by several agencies. For example, pest-resistant plants may be subject to regulation by both the Environmental Protection Agency (for its pesticidal properties) and by the Food and Drug Administration (for food safety).

Regulatory programs should be designed to accommodate the rapid advances in biotechnology. Performance-based standards are, therefore, generally preferred over design standards.

A performance standard sets the ends or goals to be achieved, rather than specifying the means to achieve it (e.g., through a design standard). This provides firms with flexibility in choosing the best means of compliance. A performance-based standard for containment, for example, would permit alternative biological approaches for assuring containment in place of a design-based standard requiring specific physical barriers.

The adoption of performance criteria in the developing regulations reduces the need to rely on a lengthy and contentious regulatory process to revise regulations. Such unwieldy regulatory procedures inevitably inhibit the changes in regulatory structure needed to accommodate advances in science knowledge. Procedures should be adopted to provide agency decision-makers with up-to-date scientific opinion and knowledge -- for example, through the use of science advisory panels.

4. In order to create opportunities for the application of innovative new biotechnology products, all regulation in environmental and health areas -- whether or not they address biotechnology -- should use performance standards rather than specifying rigid controls or specific designs for compliance.

"Design-based" requirements may preclude use of biotechnology products even when such approaches may be both less costly and more effective. For example, a requirement to employ specific pollution control equipment would prevent use of innovative biotechnology pollution remediation or control techniques.

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FEDERAL FOCUS, INC.
11 DUPONT CIRCLE
WASHINGTON, D.C. 20036
202/797-6368