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EFFICIENT REGULATION OF HUMAN HEALTH AND SAFETY UNDER UNCERTAINTY

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Potential risks to human health and safety arising as a by-product of production processes have become a major source of concern for public policy. Controversy continues to rage over the extent of and appropriate remedies for risks associated with water contamination, air pollution, pesticide use and food safety.

These risks are often quite subtle and therefore difficult to detect or verify reliably, and quantitative estimates of risk are typically subject to considerable uncertainty. The bulk of environmental and food safety legislation calls for safeguarding public health with an adequate margin of safety in recognition of these uncertainties. Efforts to mitigate these risks typically entail substantial economic costs in terms of reduced productivity, losses in output and increased prices. More recent legislation (Food Drug and Cosmetic Act, Federal Insecticide, Fungicide and Rodenticide Act, Toxic Substances Control Act, Safe Drinking Water Act) recognizes the need to balance these costs against risk reductions achieved. In sum, it is imperative to base policy determination on thorough evaluations of the tradeoffs between enhanced safety and reductions in economic well-being that take uncertainty into account.

Research in quantitative risk assessment, production management and economic welfare analysis has provided an arsenal of tools for conducting such tradeoff evaluations. This paper presents a decision methodology that integrates these components and discusses lessons from three applications of the methodology.

Efficient Risk Management Under Uncertainty

One of the key difficulties facing policy makers is the high degree of uncertainty about quantitative estimates of risk. It is difficult to determine reliably the degree to which exposure to, say, pesticide residues causes a heightened risk of contracting cancer. Contamination and exposure processes are subject to considerable randomness due to weather and other factors, and, moreover, vary substantially across locations and individuals. Dose-response parameter estimates derived from animal studies are shrouded with uncertainty because of difficulties in inter-species comparison and because of the high doses typically used. Even when epidemiological estimates are available, the statistical uncertainties are substantial.

The methodology presented here explicitly incorporates uncertainty considerations into the decision making process. It views the government as having two objectives: maximizing net market benefits and minimizing risk. Net market benefits refers to the real incomes of producers and consumers derived from production and consumption of items affected by regulation, less government expenditures. To account for uncertainty about risk estimates, the risk objective is defined as an upper bound that is not exceeded with a certain degree of confidence, for example, the level below which risk is estimated to fall, say, 95 percent of the time. This corresponds to the use of confidence intervals from classical statistics to adjust for uncertainty and addresses the need for allowing a margin of safety raised in the legislation.

The tradeoffs between these two objectives can be estimated by solving a constrained optimization problem of maximizing net market benefits subject to the constraint on the risk objective *(1)*. Solving the problem while varying the constraint repeatedly yields a set of tradeoffs between market welfare and risk and an associated set of policies.

Formally, let X be a vector indicating the extent of use of the policies to be considered. For example, X_1 may be the level of a tax on emissions of toxic elements into a body of water, X_2 may indicate the severity of restrictions on pesticide use, etc. Net market benefits are a function of these policies B(X). Actual risk is similarly a function of these policies R(X) and is a random variable. Let R_0 be the acceptable risk level and P be the desired confidence level. The optimization problem is

$$\max_{X} B(X)$$

$$\text{s.t. } \Pr\{R(X) < R_0\} > P.$$

The solution is an optimal policy vector $X^*(R_0,P)$ that is a function of the acceptable risk level and desired confidence level. Substituting into the net market benefits function gives the maximum net market welfare attainable given the risk objective and confidence level $B(X^*) = B^*(R_0,P)$. By varying R_0, one obtains the set of tradeoffs with a given confidence level P. Varying the confidence level as well gives a complete set of tradeoffs between market welfare, acceptable risk and the reliability of attaining the acceptable risk level. (The same set of tradeoffs can be obtained from a dual problem of minimizing the risk objective subject to a constraint on net market welfare.)

Two key measures derived from this optimization problem are the marginal cost of risk reduction and the uncertainty premium. The marginal cost of risk reduction is the absolute value of dB^*/dR_0, the reduction in net market benefits associated with a small decrease in the level of acceptable risk. It increases as the level of acceptable risk falls, indicating that enhanced safety is increasingly expensive. The uncertainty premium is the absolute value of dB^*/dP, the reduction in net market benefits associated with a small increase in the confidence level. It indicates the additional cost required to increase reliability in meeting acceptable risk.

The information generated by this methodology can be used to determine policy using a variety of decision criteria, including cost-benefit and risk-benefit criteria. In cost-benefit analysis, the optimal policy equates the marginal cost of risk reduction dB^*/dR_0 with the monetary value of increased health and safety at the margin. There is a voluminous literature in economics on the estimation of social willingness to pay for marginal increments in health and safety (see for example *(2)*). In risk-benefit analysis as proposed by Starr *(3)*, the appropriate policy equates the ratio of net market benefits to risk B^*/R_0 with the historical average.

The methodology can also be used to deduce implicit values of willingness to pay for reduced risk and risk-benefit ratios from existing policies--conditional on a given confidence level. This allows for uncertainty-adjusted comparisons of policies for consistency.

Case Studies

This methodology has been applied to three different problems: drinking water quality, shellfish sanitation and farmworker safety. Each application emphasizes a different aspect of environmental health regulation.

Drinking water quality. The first case study involved residues of the nematicide 1,2-dibromo-3-chloropropane (DBCP) found in drinking water wells in Fresno County, California *(4)*. DBCP had been used as a soil fumigant for orchard crops, but was banned for all agricultural uses by the U.S.

Environmental Protection Agency (EPA) in 1979 after having been implicated in adverse reproductive effects in chemical plant operators and oncogenesis in mice and rats. Because DBCP was no longer in use, the study focused on tradeoffs between excess gastric cancer risk and the cost of developing clean drinking water supplies.

Monte Carlo simulation was used to construct probabilistic quantitative risk assessment of the excess cancer risk faced by an individual drawn at random from the population of the county as a multiplicative combination of the concentration of DBCP in drinking water, error in measuring that concentration, lifetime consumption of water, an interspecies dose equivalence factor and a carcinogenic potency parameter. The distribution of DBCP concentrations in well-based water systems and the error in measuring DBCP concentrations were constructed from California State Department of Health Services data. The data presented by the International Commission of Radiological Protection were used to estimate a distribution of lifetime water consumption. The distribution of the dose-equivalence factor was estimated under the assumption that the two main hypotheses (calibrating dose on the basis of surface area versus body weight) were equally likely to be correct. The distribution of the carcinogenic potency parameter was estimated using maximum likelihood estimation of a multistage dose-response model using data from a feeding study of mice.

Costs of developing new water supplies differed between rural and urban areas. Drilling new wells was less costly for large systems, while installing filtration devices was cheaper for individual wells. Residential areas within the county thus differed in two ways: average DBCP concentrations in drinking water and cost of remediation. Least-cost strategies for meeting a risk standard for an individual drawn at random from the county population were derived for the entire feasible range of standards using an algorithm derived from the methodology described above. For ease of analysis, the relationship between risk standards and remediation costs were smoothed using a second-order polynomial regression of cost on the natural logarithms of the risk standard and confidence level.

As the preceding discussion indicates, the modeling effort demanded contributions from a wide variety of disciplines. Remediation costs were developed by engineers, the population distribution by geographers, the risk assessment by public health professionals and the overall tradeoff analysis by economists.

Figure 1 shows the tradeoffs between remediation cost and excess cancer risk for the risk standard achieved on average and for 95 and 99 percent confidence levels. It is evident that increasing the confidence level entails substantial increases in cost. A 1 percentage point increase in the confidence level raised the total cost of meeting any given risk standard by $3-4 million, or 2-10 percent. Making allowance for uncertainty in this way thus has notable effects on risk-benefit tradeoffs, suggesting that the appropriate choice of a confidence level is itself a policy issue of real importance.

Urban and rural areas differed significantly in terms of the costs of remediation, as the cost of providing clean water from individual wells in rural areas was about 2.5 times as great as the cost for community water systems in urban areas. Because of these differences, the cost-efficient strategy involved more stringent standards in urban areas and more lax ones in rural areas. In other words, heterogeneity in the population at risk implies the desirability of heterogeneity in regulation.

The marginal cost of reducing risk on average was 21 to 26 percent higher than the marginal cost with a 95 percent confidence level and 23 to 29 percent higher than the marginal cost with a 99 percent confidence level. Making allowance for uncertainty thus reduces the marginal cost, or slope of the tradeoff curve, substantially. Economists evaluating existing health and safety regulation using cost-benefit analysis applied to estimates of average risk have typically found that marginal costs exceed marginal benefits by significant amounts, suggesting that these policies are excessively stringent *(5)*. When allowance is made for uncertainty, however, marginal costs and benefits will be closer. The results obtained here indicate that the adjustment will be significant, suggesting that allowances for uncertainty account for a significant share of the observed discrepancies.

Shellfish sanitation. The second case study involved a shellfishery located in an estuary affected by dairy runoff *(6)*. During rainstorms, wastes from dairies were washed into the estuary, resulting in microbial contamination of the oysters growing there and a concomitant risk of severe gastroenteritis for anyone consuming them. The analysis centered on source reduction because open access to the fishery ruled out fishery closure as an effective means of risk reduction.

Rainfall was assumed to be the only random element affecting the risk of acute gastroenteritis, which was modeled as a multiplicative combination of parameters describing microbial contamination in runoff per cow, microbial uptake in oyster population, the probability of contracting acute gastroenteritis upon consumption of contaminated oysters and the number of cows contributing to runoff. Microbial contamination in runoff per cow was estimated from maximum fecal coliform counts observed around oyster beds in the estuary. The fraction of oysters contaminated was estimated by applying regression analysis to data in a study examining the usefulness of fecal coliform counts as an indicator of bacterial contamination of oysters. The probability of contracting acute gastroenteritis after consuming contaminated oysters was derived from epidemiological studies. The number of cows contributing to runoff in any size rainfall event equalled the number of cows at dairies with runoff control facilities with insufficient capacity of the amount of rainfall. The probability distribution of rainfall events was derived from data on local rainfall.

The dairies in the watershed differed in terms of topography and therefore in terms of the cost of constructing runoff control facilities adequate for any given size rainfall event. Data on these costs for each dairy in the region were obtained from a detailed engineering study. Least-cost patterns of runoff control facility construction and tradeoffs between gastroenteritis risk and source reduction expenditures were estimated using an algorithm derived from the methodology described above.

The optimal policy involved building holding ponds only at dairies with the lowest marginal costs. The optimal capacity at each dairy was determined by the confidence level required, and the total number of dairies subject to undertaking source reduction measures was determined by the risk standard. Because topography, and therefore cost, differed markedly at different sites, different dairies received markedly different treatment under this policy. Runoff control facilities were required at only a few sites to meet lax risk standards. As the risk standard became more stringent, the number of sites investing in source reduction grew. The optimal set of standards thus implied marked inequities among dairies, with some dairies required to undertake substantial investments in source reduction while others continued with unregulated emissions.

Economists have long argued that taxes can be used to achieve pollution control aims instead of imposing standards. In the case at hand, the per-cow tax required to meet any desired risk standard with a given confidence level equalled the marginal cost of installing runoff control facilities of the requisite capacity at the most expensive site needed. Holding pond construction patterns remained the same, but dairies not needing to invest in source reduction had to pay taxes on runoff generated. The result was a much more equitable set of losses. Figure 2 shows tax payments as a fraction of total expenditures for runoff control for different risk levels. When the risk target is lax, very few dairies find it less costly to build runoff control facilities than pay the tax, so tax payments account for almost all runoff control expenditures. As the risk target becomes more stringent and the optimal tax increases, more and more dairies find it less costly to build.

Farmworker safety. The third case study involved the use of reentry regulation to control the risk of acute poisonings of farmworkers by organophosphate pesticide residues on crops *(7)*. The study focused on the use of parathion against late-season codling moth infestation. Application of parathion reduces the damage suffered from codling moth larvae but creates a risk of acute poisoning for harvest workers. This risk can be reduced by preventing workers from harvesting treated orchards until parathion residues have degraded sufficiently, i.e., by setting a preharvest interval. But because the price received for apples declines as the season progresses, a preharvest interval that delays harvest entails lost revenue for growers.

The tradeoffs between grower revenue and farmworker poisonings were estimated by combining an economic model of growers pesticide use decisions, a crop growth/pest infestation model and a risk assessment of acute parathion poisoning.

The economic model derived the optimal timing of the parathion application given end-of-season crop growth and damage from codling moth infestation. Analysis of the model showed that the imposition of a preharvest interval can create a motivation for prophylactic treatment of an observable pest like codling moth: When the preharvest interval is binding, the time of application was determined by a tradeoff between lost revenue from delayed harvest and lost yield from preventive treatment. If the price of apples decreases faster than the pesticide decays, it becomes more profitable to treat prophylactically.

The risk assessment model derived the risk of poisoning by combining models of parathion and paraoxon decay, dermal absorption, cholinesterase depression and the probability of clinical symptoms, all of which were based on organophosphate poisoning incidents in California. Parathion and paraoxon temporal decay were assumed to be exponential, with parameters estimated from field data on citrus. Residue levels were assumed to be reduced exponentially by rainfall. Dermal exposure was assumed to be proportional to the residue level and time of exposure, with the constant of proportionality derived from citrus data. Fractional inhibition of red blood cell cholinesterase was also modeled as an exponential relationship, while the probability of clinical symptoms given cholinesterase inhibition was modeled as a logistic. Two types of clinical symptoms -- mild and severe -- were distinguished. Parameters of these relationships were based on clinical experience and the medical literature.

These models were used to estimate expected revenue losses and the expected number of severe and mild poisoning cases under alternative preharvest intervals for a 50-acre orchard block infested with codling moths four days before harvest and harvested in one day by a crew of 500. Three different rainfall scenarios were investigated, corresponding to average rainfall during harvesting periods in three top apple producing states: California (no rainfall), Washington (0.5 inches) and Michigan (1.5 inches).

The tradeoffs between a grower's revenue loss and health damage suffered by farmworkers were then evaluated by comparing marginal revenue lost with the direct medical costs and lost wages associated with expected additional severe and mild poisoning cases. The curves obtained in the California case are shown in Figure 3. The two curves cross when the preharvest interval is 15 days. The curves for the Washington and Michigan cases are quite similar but intersect at earlier preharvest intervals: 12 days in Washington and 9 days in Michigan.

These results suggest that, because weather conditions affect risk considerably, farmworker safety regulation could be made more efficient by making the length of the preharvest interval dependent on the amount of rain falling between treatment and harvest. A preharvest interval of 12 days after 0.5 inches of rainfall would protect farmworkers as much as a preharvest interval of 15 days after no rainfall, while reducing a grower's revenue loss by 0.7 percentage points ($1344 for a 50-acre block in Washington).

The current preharvest interval for parathion is 14 days, remarkably close to the "optimal" preharvest interval obtained for California when only expected direct farmworker costs are considered. Yet organophosphate poisonings cause substantial pain and suffering and may have long term neurotoxic effects as well. Revealed preference logic suggests that these broader costs, which economic theory considers essential parts of willingness to pay for risk reductions, are not considered in setting preharvest intervals.

Further Remarks

The case studies discussed above were concerned with setting appropriate levels of a single policy instrument: development of clean water supplies, source reduction for dairy runoff and length of preharvest interval. In most cases multiple policy instruments will be available, and a key task facing policy makers is to choose the appropriate mix of instruments. Theoretical analysis of the methodology suggests that every risk reduction policy has two effects: an effect on average risk and an effect on uncertainty about risk. The optimal set of risk reduction policies will be a portfolio of measures, some of which are relatively more efficient in reducing risk on average and some of which are relatively more efficient in reducing uncertainty about risk. Thus, information-gathering activities such as monitoring, development of improved models for quantitative decision analysis and long term research into environmental fate and human toxicology play an essential role in regulatory strategy, even in the short term. An example of such a portfolio of policies is simultaneous monitoring of air pollutant emissions to reduce uncertainty about health risks such as respiratory and heart ailments combined with regulation of emissions to reduce these risks on average.

The uncertainty-reducing effect of any policy depends on three factors: the overall level of uncertainty about the risk, the tractability of that uncertainty and the weight that decision makers place on uncertainty. The fact that absolute uncertainty matters, coupled with the empirical finding that making allowance for uncertainty increases regulatory cost substantially, suggests the critical importance of long term research. As improvements in knowledge reduce uncertainty about risks, policy makers can enact increasingly efficient risk reduction policies.

The analysis also indicates that the marginal cost of risk reduction depends on several factors, including the confidence level demanded, overall toxicity and the background level of uncertainty. In particular, the marginal cost of risk reduction decreases as the level of background uncertainty increases, so that more stringent risk reduction efforts become warranted. This fact may shed some light on supposed inconsistencies in federal safety regulation. It has long been noted that safety standards for nuclear power plants are much more stringent than those for coal mines, even though the number of deaths per unit of energy produced attributable to coal far exceeds the number attributable to nuclear power *(8)*. There is far more uncertainty about the risk of accidents in nuclear power plants, however. Once the effect of this additional uncertainty has been factored in, the estimated marginal costs of risk reduction in the two cases may well be comparable.

In practical applications, economists have tended to treat the benefits of safety regulation, expressed in terms of willingness to pay for risk reductions, in terms of average values derived from labor market or consumer behavior studies, which are assumed constant over the range of risks considered (see for example *(2)*). Economic theory, of course, posits that willingness to pay should be a function of the size of the risk *(9)*. Psychological studies indicate that it should depend on factors such as dread or controllability as well *(10)*. Analysis of the methodology presented here indicates that still other factors should be considered, including the level of background uncertainty and the confidence level demanded. Willingness to pay is thus best conceived of as a function of risk levels and characteristics of the risk, including uncertainty about the risk, rather than a single number.

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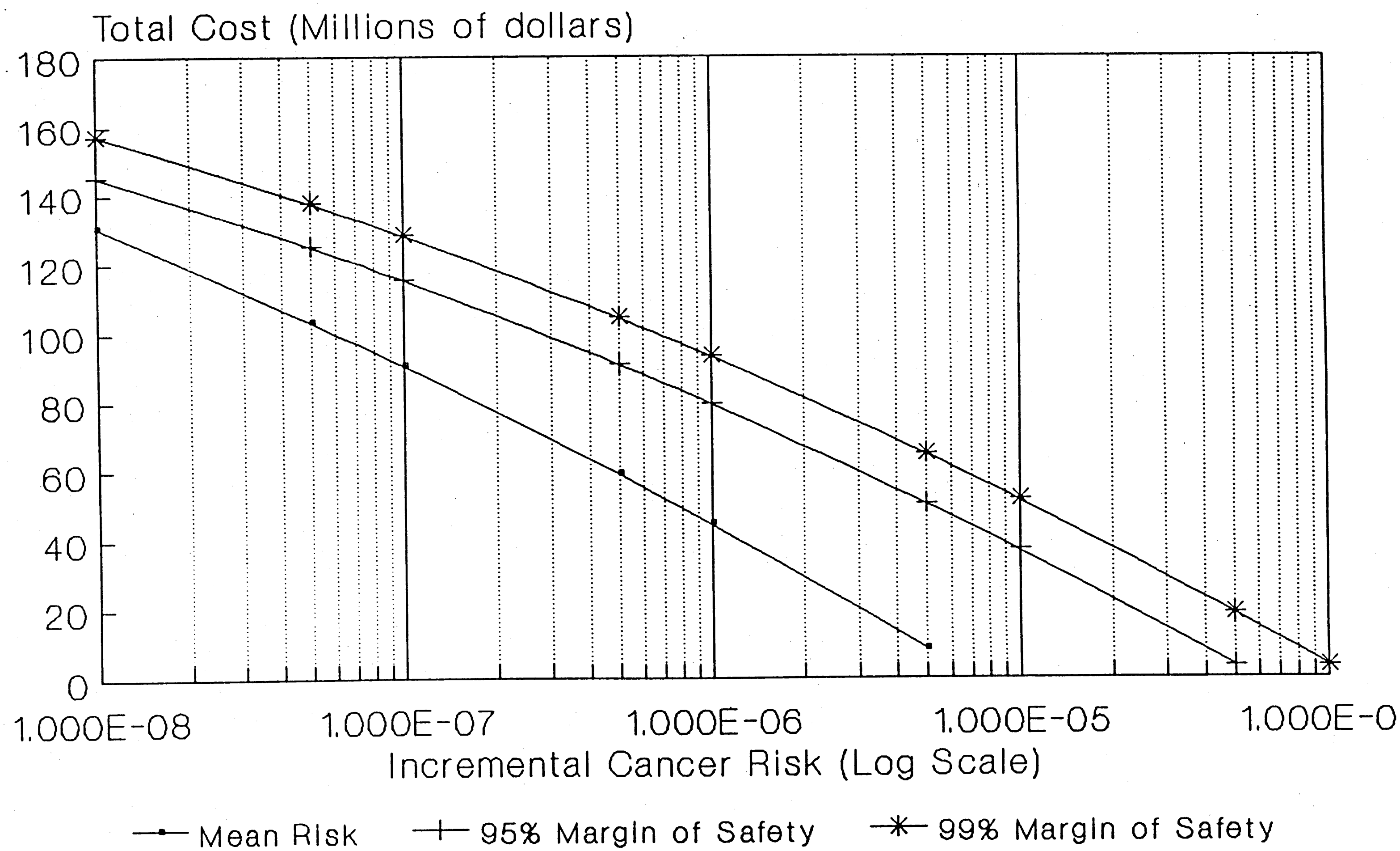
Smoothed Tradeoff Curves for DBCP in Well Water, Fresno County, California



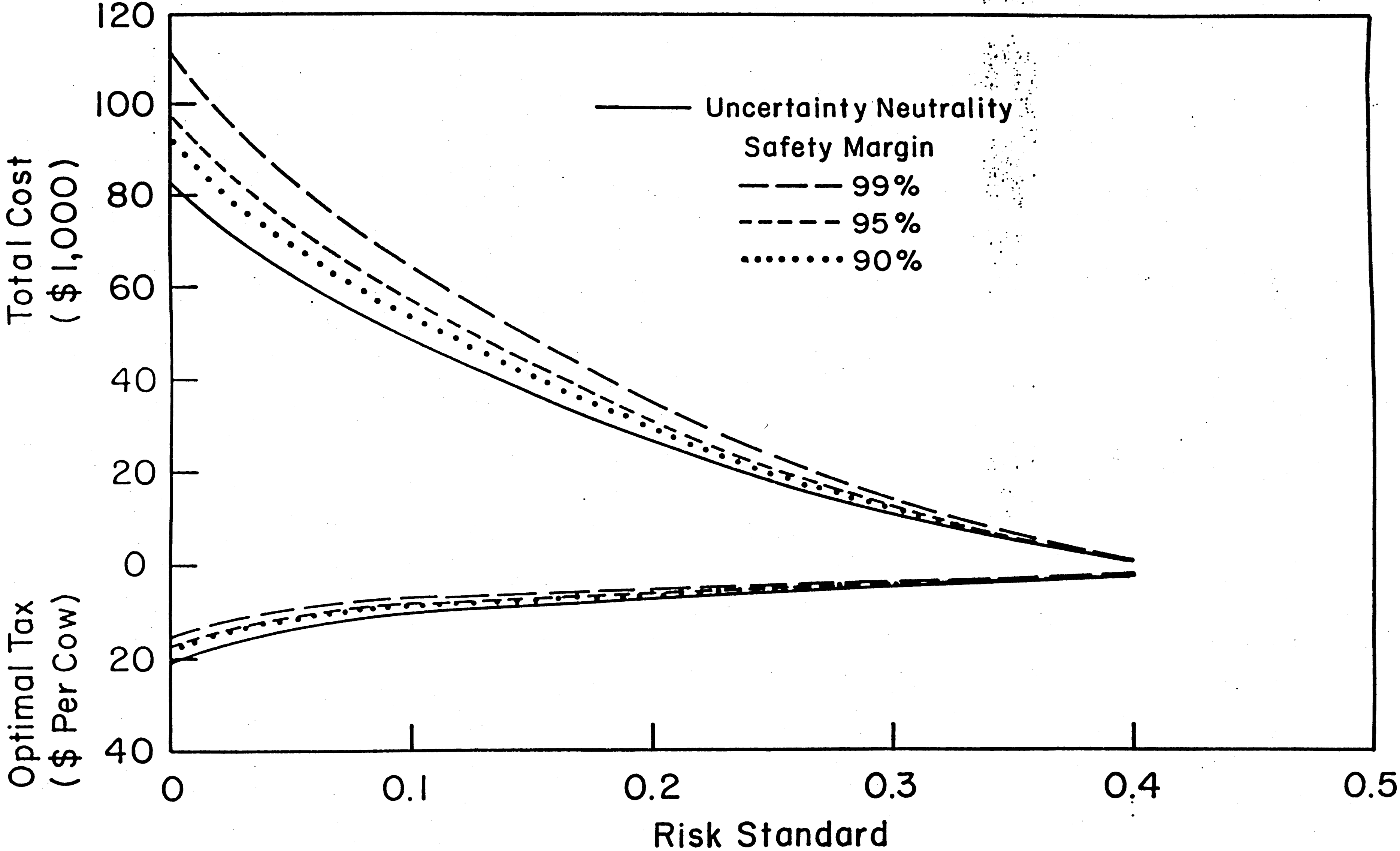


FIGURE 1. Total Cost and Optimal Taxes --Alternate Risk Standards

Figure 1
Optimal Re-Entry Interval in California