TOWARDS COST-EFFECTIVE METHODS FOR REDUCING UNCERTAINTY IN ENVIRONMENTAL HEALTH DECISION PROCESSES

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ABSTRACT

Multiple uncertainties create two major problems in reaching level-of-control decisions in environmental health decision situations: insecurity about when to stop collecting additional information and proceed with the "optimum" control strategy available, and imprecision about how to allocate resources among various possible uncertainty reductions during this research phase. This paper uses statistical decision theory and a computer simulation package to explore the properties of the response surface relating the expected value of perfect information, total uncertainty, and uncertainty in each parameter contributing to overall health risk (e.g., population exposure, carcinogenic potency, etc.). The framework is then applied to the case study of the research and control decisions EPA faced at the ASARCO smelter in Tacoma, Washington.

KEY WORDS: value of information, cancer risk assessment, error propagation, ASARCO arsenic emissions, utility theory.

I: INTRODUCTION

Surrounding all environmental health decision processes is the spectre of uncertainty, which among other effects always promotes a tension between analysis and action. Rarely is this tension more palpable than when the decision-maker is confronted with the task of balancing environmental controls against the public health risks posed by emissions of toxic or carcinogenic substances. When a potential health problem has been identified and a discrete set of control options mapped out, the decision-maker may believe his task is simply to pick the single "best" option from the feasible set. In fact, the range of choices is far broader, for each decision point has associated with it the additional variable "time"-- time that can be spent refining the knowledge of the problem in order to make more secure the wisdom of the ultimate action. Often (though see Section IV below) it is easy to generate a first approximation of the cost of continuing to analyze a risk-benefit problem.

It is, however, not nearly so straightforward to determine the value of additional information, in order to gauge whether the expected rewards of investigation warrant the various costs of obtaining it. More significantly, a truly optimal decision process would not only arrive at the solution that yields the greatest achievable net benefit, but would take the most efficient and expeditious path to that choice-- and for this it is necessary to know how to allocate research efforts to maximize the ratio of the value of new information to its price.

It is our intention to elucidate general truths about the properties of additional information in environmental health questions where uncertainties exist along two or more dimensions. In this paper, we will: 1) summarize the axioms governing value-of-information theory; 2) present the results of computer simulations that explore the relationship between value-of-information, total uncertainty, and uncertainty along individual dimensions; 3) apply these results to a familiar risk management case study (cancer risks due to arsenic emissions from the ASARCO smelter in Tacoma); and 4) describe the refinements we are currently developing to make our model more applicable for analysis of decisions such as those surrounding uncontrolled hazardous waste sites.

II: DETERMINING THE VALUE OF REDUCING UNCERTAINTY

A. Theory of Expected Value of Perfect Information (EVPI)

The value of information is determined with reference to the concept of expected opportunity loss (EOL). Opportunity loss accrues because the decision-maker must at some point select a strategy before the true values of dose and potency are precisely known. Because for each possible value of risk there is an "optimal" strategy defined by the prevailing decision rule (usually the strategy corresponding to the expected value of risk), there may be some cases wherein the choice made under uncertainty does not match the choice that would have been made were perfect information available. Although there are economic and health costs associated even with the locally optimal strategy, additional costs will accrue whenever the true risk falls outside of the range of values for which the chosen strategy is optimal. EOL is thus the integral over all possible values of risk (appropriately weighted by the probability of risk taking on each value) of the extra costs of choosing what is on average the optimal strategy for those cases where another choice would have been superior:

$$EOL = \int pdf(R)\ [C(R)-C^*(R)]\ dR, \qquad (1)$$

where C(R) is the cost of the apparently optimal strategy (evaluated at each value of R) and C*(R) is the cost of the least-cost strategy associated with that same R.

Assuming the analyst could obtain perfect information about risk at some cost, he would then always pick the strategy for which C(R)=C*(R), and his EOL would reduce to zero. Faced with a decision node where perfect information could be obtained at a cost equal to the EOL under the existing burden of uncertainty, the decision-maker would be indifferent between obtaining the information and making his best guess about control--therefore, the expected value of perfect information, EVPI, is exactly equal to EOL. Moreover, moving from a state where EVPI=$X to one where EVPI=$Y implies directly that information worth $(X-Y) has been obtained: thus, the upper bound on the value of any incremental amount of new information is simply the difference in the EOL prior and posterior to the analysis.

In our hypothetical scenarios, three strategies always define the range of control choices. Strategy 1 (no additional controls) incurs no control costs but leaves the uncontrolled health risk R unaffected; Strategy 2 incurs some costs but reduces the risk to (1-E)R, where E is the efficiency of the "best available technology" (BAT); Strategy 3 eliminates all health risk for a fixed cost [the marginal cost of this second increment of risk reduction is assumed to be higher than that of Strategy 2]. Figure 1 shows opportunity loss (OL) as a function of risk for a model scenario. Which graph applies depends on the initial choice of strategy, but EOL is always the integrated product of this function and the pdf over risk. Note that OL is always zero in the region where the chosen strategy matches the optimal strategy, conditional on the given value of risk.

Strategy	Control Costs	Risk Reduction	Total Costs
I	0	0	R
II	X	E×R	X+(1-E)R
III	Y	100%	Y

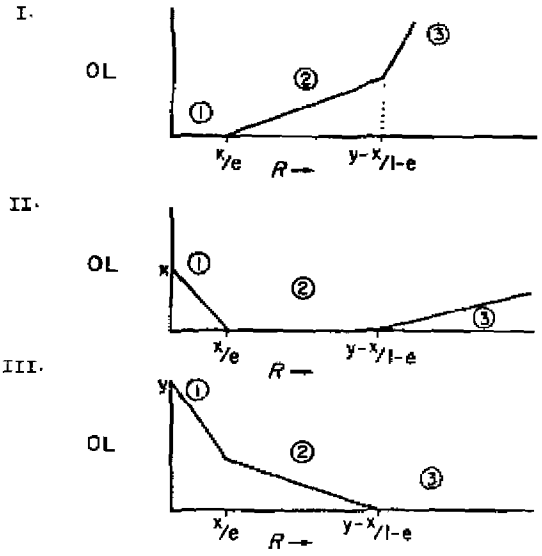

Figure 1

Opportunity Loss as a Function of Risk

B. Computer Simulation of EOL

We have developed a computer program for the IBM-PC which provides generalizable results about the relationship between uncertainty and value-of-information, using a somewhat restricted set of paradigms for

their expositional value. The major flexibilities remaining in this paradigm are the risk in the absence of control, the cost of the risk-elimination option, and the cost and efficiency of the "best available technology" strategy. The pdf for uncertainty in dose or potency could justifiably be drawn from a number of different families, including distributions generated ad hoc by eliciting and pooling the subjective probability estimates of one or more experts (Evans, 1985). We have chosen lognormal distributions primarily because they are simple to manipulate. In addition, many inputs to regulatory processes implicitly assume lognormal variability, most commonly evident in statements that a given estimate is correct "to within a factor of x."

The computer program numerically evaluates equation (1) given a median value for both dose and potency and an assumed geometric standard deviation (s_g) around each estimate. In addition to reporting the EVPI, the program notes the actual ranges of dose values for which each of the three strategies would be optimal if perfect information were available.

C. Theoretical Results

By sequentially varying the geometric standard deviation of both dose and potency over a wide range of possibilities, we were able to discern some of the properties of the response surface relating uncertainty in dose, uncertainty in potency, and value-of-information. The most basic finding concerns the behavior of the surface in the xz and yz planes-- when either uncertainty parameter is held constant, the cross-sections of the response surface are sigmoid in shape. Figures 2 and 3 show this behavior by graphing EVPI at various points and by presenting a contour map of EVPI isomquants, respectively. Essentially, when total uncertainty is very small (s_g of each parameter < 2) and again when it becomes very large (s_g of each parameter > 6), the change in EVPI with uncertainty in dose or potency is relatively small-- the value of marginal improvements in information is often negligible. However, for ordered pairs of s_g(dose) and s_g(potency) yielding moderate to large values of total uncertainty, EVPI can change dramatically following small achievements in uncertainty reduction. For example, Figure 2 shows that it would be worth a maximum of approximately \$1.6 million per year (\$3.8 million minus \$2.2 million) to both improve (s_g) of potency from 5 to 4.5 and improve (s_g) of dose from 3 to 2.5. It is clear that at least for control strategies ordered in this way, by far the most valuable bits of new information are those which enable the decision-maker to increase his confidence that "BAT" is preferred to "closure" for plausible values of risk.

D. Sensitivity Analyses

We then tested the two parameters most likely to influence the response surface. As expected, the spacing of costs for the three strategies strongly affected the appearance of the surface, although the basic shape was preserved in all cross-sections. Lowering the cost of "BAT" from \$5 million to \$2 million made it the preferred strategy over almost of the simulations and shifted the location of the steep region of the response surface. This scenario demonstrates another principle of the value-of-information function-- the greatest marginal increases in EOL occur in regions where an unattractive strategy suddenly begins to dominate for a growing region of the pdf over risk.

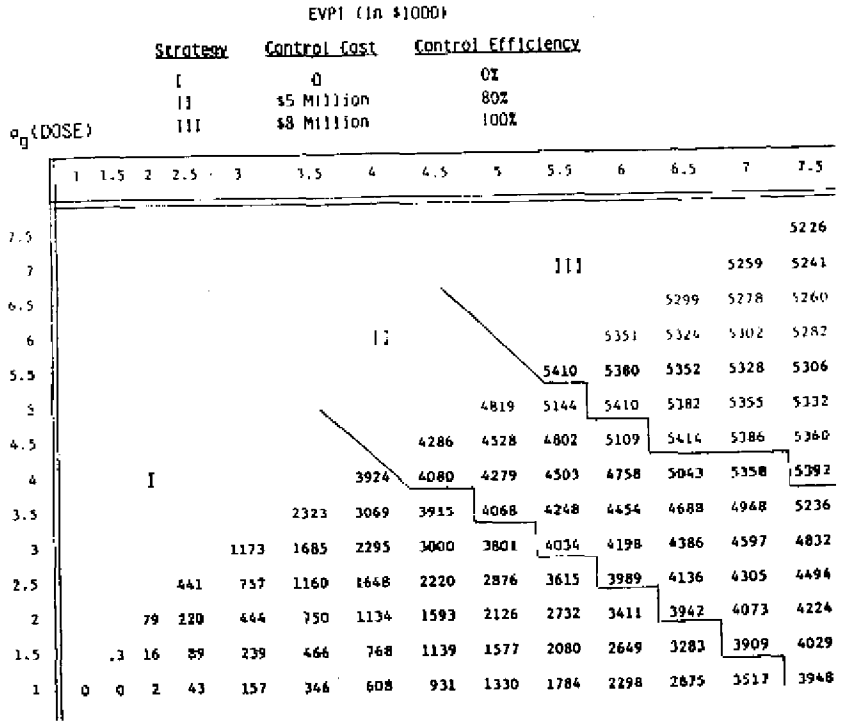

Figure 2

EVPI (in $1000)

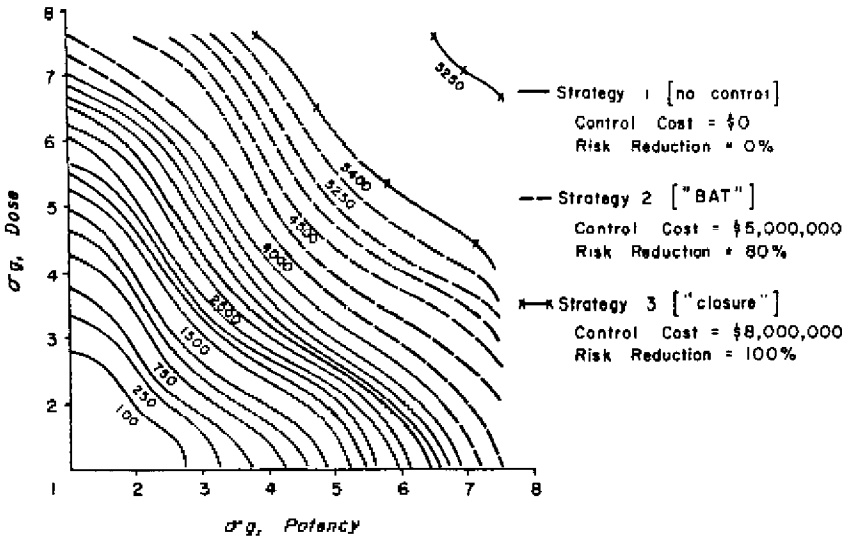

Figure 3

Isoquants of Equal EVPI (in $1000)

The monetary value placed on a statistical death definitely affects the parameters of the response surface, though not to as dramatic an extent as might be assumed. When the analysis was repeated with the value of life placed at $333,333 instead of $1 million per life, the EOL did decrease at all points, indicating that a decision-maker with this estimate of the value of life would be less inclined to seek additional information in every case. The region for which the "no control" choice was optimal also broadened significantly. However, in a substantial region of moderate uncertainty in both parameters the EOL for each case was rather similar. It appears that when one is squarely in the middle of the range for which the "BAT" strategy is locally optimal, new information is equally valuable for a broad range of opinion on the value of life.

E. Value of Dose Information

We have to this point been unable to generalize the properties of the response surface relating expected value of dose information (EVDI) to uncertainty. This relationship is of particular interest to the regulator, since reducing uncertainty in dose through ambient or personal exposure monitoring is generally more feasible in the short-run than conducting additional generic studies of potency. Our analyses indicate that EVDI is highly dependent on the relationship between the three strategies, and on small differences in the gradient of the overall

response surface, and that analysts will therefore need to examine this response surface separately for each decision problem.

III: APPLICATION TO ASARCO CASE

The attempt by the U.S. Environmental Protection Agency (EPA) to explicitly balance the risks and benefits of arsenic emissions at the ASARCO smelter is a useful paradigm not only of the difficulties of including the affected community in the risk-balancing process, but of the role of incremental reduction of uncertainty. In 1983 and 1984, EPA set about trying to apply its newly proposed standard for arsenic emissions to the ASARCO plant, the only facility in the country processing copper ore with high arsenic concentrations (Kalikow, 1984). The situation was ripe for regulation, as EPA's first estimate of the number of cancer deaths among the local population ranged from 1.4 to 22 deaths/yr. Table 1 shows the three control options EPA was contemplating at that time, along with our estimates of the costs and efficiencies of each. In this case, BAT entailed the installation of secondary hoods on the copper converters; the most stringent option, which ASARCO claimed would force closure of the plant, involved limiting the arsenic content of any ore processed to 0.7 weight percent.

Table 1

ASARCO Control Scenario

Control Strategy	Control Cost (10^6/yr)	Risk Reduction Efficiency	Expected Total Cost (10^6/yr)
A - no additional controls	0	0	$\bar{R}$
B - converter hoods ("BAT")	0.92 [a]	75% [b]	$92 + .25\bar{R}$
C - regulations forcing closure	20 [c]	100%	20

NOTES:

(a) The cost estimate is comprised of $757,000 in annual operating costs ($117,000 of which is increased electricity use) and capital costs of $3.5 million annualized over a 20-year period.

(b) EPA estimates that the hoods will remove 95% of arsenic emissions from the converters. Other fugitive emission sources will be unaffected by BAT. Since these sources account for about 50% of estimated arsenic concentrations near the plant, and about 15% in the remaining areas (where most of the predicted risks accrue), we estimate that the residual risk would be 20% from the other fugitive sources in addition to the 5% residual from the converters.

(c) Plant closure would cause the Tacoma area to lose $20 million annually in goods and services purchased by ASARCO

In June 1984, ASARCO announced it would shut down its Tacoma plant, citing falling world copper prices and difficulty meeting the state of Washington's standard for SO_2 emissions. Despite this outcome, analysis of the uncertainties surrounding the three strategies and EPA's attempts to reduce them provides a good test case for our computer model of value-of-information.

A. EPA's Dose Calculations

In the summer of 1983, EPA used the Human Exposure Model (HEM), consisting of the ISCLT air dispersion model and the MED-X data base for local population density estimates, to estimate aggregate exposure to arsenic in the Tacoma area. This combination led to an initial median estimate for the total dose to the approximately 368,000 people living within 20 km of the plant of approximately 103,000 persons*ug/m3. However, EPA soon discovered that the uncertainty around this estimate was rather substantial, as actual ambient concentration values supplied by ASARCO indicated that near the plant EPA was overestimating levels by up to a factor of 20 (EPA Region X press release, 1983). In general, the Agency believed at this time that only about half of its predicted values were within a factor of 2 of the true values. Two conditions in particular fostered this lack of precision. First, the ISCLT model does not account for potential fumigation of the plume due to the proximity of Puget Sound (leading to possible underestimation of concentrations) or peculiarities in topography (the smelter is built on the side of a steep hill) that could lead to overprediction in many instances. More significantly, once actual stack tests were conducted and fugitive emissions observed, it became clear that EPA's assumptions about emissions rates overestimated arsenic output from some sources (estimates for the main stack were lowered from 165 tons/yr. to 57 tons/yr., and for the converters from 132 to 17 tons/yr.), but underestimated the severity of other fugitive emissions at or near ground level (these estimates were revised upwards from 14 to 34 tons/yr.). Because very little of the predicted risk was due to contributions from the main stack, and because ground-level emissions are particularly troublesome, these errors tended to balance each other.

In response to these deficiencies, EPA improved their dose model using the new emissions estimates, plant-specific meteorologic data, and a dynamic algorithm that took into account ASARCO's tendency to cut back operations during weather conditions that made it probable the SO_2 standard would be exceeded (EPA, personal communication).

B. Potency Calculations

For their original estimate of the "unit risk" of respiratory cancer due to arsenic inhalation (i.e., the excess lifetime probability of contracting lung cancer if exposed to 1 ug/m^3 arsenic continuously for 70 years), EPA relied on three epidemiologic studies of occupational exposures (EPA, 1984): 1) Pinto et al. (1977), a study of workers at the Tacoma smelter; 2) Lee and Fraumen, (1969), a study of the Anaconda smelter in Montana; and 3) Ott et al. (1974), a study of pesticide workers exposed to arsenate compounds. For each of the studies, EPA fit a relative-risk model to the data, using the linear no-threshold assumption that R (the relative risk) is equal to $1+(B*D/P_0)$, where B, D, and P_0 are the potency of arsenic, the cumulative dose, and the background probability of getting lung cancer (derived from U.S. age-specific incidence data), respectively. After fitting the best regression line through the origin for each of the studies, EPA pooled the three maximum likelihood estimates of relative risk at 1 ug/m^3 by taking their geometric mean, and derived the pooled unit risk by multiplying by $(1-R)*P_0$. This pooled estimate was $2.91x10^{-3}$/lifetime, or $4.2x10^{-5}$/yr.

Recently, EPA has revised the unit risk estimate (EPA, 1984) slightly upward to $6.43x10^{-5}$/yr., making use of new data and concluding that a

linear, absolute-risk model best fit all of the suitable data. Again, EPA took the geometric mean of the unit risk estimates to establish a single point estimate.

C. Uncertainty in Dose

In their public statements about the potential risks from ASARCO emissions, EPA effectively treated the aggregate dose value as having no uncertainty, the range of expected cancer incidence deriving entirely from uncertainty in potency (see below). It is evident, though, that both the initial and final estimates of total dose have significant associated uncertainty, although substantial improvement was made during the refinement process discussed above.

We estimate the initial uncertainty as lognormally distributed with $s_g = 3.6$; i.e., 95% of the estimated doses for individual population segments would lie within a factor of 13 above or below the true value. This is consistent with EPA statements that only half of all initial predictions were correct to within a factor of two, and the observation that at least some isolated predictions were in error by a factor of 20. Formally, we arrived at our estimate for s_g by propagating three lognormal error processes: 1) modeling error for the ISCLT model when site-specific meteorologic data is unavailable (s_g=3)(EPA, 1982), 2) imprecision of emission rates (s_g=1.4); and 3) inability to predict whether the standard Gaussian plume or the fumigation model is appropriate (s_g=2).

According to EPA (personal communication), once the refined exposure model and emissions estimates were in place, the range of estimates for a given ambient concentration value were almost all an order of magnitude or less in breadth. So, we can assume that 95 percent of the predictions were within a factor of 3 of the true values, implying an "improved" s_g of 1.7.

D Uncertainty in Potency

According to EPA, the original unit risk estimate of 4.2×10^{-5}/yr. had a lognormal uncertainty of $s_g = 2.3$ surrounding it. EPA derived this figure simply by calculating the standard deviation of the logarithms of the estimates from the three epidemiologic studies and exponentiating. [The revised estimate of 6.13×10^{-5} has no uncertainty calculation with it, although we used the above procedure and got essentially the same estimate for s_g.]

We assert that this uncertainty estimate overstates the confidence with which the potency of arsenic can be known. Several factors not considered by EPA would be expected to broaden the pdf for potency, including: 1) lack of certainty about which dose-response function and which model specification (absolute or relative risk) is biologically appropriate (Crouch and Wilson, 1981) ; 2) imprecision of exposure estimates in the occupational cohorts; 3) uncertainty about whether to use national or state-specific "background" rates in calculating "expected deaths"; 4) exclusion of variations in human susceptibility from the model (Finkel, 1985a); and 5) uncertainty about whether measuring cumulative exposure as simply the product of concentration and duration is appropriate (Brown and Chu, 1983). Few of these factors are amenable to quantitative resolution. However, EPA's uncertainty estimate is undoubtedly a lower bound on the actual uncertainty in potency.

E. Results of Simulation

We then applied our computer routine to the ASARCO scenario outlined in Table 1. Unlike the hypothetical scenarios, where the median risk was set arbitrarily at 1 death/yr., the FOL takes on rather large values in this scenario because the central estimate of the number of deaths is $(6.13 \times 10^{-5})(103{,}000) = 6.3$ deaths/yr.

The simulation showed that the assumed value of improved dose information does depend strongly on what the uncertainty in potency is taken to be. If we took EPA's s_g for potency as true, our calculations show that the reduction in s_g(dose) from 3.6 to 1.7 would be worth a maximum of \$720,000 per year (for a net present value of about \$10 million assuming a 5% discount rate and a 20-year time horizon). If, however, the 95% confidence interval for potency is twice as broad as EPA believed (i.e., $s_g = 3.3$), the same achievement in reducing s_g(dose) takes on a value of nearly \$1.5 million per year. Our estimates of the value of improved exposure estimates are based on a high value for the social cost of ASARCO closure, \$20 million per year. If instead, we use closure costs one half to one fourth this large, we obtain even larger estimates of the value of improved exposure estimates.

According to EPA (personal communication), at least \$500,000 was spent, exclusive of the time spent by EPA staff, to generate the improved dose information. Thus, it seems that even if the potency of arsenic was as well-characterized as EPA's initial estimate would indicate, this money was probably well-spent.

IV. ONGOING REFINEMENTS OF VALUE OF INFORMATION MODEL

We believe that application of this simple value of information model would yield significant improvements over the haphazard way information-gathering resources are currently allocated. However, during the next year we intend to refine our analysis to more closely approximate the complexity of current environmental health decision processes. We have identified four areas where added complexity in the model is most likely to broaden its utility:

- Allowing for uncertainty in estimates of control efficiency.

- More thorough analysis of the many separable sources of uncertainty in estimates of dose. These include uncertainties in biochemical fate and transformation, uncertainties in estimating long range patterns of land use and behavior of human populations, and uncertainties in the estimates of the uncertainty inherent in application of environmental transport models in specific situations of interest.

- Analysis of the costs of obtaining improved risk estimates. Analysts need to consider not only the direct costs of obtaining information, but also the social costs and economic inefficiencies that occur as a result of delays in decision-making.

- Incorporation of "regret theory." Rather than focusing solely on measures of central tendency of risk and social cost, by incorporating utility theory we intend to more closely approximate the actual social costs associated with any specified level of residual risk.

To conclude, we envision that further applied research in this field will lead to development of an analytic tool useful for quickly differentiating situations where slight reductions in uncertainty lead to large social benefits from those where relatively large reductions in uncertainty are of almost no consequence.

ACKNOWLEDGEMENTS

We thank the many talented persons who have contributed to this effort. In particular, Bettina Burbank, Rick Letz and Avis Stiller deserve mention. In addition, we thank Henry Lee of the Harvard University Energy and Environmental Policy Center for his initial support of the work.

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PRIORITIZING HEALTH RISK ASSESSMENTS

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ABSTRACT

Health Risk Assessments are being conducted with increasing frequency. The stages of a Health Risk Assessment (HRA) are generally described as Problem Identification, Hazard Assessment, Exposure Characterization, Risk Analysis, and Risk Management. While much emphasis is correctly placed on the risk analysis step, the problem identification stage is often overlooked. When resources to conduct HRA's are limited, prioritization becomes a key process, especially for corporations faced with the need to fully assess numerous chemicals. Identifying a list of chemical candidates for HRA is only a first step that should be followed by a systematic priority analysis. Data from a priority analysis of petroleum products and petrochemicals were generated and analyzed. The data were generated through use of an Integrated Risk Index System, which was first presented by the author at the '983 Society of Risk Analysis Meeting. Conclusions are reached suggesting that the important factors necessary for informed, defensible prioritization decisions can be categorized as "inherent," "internal," and "external." The detailed description of these three factors provide a working guide for generating informed judgments how best to apply limited resources to assess the health risks of a large group of chemical candidates.

KEY WORDS: Risk, Prioritization, Health Risk Assessment

Awareness of potential health effects caused by exposure to chemicals has increased dramatically in the past few years As a result, corporations that manufacture, sell, and purchase chemicals are examining which of the chemicals they handle present health risks to their employees, their customers, or the public. In a large corporation this could be an enormous task because the health risks of hundreds of chemicals may have to be assessed.

Each individual health risk assessment (HRA) is a multi-stage process consisting of problem identification, hazard assessment, exposure characterization, risk analysis, options analysis, and finally risk management. Much emphasis is rightly placed on developing and refining the risk analysis stage. However, the practical necessity of developing a systematic approach to the problem identification stage has been somewhat overlooked.

With large numbers of chemicals to assess, corporations and regulatory agencies will no longer find it sufficient to simply identify a

list of chemicals requiring HRA. Arranging the chemical candidates for HRA according to a perceived priority is essential. The importance of prioritizing chemicals after identifying them for HRA becomes clear when it is seen that a perfectly conducted risk assessment is not very useful if the assessed chemical is of little importance to the corporation, and limited resources were diverted from the assessment of more appropriate chemicals.

When resources and the time to conduct HRA's are limited, finding the appropriate chemicals to assess becomes a key process of the identification stage, especially for the industrial companies and regulatory agencies faced with the need to assess hundreds or even thousands of chemicals. It would be difficult to specifically define a standard format that would always be successful identifying the appropriate chemicals for HRA. However, it is possible to develop some general principles for prioritizing chemicals for HRA that can be applied in a wide variety of specific situations. I will discuss these principles in terms of developing a systematic method for ranking chemical candidates for HRA.

A well designed systematic method for prioritization will be rapid, consistent, effective with limited data, and defensible. The usefulness of any prioritization system depends on maximizing all these traits. If one is traded off for another, such as reducing defensibility to gain rapidity, the overall effectiveness of the system is reduced.

A rapid prioritization system will rank a list of chemicals in as little time as possible. It is logical to assume that when more time is spent ranking chemicals on a candidate list, less time is spent conducting the HRA's on those chemicals. The system, therefore has to be designed to use time efficiently. It should not be overly complex, but instead, require only a few steps to achieve the placement of a single chemical.

I don't believe that rigorous mathematical formulations are necessary for a rapid prioritization system. When more complex mathematics are used, it seems, a deeper data search is required, which bogs the initial HRA step down in areas that are best left to the more difficult risk analysis step. Finally, the system should be designed to be computerized, for obvious time efficiency reasons.

Consistency is critical for any prioritization system, and without it, the system will be useless. Consistency allows more than one person to use the system, so that tasks can be delegated to different people. It should use a standardized format, so that there is less chance of making an error on any of the operations performed on each chemical.

Consistency can be achieved more easily when a quantitative system is employed. If each chemical can be assigned a score that represents an estimate of its potential health risk relative to the other chemicals on a list, the chemicals can be compared in a consistent manner, and appropriately ranked.

The system must be effective even when the data base for a chemical is limited. The criteria for scoring the chemicals must be developed with the understanding that there will be data gaps. The criteria for scoring the chemicals should be sufficiently flexible to allow professional judgment to substitute for incomplete information.

Consistency will lead to a more accurate prioritization of HRA candidate chemicals, which in turn creates a more defensible system.

Defending a prioritization system could be of major importance to a corporation or government agency, particularly in a courtroom where it might be necessary to explain why risk assessments have been conducted for certain chemicals, and not for others. A defensible system will also provide support for explaining to the management of a corporation why certain chemicals have been singled out for HRA's.

In order to create a rapid, consistent, and defensible system, criteria that will enable the reviewers to quantitatively assess the candidate chemicals need to be developed. I will describe those factors I have found to be well balanced between being simple and quick, and delivering a scientifically accurate representation of relative risk.

There are three groups of factors that are useful in building a successful HRA prioritization system. I call these three groups of factors the Inherent Factors, the Internal Factors, and the External Factors. Within each of these three groups are subfactors, which when assessed and quantified, can be used to rank chemicals for HRA.

The Inherent Factors describe the properties of a chemical which, as a result of interaction with a biological organism, are harmful. There are three types of hazards that can be considered as Inherent Factors when reviewing chemicals for risk prioritization.

One is the health hazard of the chemical. The toxicological data describes the biological response to contact with the chemical, and what amount of the chemical causes that response. A health hazard assessment of a chemical can consist of reviewing human data, animal bioassay data, or short-term animal or in vitro data. Sometimes a structure-activity analysis is also useful.

The physical hazards of the chemical are the next group of Inherent factors to consider. This is a review of the flammability and explosivity of the material, a type of hazard that may sometimes be overlooked in a risk analysis. For instance, a risk analysis of a chemical that is based strictly on carcinogenicity, but does not consider that the material is extremely flammable, may greatly underestimate the potential for that chemical to cause instant harm.

The third set of Inherent factors that are important to review are the environmental properties of a material. The two major categories of interest are bioaccumulation, and adverse ecological effects, which are also sometimes overlooked in risk assessments. A preliminary risk assessment should consider what damage a chemical could do to the food chain, or non-human organisms if they were exposed to the chemical.

The three factors, health hazard, physical hazard, and environmental hazard are termed Inherent factors because the specific properties of a chemical that will cause it to interact with a specific biological organism in a particular way are inherent to that chemical. These inherent characteristics can be objectively measured by using scientific methods. The ability of a chemical to explode at a particular temperature, or cause cancer in a particular species at a certain dose level, or bioaccumulate in a particular fish at a certain rate can be experimentally tested and scientifically assessed. As factors inherent to the chemical, they are not subject to control or alteration by a corporation or government agency.

Now that the first important factors have been identified, it is necessary to propose criteria that will allow a reviewer to quickly and

accurately quantify the relative level of hazard inherent to the chemical. I have used the criteria outlined in Rosenblum et al. (in press) successfully, but there is no reason why these criteria cannot be modified to suit specific prioritization needs.

Criteria were assigned to score six areas of health hazard: acute hazards, subchronic hazards, carcinogenicity, mutagenicity, teratogenicity, and reproductive effects. The actual criteria for each hazard and how they are scored are covered in detail elsewhere (Rosenblum et al., in press).

The criteria allow each type of health hazard to be rapidly reviewed, an assigned a numerical score corresponding to the level of toxicity. Higher scores indicate that the chemical is toxic at lower doses. Weighting can be worked into the system at this point to compensate for what is sometimes considered differing levels of severity among the health hazards. For instance, the carcinogenicity score can be given more weight than the mutagenicity score. The individual scores for each type of health hazard are than combined into a single health hazard score.

A similar process takes place for the physical hazard and environmental hazard review. Chemicals that are more flammable or explosive receive a higher score, as do chemicals that are highly toxic to wildlife or fish, and rapidly bioaccumulate. The result will be three numbers representing physical hazards, environmental hazards, and health hazards, which are then combined into a single "hazard" score.

Each type of hazard would ideally be scored by an appropriately trained individual. A toxicologist would score the health hazards, a fire safety specialist would score the physical hazards, and an environmental biologist would score the environmental hazards. Each could then input their number into a computer program which would store, collate, and calculate the results.

Once the inherent hazards of a chemical have been characterized by numerical scores, it is logical to then characterize the potential exposure to that chemical by a numerical score. It is interesting to contrast the control that a corporation has over either the inherent hazards (minimal) or the potential exposure (significant). A corporation can exert far greater control over potential exposure, which leads me to describe the factors used to characterize potential exposure as Internal factors. The factors are Internal in the sense that the amount of the chemical produced, and how many employees or customers will come in contact with the chemical, are largely based on internal corporate decisions.

It is possible to produce a relatively accurate representation of the potential exposure to a chemical by considering chemical related factors, employee/public related factors, and environmental discharge factors. The chemical related factors score the chemical simply on how much of it is produced. For a prioritization system it is good enough to compare chemicals based on how much is produced, rather than trying to assemble industrial hygiene data which is more appropriate for a full HRA. It does not seem illogical to assume that ten million pounds of a chemical is more likely to result in exposures to more people then ten thousand pounds.

The physical form of the chemical can also be taken into account. Chemicals can also be scored on the basis of whether they are gases, volatile liquids, non-volatile liquids, dusty or powdered solids or non-dusty solids.

It is also important to look at who could be exposed to the chemical. It would be ideal to know exactly how many people could possibly be exposed, but that data is not likely to be readily available. Instead, populations can be identified and a score assigned based on the control the corporation has over a potential exposure. This is done by characterizing the potentially exposed populations as belonging to one of three groups: occupationally exposed through production of the chemical; occupationally exposed through consumption of the chemical; or exposed through public consumer use of the chemical from a finished product.

While exposures to workers may occur in the production of a chemical, a corporation has significant control over the manner in which the chemical is handled. It can measure for the chemical in the workplace. It can provide engineering controls or personal protective equipment. It can adjust worker shifts, and the number of workers exposed. A corporation loses much of this control when the chemical leaves the production facility and goes to an industrial consumer. It can label to warn, and recommend handling procedures, but there is really no way to guarantee or control what will happen to that chemical. As a result, the potential for exposure should be considered increased.

Finally, the least control is exerted over the general public that can be exposed through use of a finished product containing the chemical. How many warning and handling labels are unread? How many inappropriate uses will be found for the product? The industrial consumer is likely to have some training in proper handling procedures. When a chemical reaches the general public, almost all control over the potential exposure is lost.

Reduced control over potential exposure translates into an increased risk of exposure to a larger number of people who will be more heterogeneous for age and sex. Therefore, chemicals with the potential for consumer use should be ranked higher than those in strictly industrial use.

If there is some doubt about precisely categorizing the extent of use of the chemical by each population, then environmental discharge, (another Internal factor) can be considered. If some the chemical is released into the atmosphere, poured into rivers, or eventually buried, there is a possibility of widespread exposure. Considering the route of environmental discharge, if any exists, and approximating how much discharge occurs is useful for gauging and scoring the potential exposure.

The two potential exposure scores I've used consist of estimating the amount of chemical produced, then assessing the populations that use the chemical, and weighting that score with consideration of the potential for exposure through environmental discharge of the chemical. These two scores are then combined into the potential exposure score.

Once the inherent hazards and potential exposure of the chemical are estimated and represented by two numbers, a relative risk estimate can be calculated by multiplying the two numbers, simply based on the concept that risk is a function of hazard and exposure. In fact, an Integrated Risk Index System developed by Rosenblum et al. (in press) was based on that concept.

However, after applying the system to rank chemicals for the development of hazard warnings, it became clear that to provide a system for accurately reflecting a corporation's priorities for HRA, another group of factors had to be considered.

Including another group of factors into the risk prioritization calculation resulted from the realization that corporations do not set priorities and commit resources to HRA in a vacuum. There are extensive, and powerful influences from outside of a corporation that can significantly impact on a risk prioritization decision. These influences, which can be termed External Factors, include commercial importance, government regulation, litigation, and media coverage of a chemical.

While the latter three factors are beyond the direct control of a corporation, the first factor, commercial importance of the chemical, is within the realm of corporate control and has significant impact on corporation HRA decision making. This factor is external in the sense that revenue derived from a chemical depends on its position in the marketplace, and it is becoming increasingly clear that the marketplace is responding to concerns about health risks. It is becoming more common to find certain products being touted as "safer" than a competitor's product.

The External factors that a corporation has little direct control over also can have a major impact on HRA priority. Toxic tort litigation is beginning to be recognized as a potentially major drain on the financial resources of a corporation. Sometimes out-of-court settlements have the effect of suspending scientific judgment of a chemical's actual level of risk. A settlement creates a precedent suggesting that any exposure to the particular chemical involved in the litigation can be harmful. These precedents can provide ammunition for further litigation. The only real defense against future litigation is to control present and future exposures. Increased litigation concerning a chemical can be used as a signal to a corporation that the risks posed by the chemical should be assessed and managed.

Societal concerns about a chemical are eventually reflected by the extent of government activity to characterize and control the chemical's risk. An assessment of External factors should include a review of government activities such as lists of hazardous substances for right-to-know laws, rebuttable presumptions of adverse effects, health effects test rules, and TSCA 8(e) and 8(c) notifications. It is also obvious that a chemical should be considered a high priority if a government agency is already proceeding with risk assessment activities on that chemical.

If government activity concerning a chemical reflects societal concerns about the chemical, what influence shapes society's opinions? Clearly, the news media can play a major role in determining the public's opinion of the health risk presented by a chemical, and it seems logical therefore to consider this as an External factor as well. When public attention is focused on a chemical by the news media, the perceived risk, which in many cases can be as important as the "actual" risk, increases dramatically. Both government activity and toxic tort litigation seem to increase in direct proportion to the extent of the media coverage. The recent media event and subsequent government response concerning ethylene dibromide (EDB) is a classic example of this effect.

The criteria for quantifying the External factors can be flexible, but there seem to be some useful possibilities for scoring the extent of the commercial importance of the chemical, and the influence of litigation, government activity, and the news media. The simplest method to quantify the commercial importance of a chemical is to determine the revenue derived from its sales. This information may sometimes be difficult to acquire, so other means such as number of units sold could be used. It is also not strictly necessary to directly input commercial

importance into the risk prioritization process because the "amount produced" factor, which was assessed as part of the potential exposure category, could be considered an indirect measure of a chemical's commercial importance.

Litigation can be scored by considering the number of cases, the number of plaintiffs, and the dollar value of the cases. Government regulation can be quantified by assigning point values to different areas of toxic substance regulation based on the impact the type of regulation could have on the company. Higher values would be assigned to those government activities that occur after an agency has already identified the chemical through their own risk prioritization process. The news media impact can be scored simply on whether the chemical has been covered by local, regional, or national news media, with the highest score going to national coverage. The External factor can then be derived from a summation of these four scores, and can provide a corporation with an indication of whether a chemical can be described as having a "high profile" externally.

Scoring the factors I've identified will result in three numbers: the ratings for relative hazard, exposure, and External factors. The Integrated Risk Index System that I have used for prioritizing a group of petroleum products, and a group of petrochemicals multiplies the hazard score by the exposure score, which leads to an indication of relative risk. An External factor score could then be multiplied by the relative risk score to provide further input into the prioritization process. It seems desirable to input the External factor after the relative risk is indexed in order to better visualize the differences between priority based on "actual" risk, and priority based on "perceived" risk. Also it could be decided to apply the External factor only to the "top ten" of the relative risk list, in order to fine tune the priorities of the clearly high risk chemicals.

This discussion of developing a risk prioritization system is intended as a guide not a blueprint. I have covered what I believe to be the significant factors that should be considered when the risks of a large group of materials must be assessed. It is up to the individual or the corporation to decide which factors are necessary for generating an informed judgment how best to apply limited resources to the risk assessment process It is hoped that this discussion makes the enormous task of conducting Health Risk Assessments on numerous chemicals easier, more efficient, and more accurate.

REFERENCE

Rosenblum, G. R , Effron, W.S., Silva, J.L., Mancini, E R., Roth, R.N. (in press) An Integrated Risk Index System, Proceedings of the Society for Risk Analysis, 1983 Annual Meeting, New York.