REGULATORY NEGOTIATION: LESSONS FROM BENZENE

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ABSTRACT

Recent efforts by the Occupational Safety and Health Administration (OSHA) to negotiate an agreement on a revised standard for occupational exposure to benzene represented an important initiative by the Agency. Increasingly, the Government is seeking more efficient and effective ways to establish health and environmental standards, and negotiation is a promising alternative for promoting this goal. While use of negotiation in rulemaking proceedings is new, negotiation has been common in other contexts for many years. It is important, however, not to assume that the lessons learned in these other contexts can be applied automatically to rulemaking negotiations. The paper discusses some of the most significant distinctions among the different contexts in which negotiation occurs.

KEY WORDS: Rulemaking, Rules, OSHA, Negotiation, Mediation, Benzene, Environment, Health.

INTRODUCTION

In 1978 the Occupational Safety and Health Administration (OSHA) promulgated a new standard lowering the permissible exposure limit (PEL) to benzene from 10 ppm to 1 ppm. The revised standard was challenged in court, and ultimately the Supreme Court ruled against the agency.[1] The Court rejected OSHA's contention that the applicable law permitted the Administrator to reduce the standard simply because benzene is a carcinogen and there is no proven safe level of exposure. The agency had to show that exposure at current levels creates a significant risk that would be significantly reduced by the new standard. OSHA's failure to do this meant that it had not met its statutorily-imposed burden of showing that the lower standard is "reasonably necessary and appropriate."[2]

*This paper expresses only the views of the authors and does not necessarily represent the position of the American Petroleum Institute or any of its members.

[1]Industrial Union Dept., AFL/CIO v. American Petroleum Institute, 448 U.S. 607 (1980).

Following this decision, OSHA could have reopened the proceeding to introduce additional evidence on the significant risk point. It chose not to do so, however, and the 10 ppm standard remained in force. In 1983 OSHA received petitions from labor and public interest groups asking it to revisit the issue and lower the PEL.

In the period between the Benzene case and the 1983 petitions the government had developed an increasing interest in the concept of "regulatory negotiation." This is the idea that in some instances an agency might develop regulations through negotiations among all the interested parties (including the agency) rather than through formalized rulemaking processes. The arguments for and against "Reg Neg" are complicated and we will not try to recapitulate them here. Probably the most complete treatment is the 1981 report that Philip Harter wrote for the Administrative Conference of the United States, and anyone wanting to explore the topic in more depth is urged to consult that work.[3] For present purposes the important point is that the idea of Reg Neg was in the air and some OSHA staff members had become interested in its possibilities.

The 1983 petitions asked for not only a revised PEL but for an Emergency Temporary Standard (ETS) as well. OSHA denied the request for an ETS, but in the course of doing so it committed itself to a proceeding to inquire into the need for a lowered PEL. Furthermore, OSHA announced its intention to follow a stringent schedule for the rulemaking. A final rule was to be in place by June 1984.

This was the context in which OSHA suggested to a number of organizations having a stake in the issue that they meet and explore the possibility of negotiating the provisions of a proposed rule that would be acceptable to the parties and to the agency. The parties were interested, and the ensuing discussions continued intermittently from the fall of 1983 to the fall of 1984.

The ultimate participants were:

Labor

- Industrial Union Department, AFL/CIO
- Oil, Chemical and Atomic Workers
- United Rubber Workers
- Steel Workers of America

Industry

- Chemical Manufacturers Association
- American Petroleum Institute
- American Iron and Steel Institute
- Rubber Manufacturers Association

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[2]Occupational Safety and Health Act, 29 U.S.C. § 652(8).

[3]Philip Harter, "Negotiating Regulations: A Cure for Malaise," 71 Georgetown Law Journal 1 (1982). See also Henry Perritt, "Analysis of Four Negotiated Rulemaking Experiments," A Report to the Administrative Conference of the United States, Sept. 4, 1985 (Draft).

In the end the parties were not able to reach agreement, and so informed OSHA. As of this writing, OSHA has not released a proposed revised benzene standard.

The main point to be made here is that in analyzing the benzene negotiation -- or any other regulatory negotiation, for that matter -- it is important not to be too quick to analogize the process to other, more familiar kinds of negotiations. One frequently hears analogies drawn between efforts to negotiate a benzene standard and:

- Labor negotiations over wages and hours
- OSHA advisory committees and science advisory panels, such as the NSF or EPA's SAB
- Negotiated settlements in environmental litigation

As a general proposition, analogies and models are important and useful. Used appropriately, they can give essential structure to an unfamiliar situation by providing ready-made expectations and behavioral norms. Used inappropriately, however, they can create false expectations that can lead parties seriously astray. In the authors' view, one of the most important lessons of the benzene negotiation is the limited applicability of any of the models listed above.

Explaining the reasons for this requires some additional background on two key aspects of a regulatory negotiation.

The first of these involves a core concept of negotiation theory called BATNA -- "Best Alternative To a Negotiated Agreement."[4] This means simply that each party to a negotiation, before entering an agreement, will have to decide that the result is superior to what it thinks will happen in the absence of agreement. If the party would prefer the alternative to the agreement, then of course it has no incentive to sign.

In most cases, of course, the alternative to an agreement will not be entirely clear. There will be a range of possible outcomes with varying probabilities attached to them. A party's willingness to accept an agreement will depend on its appraisal not only of what will most probably happen otherwise but also of the worst that might happen. One of the benefits of reaching agreement is the guarantee of avoiding the worst, and an important element in a negotiation is the comparative risk preference of the parties. One could speculate that a more risk averse party, all other things being equal, would have a larger appetite for negotiation than a less risk averse party. Thus a risk averse party might enter an agreement even though it estimated that it had, say, a 90% chance of attaining a substantially better result without an agreement if the remaining 10% represented a very disadvantageous outcome.

The BATNA concept had several applications in the benzene negotiation. Looking at the situation objectively, it seems safe to say that each participant had reason to think that negotiation might produce an outcome superior to the outcome the participant foresaw if OSHA proceeded in a conventional manner. In addition, each had to face the fact that some extremely poor possible outcomes could not be totally discounted.

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[4]Roger Fisher & William Ury. Getting to Yes, 104-11 (Houghton Mifflin Co. 1981: Boston).

All the parties recognized that the alternative to reaching an agreement was an administrative rulemaking proceeding, not the status quo. They also knew that a prudent participant would have to recognize that OSHA would go into such a proceeding with a presumption that the standard should be lowered, given the agency's position of three years before.

At the same time, a prudent participant would recognize that an agency desire to lower the PEL would not necessarily translate into quick action. As a matter of historic fact, OSHA proceedings have tended to be long, and there was no reason not to think that a benzene rulemaking would not follow the pattern. Nor could there be any guarantee that a new standard would survive judicial review. The exact dimensions of the "significant risk" standard articulated in the Benzene case remain unclear, and there was always a chance that the agency could go through a lengthy rulemaking only to be overturned again.

Given these realities, each party had an incentive to give serious consideration to the possibility that negotiations could produce a result superior to its BATNA.

There is an important additional BATNA issue. Historically, the rulemaking process has been poor at identifying possible trade-offs arising from the differing values that affected parties may place on various parts of a rule.

The essence of any bargaining process is that people place different values on different things. In a sales transaction, to take the most elementary example, the seller would rather have the money than the goods while the buyer would rather have the goods than the money.

In a rulemaking context, when the parties are considering the different possible combinations of provisions it is likely that the values they attach to the different provisions will vary. Consider an occupational exposure standard, for example. A union may press for a low exposure limit with no "exceedences" of that level allowed.[5] In fact, the union may think it very important that the average level of exposure be kept down, but not be worried about random exceedences. Industry may press for a higher exposure level with wide latitude for exceedences. In fact, it might not object to the low exposure limit desired by the union if exceedences were allowed.

This is precisely the stuff of which bargains are made, but the parties' true positions are not likely to surface in a rulemaking proceeding, in which each feels compelled to maintain a hardline posture on every individual issue. The rulemaking process may actually produce a combination of provisions representing the least desirable outcome for all parties.

This concept of differential value is important. It means that even if one neglects factors like delay and potential judicial reversal a negotiated agreement can be a positive sum game. In the right circumstances every participant can be better off under the agreement than it would be under a rule imposed by an agency.

[5]Exceedences are defined here as periodic excursions above the PEL but less than the short-term exposure limit

The second important factor in considering the applicability of these other models to negotiated rulemaking is the nature and uses of information brought to bear in the process.

In a negotiation over a proposed rule, information is evaluated by the participants from a number of perspectives.

An obvious consideration is that each party wants to convince the others of the correctness of its own position. No party believes that the others are totally irrational or malevolent. If the unions could convince industry that a lower PEL were necessary to protect workers then industry would stop protesting. Similarly, if industry could convince the unions that a lower standard was a pointless waste of money the unions would stop pressing for it.

It is easy to discount this itch to convert the opposition as naive, but it is an important factor in negotiations. And, one might add, it can have an effect. We all know how often organizations or individuals will adopt an official truth, regarded as so obvious that it is exempt from analysis or reconsideration. To have such truths questioned by an intelligent and articulate adversary can be a valuable educational experience. In the benzene negotiation the participants, positions had hardened in the earlier rulemaking and the litigation that followed it, and it seems likely that all parties emerged from the bargaining sessions with new perspectives.

Another use of information is closely related to the one discussed above. A party might not convince an opponent of the correctness of its views, but it can convince the opponent that the party itself is sincere in these views, and thus not easily budged. Consequently, information is constantly being evaluated in terms of whether it represents the real views of the party presenting it.

In a negotiation such as the one over benzene, information must also be constantly evaluated in terms of its probable impact on the agency. If a representative of a company or a union regards a piece of information as likely to cause OSHA to be moved in one direction or another then the parties must consider this as the bargaining proceeds.

Obviously, scientific information is very important in this context, since the parties know that OSHA will react to it. There are some countervailing considerations that may dilute the purity of the participants' technical presentations, though. All participants have to work with at least one eye on possible court challenges should the negotiation fail. Intermediaries in a negotiation must remain aware that the parties will have a well-founded fear of pronouncing outcomes in a "failed negotiation" that might undermine their case at a later time.

Another potential problem is that a participant may find it difficult to judge exactly the impact a particular piece of information may have on OSHA. The information ultimately provided to the agency decisionmakers flows through a filter of many layers of bureaucracy. This makes it hard for the participants to assess what will influence the decisionmaker, or how much. Consequently, it is difficult for participants to assess precisely the bargaining value of particular information. Also, different evaluations of the same information can lead to a deadlock.

This problem of appraising the value of information is exacerbated in the context of health and safety regulation by the immense uncertainties

involved. Almost every aspect of the problem, ranging from the risks presented at particular exposure levels to the costs of compliance with proposed rule provisions, presents substantial and usually irreducible uncertainty. One of the most difficult aspects of rulemaking (or negotiating) in these conditions is developing an appropriate response to the uncertainties that cannot be eliminated.

However, this raises an interesting comparison between formalized rulemaking and negotiation. In rulemaking, an agency will often tend to follow a legal model of decisionmaking in which the agency resolves uncertainties by making "findings of fact" that treat anything that is "more probable than not" as if it were 100% certain, and then bases agency policy conclusions on these supposed "facts." In other words, most of the uncertainty is assumed away.[6] In negotiation, the parties will not agree to such artificial resolutions of uncertainties. Consequently, they are forced to seek solutions that do not depend on eliminating uncertainties and that would be acceptable across a range of possible states of the world. This can result in a more realistic treatment of uncertainty than would emerge from the supposedly more rational process of formalized rulemaking.

A final important kind of information in negotiation concerns the values parties place on the different possible provisions of an agreement. Since such information delineates the bottom line of a party's negotiating position, it will always be exchanged cautiously, and often only by implication. An important part of the negotiation process revolves around a party's making a tentative or partial disclosure of this kind of information and then waiting to see if other participants reciprocate.

Information introduced into the negotiating process is used in all of these contexts at once, which creates a very complex system. Parties are constantly weighing the utility of a piece of information in one context versus another.

These two dimensions -- BATNA issues and information issues -- are crucial to any effort to use other kinds of negotiation as a paradigm or model for Reg Neg. If the proposed paradigm does not correspond with Reg Neg in terms of these two dimensions, its utility as a model is likely to be quite limited.

Analysis of the three models often cited as paradigms leads to the conclusion that none of them is satisfactory.

Labor Negotiations

The most commonly-drawn analogy is between regulatory negotiation and labor negotiations. This analogy is particularly appealing when a

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[6]For further discussion of this problem of the artificial elimination of uncertainty, see James DeLong, "Informal Rulemaking and the Integration of Law and Policy," 65 Virginia Law Review 257, 346-47 (1979); James DeLong, "How to Convince an Agency," Regulation, Sept./Oct. 1982, at 27, 33-35. See also American Petroleum Institute, Comments on EPA, "Proposed Guidelines for Carcinogen Risk Assessment," 49 Fed. Reg. 46294 (November 23, 1984) (Filed Jan. 22, 1985); American Petroleum Institute, Comments on EPA, "Formaldehyde; Determination of Significant Risk: Advance Notice of Proposed Rulemaking and Notice," 49 Fed. Reg. 21869 (May 23, 1984) (Filed August 3, 1984).

regulatory negotiation involves an OSHA health or safety standard because the principal interests are the same -- management and labor. However, there are a number of crucial differences between the two contexts, and too facile a reliance on the collective bargaining analogy can lead to serious mis-estimates of the situation.

An initial, and important, distinction is that a regulatory negotiation may involve many different participants interlocked in a complex jigsaw of congruent and conflicting interests. A collective bargaining situation usually involves only two parties, the company and the union. The difference has a major impact on both BATNA and information issues.

A particularly crucial dimension of the two-party character of a labor negotiation is that there is no outside agency waiting to act if the parties do not agree. At any given time, the alternative to agreement facing each party is a work stoppage and consequent economic loss, followed by some agreement when one of the parties exhausts its capacity to take punishment. This creates quite a different BATNA structure than exists in the regulatory context.

There is also less room for bargaining over differential values. While the participants in collective bargaining may find some areas that present the prospect of trading off differential values, (work rules versus pay rates versus fringe benefits, for example), for the most part the disagreements involve tangible questions of money. This tends to make the game zero-sum (or even negative sum, if a long work stoppage occurs) and reduces the prospects for finding positive sum outcomes.

The nature and use of relevant information is also rather different. While some of the same considerations apply to collective bargaining as to regulatory negotiation, such as the need to convince the other party that one is serious and committed, many do not. The primary differences are, again, that in a labor negotiation there is no independent entity waiting to act, and scientific information and analysis of uncertainty are of lesser importance.

OSHA Advisory Committees and Science Advisory Panels

The Occupational Safety and Health Act allows the establishment of advisory committees to assist in standard setting. Any advisory committee "shall include among its members an equal number of persons qualified by experience and affiliation to present the views of the employers involved and of persons similarly qualified to present the viewpoint of workers involved ..."[7] An advisory committee is also to include representatives of state and federal agencies and outside experts.

On the face of it, such a group might appear to present a reasonable paradigm for regulatory negotiation. In practice, though, OSHA Advisory Committees have been used as scientific advisory committees, concerned with evaluating and advising the Administrator on the scientific information relevant to a standard. Thus they can best be considered together with groups which are more explicitly designated as "Science Advisory Boards."

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[7]Occupational Safety and Health Act, 29 U.S.C § 656(b).

The process of "negotiation" that occurs in the context of a board of scientific advisors is quite different from regulatory negotiation. While science panels are often put together with an eye to obtaining diverse viewpoints, scientists seek professional consensus, which is a different type of negotiation than the attempt to reconcile competing interests that characterizes the regulatory negotiation process. Scientists are attempting to reach consensus on technical matters according to certain well-defined canons of inquiry. A certain amount of compromise may take place, but the scope for horse-trading is severely limited by the nature of science itself.

In addition, a science panel is not expected to develop a rule which an agency can then propose forthwith. Almost always, it is expected that other considerations, such as cost or technical feasibility, will have to be combined with the scientists' judgment to produce a finished product. (For example, the Science Advisory Board of EPA reviews the agency's risk assessments, but is not asked to comment on the risk management decisions that flow from them.)

Furthermore, a failure of an advisory group to reach agreement does not mean that the agency will automatically act, or decline to act, to the benefit or detriment of the negotiating parties.

In terms of our two axes of comparison -- BATNA issues and information use -- it is difficult to find any significant similarities between science advisory groups and regulatory negotiation. The only point of comparison seems to be that both will, on occasion, make use of scientific information. In fact, if one were to find that the principles applicable to regulatory negotiation were in fact relevant to the operations of a science advisory board, one would be sure that the board was acting as a policy making body, not as a scientific counselor.

Negotiated Settlements in Environmental Litigation

In several respects, this analogy is better than the others. Here, as in regulatory negotiation, if the negotiations fail then an institution with authority over the parties to the dispute will resolve the issue. There is also substantial scope for the interplay of differential assessments of the value of different segments of a proposed settlement and for the development of positive sum games in which everyone is better off than they would be if the authority imposed a settlement. Consequently, many of the same BATNA incentives are at work as are operating in a regulatory negotiation.

Some of the issues involving the use of information are also similar to those that exist in regulatory negotiation. The parties must assess the potential impact of information on the outside decisionmaker, and must also assess the utility of information in various contexts. There are substantial uncertainties over key issues

In one respect, this analogy fails -- the issues in a specific piece of environmental litigation are usually more narrow than those in a rulemaking. In a rulemaking, the question is usually, "What should the standard be?" In a lawsuit, the question is more likely to be, "Given the standard that exists as a result of a statute or existing rule, has it been violated and what should happen as a result?" The uncertainties more often than not involve questions of factual proof and timing more than they involve fundamental questions of science, economics, and values. Consequently, there is less scope for compromises that leave both sides better off than they would be under an imposed solution. There is also a

considerable difference between the kinds of information relevant to this type of negotiation and the kinds relevant to a negotiation over a rule[8]

For the reasons stated, none of these oft-suggested paradigms is directly on point. There are, however, enough similarities to create a temptation to analogize between familiar kinds of negotiation and the regulatory situation.

The limits on these analogies must be kept firmly in mind. If regulatory negotiation is to be useful in the future, it is important that everyone interested in it help develop our understanding of the nature and dynamics of the process. Relying on seductive, but only partially applicable, paradigms will lead to unreasonable expectations and disappointments.

The importance of maintaining a realistic view of regulatory negotiation is shown by events since the end of the benzene affair. A lively literature of evaluation has developed, much of it directed at the question of whether the negotiations "succeeded" or "failed." As a matter of fact, there seem to be far more people interested in helping perform the autopsy than ever worked to keep the patient alive.

The end point sought in the benzene negotiation was a draft proposed rule which would then have moved through the normal administrative structure of proposal and final rule. As stated at the outset, the parties were not able to achieve this, and to this extent one could say the process failed.

On the other hand, the parties did work towards some creative solutions to problems in a less adversarial setting than exists in a conventional rulemaking. The understanding of the problems attained during the negotiations will certainly have an impact on the rulemaking proceeding when it finally commences. The efforts during the negotiations were marked by a more cooperative spirit than had characterized some industry/union contacts in the past, and it seems fair to say that all parties achieved a better grasp of the problems and positions of the others. Important lessons were learned about both the regulation of benzene and the process of regulatory negotiation. In all of these dimensions one would have to count the experiment a success.

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[8]The term "usually" in this paragraph deserves particular emphasis. In some cases, settlement discussions will in fact revolve around the broader question "What should the standard be?" and the process can become very much like a regulatory negotiation. In such a situation the judge may play the role of mediator, albeit a mediator of unusually large authority.

TOWARDS AN ACCEPTABLE CRITERION OF ACCEPTABLE RISK

Paul Milvy

ABSTRACT

The determination by federal risk managers of an acceptable level of carcinogenic risk depends upon many factors. Several of the factors are amenable to objective analysis while others remain largely subjective and/or culturally determined. The size of the population that is at risk influences our perception and analysis of what level of risk constitutes an acceptable risk. The rate of risk and the total or population risk are often used uncritically or interchangeably to express risk. Yet the rate of risk and the total or population risk seem to modulate our notions of what level of risk is perceived as acceptable. This general problem is explored and an approach for the resolution of this perplexing situation is suggested and compared to empirical data.

KEY WORDS: Acceptable risk, Population risk Individual risk, Risk Management, Carcinogenic risk

The paradox is a way station to knowledge. It implies some degree of insight into the way the world is and the way it works. But the inability to resolve a paradox attests to the limitations and the incompleteness of understanding and of knowledge. By begging to be resolved, the paradox is a reflection of the dichotomy between appearance and reality, between our limited knowledge and our urge to understand ever more deeply. Perhaps paradoxes confirm that scientific efforts are squarely placed at the interface of knowledge and ignorance. To resolve a paradox is to move forward in the never-ending struggle to understand better the world in which we exist. Paradox is but knowledge in the making.

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The new discipline of risk management abounds in paradox. In this communication I examine one aspect of a central conceptual problem of risk management that has been analyzed many times already. The problem I address is that of "acceptable risk." In the phrase "acceptable risk" there exists a tension between the noun "risk" which in principle can be objectively measured and the adjective "acceptable" that modifies it and is largely subjective. Society's lack of consensus as to the meaning of the term "acceptable" in this phrase leads directly to such questions as "How safe is safe enough?" and "acceptable to whom; those who profit from the risk or those who must endure it?" The concept of a risk sufficiently small or sufficiently safe to be acceptable when compared to other risks to life and limb is straightforward. It is the application of this standard to the real world in which we live and die that has proven so difficult. Attempts to define the term "acceptable risk" illustrate the dilemmas and paradoxes that bedevil regulators and managers of risk. Risk is an objective, quantifiable externality. In principle it is knowable, although the scientific methodologies and armamentaria presently available to estimate carcinogenic risk are not nearly as powerful as we might wish. Of yet greater concern is the recognition that these tools provide no more than a very limited glimpse of the myriad of carcinogenic species that we know must confront us. A recent study by the National Research Council (National Research Council, 1984) provides a sobering perspective regarding the efficacy of present testing methodologies on our ability to identify chemical carcinogens. The NRC estimates that of the more than 65 thousand chemicals in what it defines to be the "select universe" of its study, approximately 48,000 are used in commerce. The study estimates that no toxicity information of any kind is available for about 79% and no carcinogenicity tests have been conducted on 85-90% of these chemicals. In view of the hundreds of new chemicals added annually to the inventory of commercial chemicals, one concludes that fundamentally new technologies must be developed if the fraction of chemicals for which carcinogenic information is available is not to become even smaller. Automated short-term mutagenicity tests that correlate fairly well with animal bioassay studies to predict mammalian carcinogenicity are already a viable option. As the Ames test is improved or as other tests that may complement and/or be superior to it are developed, this would become an increasingly attractive and cost effective approach.

We acknowledge, therefore, that however formidable the obstacles faced by risk analysts may be, in principal cancer risk from man-made carcinogenic chemicals can be measured quantitatively and its impact on mortality evaluated objectively. But it is a different matter to determine empirically or define abstractly a level of acceptable carcinogenic risk that is itself acceptable to society at large. The notion of "acceptability," as already noted, is largely subjective. Dictionary definitions themselves revert to subjective terms to illustrate its meaning. Neither dictionaries nor experts can be expected to agree on this term, nor on the criteria that can best be used to evaluate it.

The public generally does not estimate or evaluate risk objectively (Slovic et al., 1979; Litai, et al., 1983; Corvello et al., 1983; Milvy, 1986). Individuals do not reach decisions regarding personal conduct based exclusively or even in large part on such considerations. But the federal risk manager ignores the public's judgment of acceptable risk levels only at his or her own peril. To suggest that the added incremental risk is very minute, or that it is smaller than the 1.4×10^{-2} lifetime risk of death from automobile accidents, is arguably beside the point. To argue that a reduction in mortality has accompanied industrial progress (e.g. U.S. life expectancy at birth has increased more than 5

years since 1965 and 28 years since 1900) also does not demonstrate that the added risks from new carcinogenic chemicals are acceptable. For it does not demonstrate that a policy more prudent with respect to the management of carcinogens would not have achieved an even more rapid improvement in the nation's health. Finally, it has not generally been demonstrated to be true that the introduction into commerce of a new carcinogenic chemical, by replacing an existing more potent one or by decreasing total mortality in some other way, lowers total risk, although in specific instances this is obviously quite true.

The problem of defining a general algorithm or general approach for establishing levels of acceptable risk remains. It would seem to be largely intractable. Quantitative risk analysis (QRA) tries to diminish the distortions that subjective perceptions of risk introduce into the management of risk. As the methodological and technological weaknesses of QRA are overcome, the analysis of risk becomes more objective and more reliable. But this will not necessarily change the distortions involved in the public's perception of risk. It may be argued that these distortions tend to diminish in time with the dissemination of pertinent information. But these distortions do not result solely from a lack of information. When we look at optical illusions, an Esche lithograph is a case in point, it is not ignorance that leads to the distortions of our perceptions. It is one of the major roles of science to overcome our propensities to distort reality (it has been observed that "were appearance and reality identical there would be no need for science".) Education can go only so far to reduce such dichotomies. Lital, et al., (1983) and Slovic, et al., (1979) have shown, for example, that a voluntary[1] risk that is two or three orders of magnitude higher than an involuntary risk is equally acceptable given similar benefits from each. This is not a distortion of perception in the usual sense: it is an additional dimension or characteristic of the risky activity that influences our attitudes about its acceptability. The acceptability of a risk is a function of more independent variables than just the rate of risk or the absolute risk alone. I do not calculate cardiovascular benefit versus risk of skin cancer while jogging on a sunny afternoon. I may prefer Mozart's string quartets to hard rock, not because the risk of an injury to my hearing is less, but for reasons totally unrelated to risks. Risk quantification can help us to clarify such preferences only marginally, if at all. Individuals consciously and unconsciously assess relevant variables (within certain restraints for which the umbrella term "voluntary" seems largely to apply) and reach decisions. It is clear they can do this "gut calculus" best only when they have full access to the relevant facts, and full freedom to act on these facts. If an item - be it a food, an indoor environmental pollutant, or a workplace chemical - is carcinogenic yet those at risk are unaware of this, the uninformed judgment that is made may be inappropriate. If the risk is not totally voluntary the freedom to make an informed decision is circumscribed.

Several attributes of risk in addition to the quality of being voluntary influence levels of risk perceived as acceptable, as Table I indicates. Two additional factors that effect perception of an acceptable risk level merit attention. We begin by noting two conventional methods for expressing levels of mortality. The rate of risk, often called individual risk, expresses either the number of deaths as a fraction of

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[1]Slovic et al. ('980) have conjectured that "voluntariness" may be surrogate variable closely linked to other characteristics.

the total number of people exposed and actually at risk or it uses some more convenient denominator, for example, 10^{-4} or 10^{-6} to express this fraction. Thus a cancer risk of 3×10^{-5} implies that three of every 100,000 people will die from cancer that results from exposure to a carcinogen. It indicates an annual risk if this is the annual rate, a lifetime risk if the deaths occur over a lifetime, generally assumed to be 70 years. The alternative approach to expressing risk defines risk in terms of total risk, sometimes called population risk. This expresses the excess mortality arising from the risk in terms of the total number of deaths. If 674 people die from cancer by virtue of exposure to an environmental or industrial carcinogen, this is the risk incurred and no explicit mention of the number of people at risk is made. These two ways to express risk are easily interconverted when the number of people at risk is known. In terms of the regulation of a risk, however, each carries different implications and the germ of paradox exists in these alternative approaches to formulating risk.

The concepts of equity and equality under the law and the dictates of common sense would seem strongly to suggest that the standards of acceptable risk for an individual be independent of the number of people similarly at risk from the same hazard. Yet in the real world this seems not to be the case, as the following examples illustrate. During a 70-year interval 236 deaths from cancer in the United States is often thought of as the bench-mark for the level of acceptable risk from a single man-made carcinogenic chemical.[2] This criterion of acceptable risk is more generally expressed as a lifetime rate. Since the 1984 population of the United States was 236 million these 236 deaths are equivalent to a rate of one in a million, or 10^{-6}. Yet 236 deaths would not be perceived as acceptable if they were to be limited to the workers in a chemical manufacturing plant that employs 250 people, the citizens of a small village of similar population, or some other small and discrete population. In both examples, when viewed from the perspective of the United States, 236 cancer deaths in a total population of 236 million have resulted from the carcinogenic chemical. But these deaths are discrete and localized they are likely to be perceived as a catastrophe; when they are dispersed over time and space, if perceived at all, they are probably considered to be background noise: a negligible, random, uncaused, rather trivial perturbation. In the one case the individuals who die of cancer can be identified with a high degree of statistical confidence. In the other case the 236 deaths, unless the primary tumor is a rare and unique tumor not normally seen in the population at large, are unidentified and unidentifiable. Epidemiologists are unable to separate those who die from these cancers from the total of 32 million cancer deaths that also occur during the 70 years interval. From this example I am persuaded that the criterion of acceptable total risk is somehow dependent on the size of the population that is at risk. But if the size of the total population that is at risk is included, we have implicitly reverted to using the rate of risk.

On the other hand, only a very small chance of even a single cancer death results if the 10^{-6} criterion of acceptable lifetime risk is applied to the factory or village cohort of 250 people.[3] Such a minute

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[2]One should explicitly add the caveat that this chemical must fulfill some socially beneficial role, as well. How we quantify this requirement does not here concern us.

[3]250 people $\times$ 10^{-6} << 1 cancer death. On an annual basis we expect about two people to die annually in a population of 250. Because of the added 10^{-6} risk we now expect 2.000004 annual deaths.

incremental risk of cancer is acceptable from the point of view of incremental mortality.[4] But a 10^{-6} rate of risk is impossible to achieve for each individual while at the same time maintaining a viable economy. It is three orders of magnitude smaller than the white collar fatal accident rate, which is, in turn, significantly smaller than accident rates among blue collar employment categories. The radiologist, the farmer, the carpenter, the short-order cook and the individual cooking meals at home, to name a few classes of people, all are at a risk much higher than 10^{-6} from individual carcinogens (e.g. x-rays, sunlight, sawdust, benzopyrene, and benzopyrene, respectively.) Whether we like this or not, it remains a fact that we can do little to reduce to 10^{-6} each of these small risks that effect small, discrete sub-populations, although a ten-fold reduction is generally technically quite feasible.

I have sought, by the analysis of this example, to make the case that the size of the population in which specific number of cancer deaths occur influences our perception of what constitutes an acceptable level of risk. But it is not only our perception (which connotes a subjective quality) of acceptable risk that is influenced by the size of the population exposed to the hazard. Objective analysis would seem to lead to similar conclusions. No expert would reach the conclusion that, in spite of the fact that most of a small village's mortality is known to result from a single carcinogen, regulatory action is unnecessary because nationwide the number of victims is not in excess of 236 deaths; no greater that is, than a rate of 10^{-6}. This conclusion would be unanimously rejected by company safety officers, hygienists, public interest group advocates, medical epidemiologists and risk managers. These professionals have reached this conclusion using the expertise of their disciplines and consequently their expert judgment takes on an "objective" quality, albeit one that really is no more than a consensus in a Delphic oracle-type exercise. Because it is a human exercise, it is inherently "subjective." The subjective/objective duality of our knowledge never be totally eliminated, but such philosophical nuances can largely be ignored by those seeking rules of thumb for effective management of risk.

In view of the above considerations, we see that as the population at risk becomes larger, the random, accidental, or "uncaused" quality of the cancer deaths seems to become more pronounced. As the population size decreases these deaths are seen by expert and non-expert alike as less random and more causally related to the carcinogen. The random quality is inexorably linked to the population size and both influence the conclusions of our analysis of criteria of acceptable risk. These two risk characteristics are also shown below the dotted line in Table I.

How do the above considerations help to resolve the subjective/objective and the rate of risk/total risk dichotomies that are endemic to the setting of acceptable criteria of risk?

Figure I presents risk as a function of population. The line representing a lifetime rate of risk $R'_L = 10^{-6}$ and the line representing

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[4] I should emphasize that if 1000 similar factories or small villages each were exposed to the 10^{-6} risk, the population at risk would total 1000 x 250 = 250,000. With this population at risk there is now a 25% chance that a single additional person would die every 70 years. But in the example I am discussing, a single exposed population of 250 is considered.

236 deaths ($236 = PR''_L$) are both shown as a function of population (P) and of rate of lifetime risk (R_L). I have argued above that neither a constant number of deaths from a carcinogen (Figure 1, Curve A: mortality $M' = 236$) nor a constant rate of risk (Figure 1, curve B, for which the rate is constant and equals 10^{-6}) can simultaneously satisfy reasonable objective and subjective criteria for acceptable risk. The expressions for curves A and B have been constructed so that they result in the same acceptable risk at P = 236 million, where the curves intersect. As the population at risk decreases the two expressions increasingly diverge, one indicating a criterion for an acceptable risk level that I have argued above is too large, the other too small for the population actually at risk. Curve C, based on the expression $R_L = 0.015/P^{.5}$, represents the geometric mean of curves A and B [$R_L = (R'_L R''_L)^{.5} = .015/P^{.5}$]. By averaging the two more extreme risk expressions, it provides a criterion for acceptable risk as a function of population that represents a reasonable compromise. This criterion of acceptable risk explicitly incorporates the size of the population at risk as an independent variable. However it has been developed with little recourse to empirical data. If it is intended for use in the real world of carcinogenic risk, federal risk management, and public perception of reasonable and safe risk rates it must be compatible with these realities. At the same time it should provide general guidance that can help resolve substantive questions related to risk policy and management.

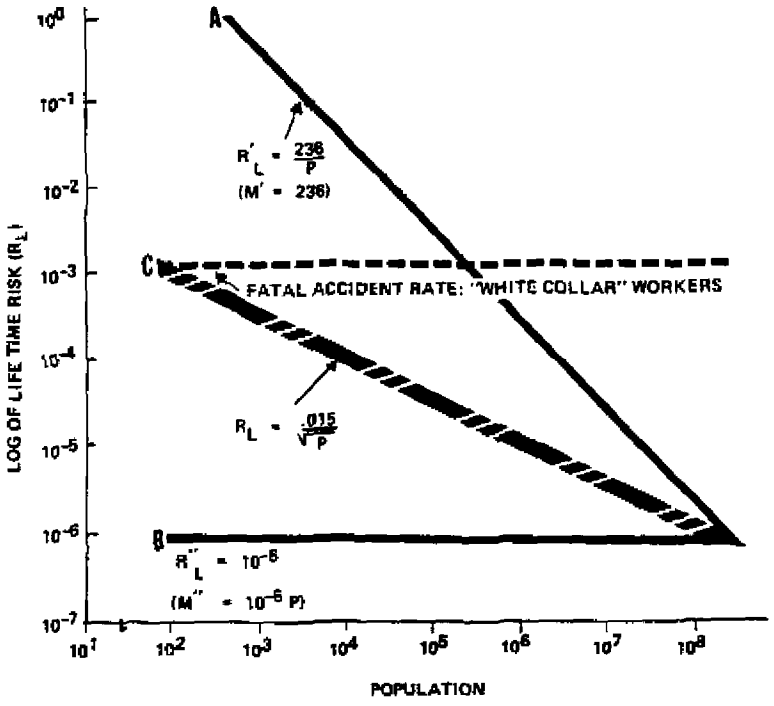

Figure 1

Figure 2 presents data points for 90 circumstances of human exposure to 42 carcinogens and carcinogenic mixtures. These points are plotted on coordinates that indicate the estimated size of the population at risk and the estimated lifetime cancer risks prior to any regulatory action that may have been taken. In this figure those chemicals for which a federal decision was made not to promulgate a regulation to reduce risk are shown by open triangles. The solid squares represent carcinogens for which regulations are currently under consideration or have already been promulgated. The dotted diagonal line is the best fitting straight line for the data shown by the black squares. Its slope is -0.047. The solid line represents the expression $R_L = .015/P^{.50}$ which has been discussed previously.

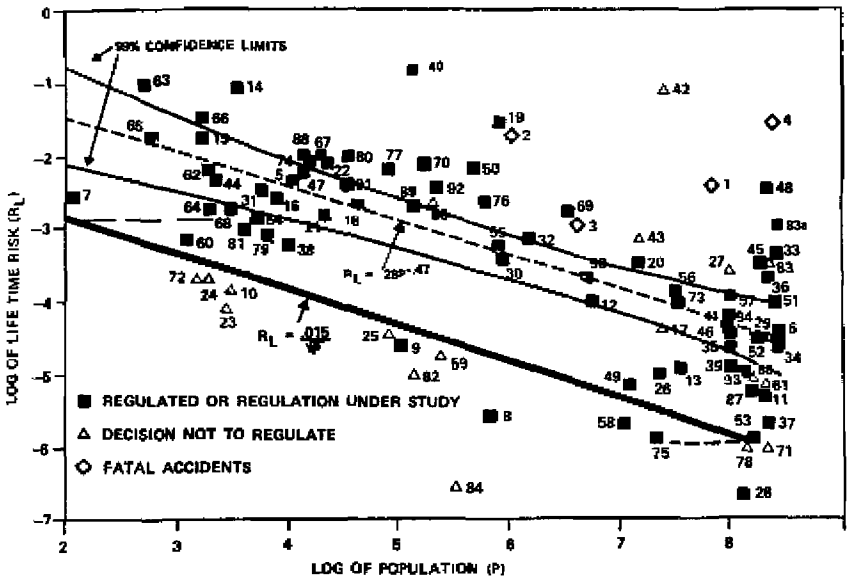

Figure 2

Figure 2 shows 19 hazards for which the decision not to regulate has been made by EPA. Ten of the triangles representing these hazards lie below the $R_L = .015/P^{.50}$ line. Of the nine that lie above the line, the greatest risk is cigarette smoking by men[5], represented by point #42.

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[5]One might argue that cigarettes are regulated: the packs are required by law to bear four rotating warnings. I have chosen, however, to use a triangle to designate this risk in view of this near minimal regulatory requirement. If the risk associated with this hazard were thousands of times smaller - in the 10^{-4} to 10^{-5} range - I would consider the rotating warnings to be appropriate (e.g. saccharin.) My use of the triangle in effect provides the clue that I perceive this "regulation" to be tantamount to no regulation at all and to be quite inappropriate in view of the magnitude of the risk and its social costs. This in spite of the fact that this carcinogenic risk has a significant voluntary quality associated with it.

Key to Figure 2*

1. Accident, fatal - private sector 1982
2. - mining
3. - finance, insurance and real estate, 47 yrs. (18-65)
4. - all, 1982 rate for 70 yrs.

5. Acrylonitrile

6. Alachlor - dietary
7. - flaggers
8. - farmers
9. - ground applicators

10. Amitraz - apple & pears sprayers
11. - apple & pears consumers
12. - apple, dietary
13. - pears, dietary

14. Arsenic - copper smelters - high
15. - copper smelters - low
16. - glass manufacturing
17. - Inorganic, neighboring population average exp.
18. - maximum exp.

19. Asbestos - occupational
20. - school; students & teachers

21. Benzene - fugitive emission
22. - coke by-product
23. - maleic anhydride
24. - ethylbenzene/styrene
25. - storage
26. - Stage II gasoline market
27. - urban
28. - average population exposure - drinking water
29. - average population exposure - air

30. Beryllium

31. Butadiene,1,3 - occupational

32. Cadmium

33. Captan - food consumption

34. Captofol - food consumption

35. Carbon tetrachloride - urban

(continued)

Key to Figure 2 (Continued)

36. Chlordane/heptachlor - food consumption

37. Chlorobenzilate - citrus consumers
38. - citrus applicators (population size assumed)

39. Chloroform - urban

40. Chromium - occupational

41. - urban

42 Cigarette smokers - male

43. Coke ovens - average exp. for U.S. population at risk

44 Occupational

45. Daminozide - food consumption

46. 1,2-dichloroethane - urban

47. Ethylene dibromide - occupational
48. - immediate post-regulatory dietary

49. Ethylene dichloride - workers

50. Ethylene oxide

51. Folpet - food consumption

52. Formaldehyde - urban ambient
53. - production
54. - resin manufacturing workers
55. - apparel workers
56. - mobile homes
57. - non-urea/form. homes

58. Lindane - shelf paper
59. - livestock applicators
60 - pecan applicators
61. - food

62. MBOCA - indirect occupational exposure
63. - direct occupational exposure
64. - non-production workers (occupational)

65. MDA - manufacturing workers
66. - processing workers
67. - all workers - OTS based

(continued)

Key to Figure 2 (Continued)

68. - all workers - TLV based

69. Nickel

70. Nitrosamines - occupational exp. from metal working fluids

71. NTA - public drinking water
72. - formulators (occupational)

73. PCB - dietary fish

74. Pentachlorophenol - applicators/workers
75. - air

76. Radiation, ionizing - all workers in medicine and industry
77. - power reactor workers
78. - coal-fired boilers

79. Radionuclides - DOE facilities
80. - uranium mines
81 - elemental phosphorus plants
82. - phosphate industry

83. Radon - drinking water

84. Styrene monomer - occupational

85. Tetrachloroethylene - urban population
86. - dry cleaners

87. Trichloroethylene - urban air

88. Uranium mill tailings - inactive sites
89. - active sites
90. Vinyl chloride - average exposure for population - air
91. - max exposure (occupational)
92. - workers (occupational)
93. - average exposure for population - water

94. Volatile Synthetic Organic Compounds

—— —— —— Risk - fatal "white collar" accidents (finance, insurance, real estate) for 70 years.

— — — — 10^{-6} risk

* Source: Milvy, 1986

TABLE I

Characteristics of Risk

Voluntary	Non-voluntary
Delayed	Immediate
Old	New
Necessary	Luxury
Ordinary	Catastrophic
Controllable	Uncontrollable
Natural	Man-made
Large population	Small population
Random and "uncaused"	Non-random, caused

(Source: Taken from Litai, et al., (1983))

TABLE II

Carcinogens (and years) for which Final Regulations have been Promulgated by EPA

1970:	Kanechlor		Sulfamic acid cyclohexyl
1972:	DDT		Safrol
1973:	Beryllium (*)		Arsenic Oxide (*)
			Telvar
1974:	Aldrin		
	Dieldrin	1978:	Paraquat
	Chlordane (*)		Asbestos (*)
	Heptachlor (*)		Hexachlor
			Lindane (*)
1975:	Selenium		Acrylonitrile (*)
	Strobane	1979:	DBCP
	Pestox		Pronamide
			Difluron
1977:	Paris Green		Chlorobenzilate (*)
	Vinyl Chloride (*)		
	Benzidine	1980:	Erbon
	PCBs (*)		PBBs
	Benzac		Tris
	Kepone		Perthane
	Chloranil		
	Mirex	1981:	Benzol

* Shown on Figure 2

Source: U. S. EPA, (1984).

Radon in drinking water[6] (#83) and urban benzene (#27) are objectively the next most serious carcinogens for which regulations have been considered and rejected. Five hazards for which federal regulation is being considered fall below the R_L line and, by the criterion of acceptable risk developed here, represent risks for which regulations are unnecessary The other 66 hazards fall above the line that demarcates acceptable and unacceptable risks.

Chemical carcinogens have also been regulated by EPA for which both risk and population at risk estimates are not available. Such chemicals cannot be shown in this figure and are listed in Table II.

CONCLUSION

The empirical data and the decisions made and under consideration by federal risk managers and shown in Figure 2 are largely consistent with the acceptable risk equation that expresses lifetime risk as a function of exposed population size. This expression uses the geometric mean of the constant rate of risk and the constant total risk.

By adopting this acceptable risk criterion I have sought to resolve the paradoxical situation whereby neither a constant rate nor a constant total risk of cancer can be selected which provides an acceptable guide to regulating carcinogenic chemicals. The formulation of an acceptable risk criterion that is suggested here is not invariate with respect to population size. Some may well fault it for this reason. But when the size of the population that is at risk is considered, a constant value for either criterion invariably can be shown to be unsatisfactory both from objective and subjective perspectives even though both would seem to fulfill the requirement of legal equity.

Variables other than risk and population size are also generally considered by risk managers to be pertinenet to the decisionmaking process. These have not been addressed in this analysis. In particular, the economic costs of regulation obviously affect the regulatory process, either by influencing the decision whether or not to regulate, or by influencing how stringently to regulated. Thus a comparison of the pre- and post-regulatory risks posed by those carcinogens that have been regulated would provide further insight into risk-managers' regulatory modus operandi. Two articles that touch on these considerations, by Anderson (1983) and by Byrd and Lave (1986), have appeared recently.

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[6] Indoor radon has not been included in the figure. The average risk from this hazard is about 3×10^{-3} to the U.S. population.

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