FACTS AND VALUES IN RISK ANALYSIS
FOR ENVIRONMENTAL TOXICANTS

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DEPARTMENT OF STATISTICS
STANFORD UNIVERSITY
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Facts and Values in Risk Analysis for Environmental Toxicants

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ABSTRACT

The US Office of Science and Technology Policy describes toxic substance regulation as composed of two stages. Stage I (FACTS) uses empirical data and scientific judgment to characterize human exposure and risk. Stage II (VALUES) uses social and political judgment to decide regulatory action based on significance of the risk, benefits of the agent, and costs of its control. This paper argues that such a view represents an unrealistic and unattainable goal. We present examples showing how values enter virtually every part of risk analysis, and we review work on the vagaries in human judgment concerning both facts and values. These issues indicate that US regulatory policy needs reconsideration.

KEY WORDS: environmental toxicants; facts; judgment; risk analysis; values
1. INTRODUCTION

The recommendations of the Office of Science and Technology Policy, Executive Office of the President\(^{(1)}\) represent a widely accepted view of the regulatory process for toxic substances. According to this view, decision-making involves two stages. Stage I consists of research and evaluation to characterize human risk attributable to exposure to a particular toxicant. This risk is, to the extent possible, expressed in quantitative terms that describe the various levels of uncertainty. Stage II consists of evaluation of the significance of the assessed risk, the benefits to be derived from the toxicant, and the means and costs for limiting its use. These considerations determine the standard for the toxicant. Stage I relies on scientific activity and scientific judgment; Stage II relies on political and social judgment.

This paper argues that such separation of science and policy is an erroneous description of reality and an unattainable goal for the regulatory process. It presents examples showing how values unavoidably enter virtually every aspect of toxicant risk analysis. The complex intermingling of facts and values is worrisome, because recent evidence suggests that human judgments concerning questions of fact and value are inconsistent and extremely sensitive to the way such judgments are elicited. The paper reviews this evidence as it relates to the regulation of environmental toxicants. It concludes with a discussion of the implication of these effects, and with suggestions for new directions.

The following regulatory dilemma illustrates the depth and complexity of scientific, political, legal, and ethical issues tapped in the regulation of toxic substances.

2. EDB AND THE MEDFLY

The risks and benefits of ethylene dibromide (EDB) are substantial. One of the most effective and widely used pesticidal fumigants for fruits, grain, and vegetables, EDB is also used as an antiknock in leaded gasoline, as an intermediate
in the synthesis of dyes and pharmaceuticals, and as a solvent for resins, gums, and waxes. But animal tests have indicated that this chemical is a carcinogen and a mutagen. Indeed, animal experiments have found EDB carcinogenic in both sexes of both mice and rats when inhaled at airborne concentrations of 10 and 40 parts per million (ppm), levels below and above the Occupational Safety and Health Administration's (OSHA) standard of 20 ppm.\(^{(2)}\) This compound is atypical of the approximately 250 chemicals tested in the National Toxicology Program-National Cancer Institute (NTP-NCI) Bioassay System, because the experimental results are unequivocal: no case of marginal significance in only one tissue of only one sex or species, no excess of benign and not malignant tumors, and no doubts about experimental adequacy due to inappropriate doses and/or premature mortality from causes other than cancer.

On the other hand, studies of occupational exposure to EDB have not revealed a human hazard. Defenders of the chemical suggest that the lack of convincing epidemiologic data vitiates the animal studies. However, the occupational studies suffer from small sample size, incomplete or missing exposure data, and insufficient follow-up for carcinogenic effects.

Table 1 shows the extent of exposure to EDB, as estimated by the National Institute for Occupational Safety and Health (NIOSH).\(^{(3)}\) Both the federal Environmental Protection Agency (EPA) and OSHA have proposed stricter regulation of EDB. As a pesticide, EDB is regulated under the Federal Insecticide, Fungicide and Rodenticide Act. This Act specifies that pesticides already on the market must be restricted if they present "unreasonable adverse effects on the environment or will involve unreasonable hazard..."\(^{(4)}\) (my italics). The definition of "unreasonable" is left to the regulatory agencies. The problem with regulating EDB is that no adequate substitute is available.

The regulatory hassle over EDB, which began in the mid-1970's, flared up in 1981 when the pesticide was used in California to fight the Mediterranean
fruit fly. At stake were hundreds of millions of dollars per year in fruit exports, and the health of packers, truckers, longshoremen, supermarket personnel, and the fruit-eating public. California's Occupational Safety and Health Administration (CALOSHA) proposed a drastic tightening of the standard in ambient air to 0.015 ppm from the federal standard of 20 ppm. This proposal was rejected by the California Office of Administrative Law, and a compromise of 0.13 ppm was set.

The events in California have had several consequences: (1) a public dispute between an EPA scientist and agency officials over the level of risk posed by EDB; (2) the boycotting by local supermarkets of produce from Texas and Florida, both of which use EDB. (CALOSHA's new rulings specified that workplaces in which EDB might be present must have hazard warning signs. The supermarkets apparently elected to boycott the out-of-state fruit in order to avoid alarming their workers and customers.); and (3) the institution of review by the federal OSHA of its 20 ppm standard, which, at this writing, is still underway.

The EDB controversy, which promises to intensify with this year's generation of medflies, illustrates some of the formidable scientific and political issues that lie below the surface of every regulatory decision. On the science side, one might ask how the regulatory agencies arrived at the numbers 20 ppm, 0.015 ppm, and 0.13 ppm. More generally, how does one estimate risk to mice and rats at the low dose of 0.015 ppm from experimental results at 10 ppm or higher? Fig. 1 shows dose-response curves for tumors of the nasal cavity among male rats, corresponding to three commonly used models. The predictions of these models for risk to rats at 0.015 ppm are displayed in Table 2. Discrepancies of more than two orders of magnitude are typical of such predictions, and can run as high as six orders of magnitude.

An even tougher question concerns the relevance of animal experiments for
human risk. If an agent causes cancer in mice but not, say, in monkeys, how
do we decide what it is apt to do to humans? What weight do we give to the
negative human data for EDB? To what extent does inadequate study sensitivity
explain these negative results? How should one resolve disputes among scientists
about levels of risk?

On the policy side, there is the question of how one should set a standard
for EDB. What should be the role of the public, of the workers who bear much
of the risk, and of those in the agricultural industry who assume a large share
of the economic costs and benefits? How should one resolve the conflicting values
of different segments of society?

The EDB quandry illustrates the kinds of dilemmas faced by scientists,
regulators, legislators, and the public when dealing with risks due to
environmental toxicants. Such dilemmas have several common features:

- Huge uncertainties characterize the estimates of risk, of extent and
  intensity of exposure, and even of economic costs for controlling risk.
  Neither the risks, nor the extent of uncertainty in the risks, are
  quantifiable.

- The hazardous consequences for health (e.g., cancer) are serious and
dreaded, delayed, and occur with very small probability.

- The risks escape individual awareness and control.

The uncertainties in risk reflect lack of knowledge concerning fundamental
mechanisms for human disease, and therefore this century is unlikely to see
substantial progress in reducing their magnitude. Nevertheless, decisions,
including decisions to wait for more information, must be made now. Consequently
we must base risk assessments on "scientific" judgment, and we must base risk
analyses (i.e., the weighing of risks, costs, and benefits to arrive at regulatory
decisions) on "subjective" judgment. These exigencies present two major difficulties.
One is that values enter the assessments and analyses in ways that are not easily
recognized. The other is that human judgment is often inconsistent and highly
sensitive to the way it is elicited.
3. THE SUBTLE BLEND OF FACTS AND VALUES

Values often determine the quality and quantity of information used in risk analyses. Table 3 shows that only about 6% of the more than 100,000 potentially toxic chemicals in the marketplace have been tested for carcinogenicity in animals. Many of these tests are inadequate in sample size or other design aspects. At a cost of one-half million dollars per bioassay, and with approximately 500 new chemicals introduced into commerce each year, it is clear that we need some priority scheme to decide what information to collect on which chemicals. Such a scheme requires value judgments concerning extent and type of exposure, magnitude of potential hazard, and costs of control. Moreover, once we select a chemical, our values may enter decisions concerning the information-value of additional research.

Values enter risk assessment in other covert ways. The evaluation of toxic risk necessarily entails the use of mathematical models. Such models are sets of assumptions concerning underlying toxic mechanisms, together with deduction of the consequences of these assumptions for risk. Our limited understanding of the underlying disease processes prevents verification of the assumptions. Although some of them are value-laden and greatly influence risk predictions,\(^6\) we usually forget them when using the model.

Values affect the scientific interpretation of experimental results. The line between benign and malignant rodent tumors is sometimes a fine one, and the extent to which a pathologist's values affect his decision is unclear. In every animal bioassay there is the probability that a noncarcinogen will, by chance fluctuation, test positive. We can lower this false positive probability by reducing the bioassay's power to detect a true carcinogen - a value-laden tradeoff. Page\(^7\) has argued that the low statistical power of many toxicological studies effectively protects chemicals more than people. Conversely, the opening paragraph of each NTP-NCI bioassay report ignores the possibility of false positives:
"...Negative results, in which the test animals do not have a significantly greater incidence of cancer than control animals, do not necessarily mean the test chemical is not a carcinogen because the experiments are conducted under a limited set of circumstances. Positive results demonstrate that the test chemical is carcinogenic to animals under the conditions of the test and indicate a potential risk to man." (my italics)

The asymmetry between false negatives and false positives in this paragraph reflects a value judgment.

Values also play a role in the choice of weights used in combining conflicting data, such as the positive animal and negative human data for EDB. Extrapolation to humans using results from the most sensitive animal species places a higher value on losses due to underestimation of risk than on those due to overestimation. With the emerging plethora of short-term genetic toxicology tests, and with no gold standard of truth to rely upon, the integration of conflicting data has become a complex task and a fertile field for hidden value judgments.

Regulatory decisions that attempt to quantify and balance risks and benefits involve many highly technical steps that are fraught with unverifiable value-laden assumptions, such as the discount rates for future risks and benefits, and the costs of regulatory compliance. This has led some investigators to label risk-benefit analysis a "numbers game" in which prejudiced analysts "push the numbers" to reach predetermined outcomes. Even those in favor of some form of risk-benefit analysis argue that values properly drive the science and should enter the analysis from the start.

The interplay between matters of fact and value suggests the use of formal methods for combining risk information and choosing between regulatory alternatives, and the interpretation of results with caution because of their judgmental component. Although we cannot separate factual and value judgments in risk analyses, we should not confuse them. A decision process should include a framework for organizing
and structuring complex and confusing sets of issues and data, for using what we know and sensitizing us to what we do not, and for identifying value issues when they occur. Whenever possible, we should determine the inputs to each step of the process independently of those in the remaining steps, and make all inputs available for inspection by all interested parties.

4. THE VAGARIES OF HUMAN JUDGMENT

Recent work by experimental psychologists has revealed disconcerting anomalies in the way people make judgments and decisions in the face of uncertainty. This section reviews examples that apply to regulatory decisions concerning environmental toxicants.

4.1 Anxiety about Uncertainties Leads to Overconfidence in Risk Estimates

The large uncertainties endemic to risk analyses create anxiety. We often reduce this anxiety by denying the uncertainties and placing unwarranted confidence in experimental results, the judgments of authorities, or our own risk perceptions. For example, an educated and intelligent friend remarked recently that NIOSH findings of an airborne animal carcinogen in a Rutgers University building "proved" that exposures in the building caused cancers among faculty and students.

Scientists deal with uncertainty by refusing to draw conclusions, calling instead for additional careful study and research. Those who must make decisions often resent such cautious hedging. Former Food and Drug Administration Commissioner Alexander Schmidt, upon advice from a panel of scientists on the probabilities that cyclamates do and do not cause cancer, said, "I'm looking for a clean bill of health, not a wishy-washy, iffy answer on cyclamates." (10)

Both scientists and laymen underestimate the error and unreliability in small samples of data, particularly when the results are consistent with preconceived, emotion-based beliefs. (10, 11) To cope with the magnitude and complexity of information in risk analyses, we tend to label complex human and animal toxicity studies as "positive" or "negative", effectively ignoring
the underlying uncertainties. Empirical studies show that we also place inappropriate confidence in our own subjective estimates of frequency, and in predictions based on highly correlated predictors (such as the conclusions of a committee of experts). (10,11)

4.2 New Evidence is Poorly Integrated with Prior Information

Research indicates that highly valued prior beliefs are tough to budge. (12) Once formed, such beliefs change slowly, and persist tenaciously in the face of contrary evidence. We consider new evidence reliable and informative if it is consistent with our initial beliefs, whereas we dismiss opposing evidence as biased, unrepresentative, or erroneous. This fact explains some of the heated public debate between government and industry representatives over the fraction of all US cancer deaths due to occupational exposures (13,14) and the divergence of opinion on the relevance of the positive animal and negative human studies of EDB.

By contrast, we often ignore emotionally neutral prior contingencies when presented with new evidence. The following problem posed by Page (7) illustrates this phenomenon, which Tversky and Kahneman (17) have called a "pseudocertainty effect":

"...suppose that 60 of 10,060 chemicals are highly carcinogenic to humans and that a test has been developed which in the following sense is highly reliable. The test scores positive for carcinogenic chemicals ninety-five percent of the time and scores negative for noncarcinogens ninety-four percent of the time. A chemical, drawn from the 10,060, tests positive. What is the probability that the chemical is carcinogenic? Many people are surprised to learn that the actual probability, which can easily be derived from Bayes Theorem, is only 0.09."
4.3 Hazard Characteristics Determine Risk Perceptions

Slovic et al.\(^{(10)}\) asked college students and other study subjects to rate the 90 hazards shown in Table 4 on such characteristics as voluntariness for those exposed, immediacy of harmful effects, familiarity to those exposed, dreadedness, severity of consequences, and numbers exposed. They also asked the subjects to assign numerical risk values to the hazards by assigning a rank of ten to the least risky item and rating the others accordingly. The investigators then correlated the hazard characteristics with the perceived risks. They found that they could predict the magnitude of lay risk perceptions from such characteristics as dread, severity of consequences, and unfamiliarity, all of which describe the effects of toxicants. Indeed, DDT ranked third in riskiness, preceded only by nuclear weapons and warfare. The fact that motor vehicles ranked only 17th suggests that repeated uneventful experience with a hazard tends to reduce disproportionately its perceived risk.

The "availability" or imaginability of the hazard can also distort perceived risk. Lichtenstein et al.\(^{(15)}\) asked subjects to estimate the annual number of US deaths due to various hazards. Their subjects often overestimated mortality risks due to sensational causes such as botulism, homicides, and cancer, and underestimated those due to less easily imagined causes such as smallpox vaccination, asthma, and emphysema.

We sometimes discount risks with delayed consequences. For example, a smoking 15-year-old, when lectured by her mother on the increased mortality risks in mid- and later life, replied, "By the time I'm 40 I'll be such an old hag I might as well be dead!"

We also tend to be unduly optimistic about risks under our own control. In a report titled "Are We All Among the Better Drivers?", Svenson\(^{(16)}\) showed that most people rate themselves as among the most skilled and safe drivers in the population.
4.4 Hazard Descriptions Determine Risk Perceptions

Recent important work has demonstrated that inconsequential changes in the
formulation of decision problems significantly affect our preferences.\(^{(17,18)}\)
Our risk perceptions hinge critically on the setting in which they are described,\(^{(18)}\)
on the way death probabilities are expressed,\(^{(19)}\) and on the description of
benefits (e.g., tobacco advertisements). A potential factory employee may treat
the information that exposure could double his bladder cancer risk quite
differently from information that exposure could increase his lifetime risk by
0.002%. Similarly, how does a woman evaluate the information that each mammogram
she receives may reduce her life expectancy by 10 seconds? As noted by Slovic
et al. in another context,\(^{(20)}\) the mammogram either will or will not cause her
death, and if it does, it is highly likely to shorten her lifespan by more than
10 seconds. These examples illustrate the difficulty with which we evaluate
the very small risks associated with most environmental toxicants. Tversky
and Kahneman\(^{(17)}\) hypothesize that we overweight low probabilities, and underweight
middle and high probabilities. Moreover, although we assign a weight of zero to
impossible events, we do not give well-behaved weights to risks very close to zero.
This suggests that value judgments concerning risks from toxicant exposures are
highly labile and sensitive to the eliciting procedure.

We tend to be more callous about accepting risks leading to statistical
deaths than to deaths of identified individuals. We are also disproportionately
affected by risks which are concentrated on a small segment of the population.
Crandall\(^{(21)}\) asks us to imagine a toxicant that causes a 5% lifetime risk of
cancer and to which .02% of the US population are exposed. He notes that we
might react quite differently if the 44,000 exposed people experiencing the
2,200 additional cancers all lived in one county than if they were spread
throughout the US.
5. DISCUSSION

The above anomalies in human judgment are important in risk analysis because their effects are large, because they run counter to existing tenets of rationality, and because they influence not only regulatory decisions, but how we perceive the consequences of such decisions. They indicate that judgments of fact have persistent biases that we do not understand. People have trouble both in assimilating complex and uncertain bodies of information and in making valid inferences from such information. More disturbing is the evidence that judgments of value are sensitive to the way one poses the eliciting questions. The questions may even create opinions where none existed.

The lack of critical information, the bias in factual judgments, and the lability of value judgments complicate the integration of facts and values needed for toxicant regulation. Further intractable problems arise in combining several conflicting judgments of fact and value. How then, in a democratic society, should this integration be achieved? To answer this question, we need improved understanding of human judgment in several problem areas.

5.1 Revising Misconceptions

A first step in dealing with the above difficulties is awareness of their existence. We need to recognize that a neat separation of risk analysis into matters of fact and value is illusionary, and to sensitize ourselves to value judgments whenever they occur.

Our current thinking about toxicant risks and risk analyses has hampered regulatory efficacy and it needs revision. Harrison has illustrated how public need for "safe" toxicant levels and regulators' need for protecting everyone have straightjacketed the agencies into decisions that no one would consider warranted and that deflect them from areas offering greater public health benefits. Dependence on the chimera of absolute safety has also produced the inconsistencies of cyclamates and saccharin regulation. Relinquishing our ideas about safety implies relinquishing our repugnance for evaluating human
life and recognizing instead the values for life implicit in regulatory decisions.

5.2 Coping with Uncertainty

Quantitative risk analyses produce numbers that, out of context, take on lives of their own, free from the qualifiers, caveats, and assumptions that generated them. We can counteract this effect by learning to cope with uncertainty and resisting our attempts to deny it. We need new tools for quantifying and ordering sources of uncertainty and for putting them in perspective. For example, Page and Ricci (9) claim that uncertainties in benefits due to divergent estimates for the monetary value of human life are overshadowed by uncertainties in risk due to differing choices for dose-response model.

5.3 Understanding Risk Perceptions

The enigmas and inconsistencies of human decision-making indicate a need for more work to understand the logic behind its vagaries. Judgment is a human cognitive activity, and as such, it is amenable to systematic analysis and prediction. We also need tools for eliciting value judgments in ways that will help us determine what we really want.

5.4 The Decision Process

Many believe that the existing regulatory process vests too much power in the hands of technical experts and agency administrators who are not accountable to the public. Field (24) has argued that Congress should use the legislature to make the necessary value judgments:

"Insofar as statutes do not effectively dictate agency actions, individual autonomy is vulnerable to the imposition of sanctions at the unrulled will of executive officials, major questions of social and economic policy are determined by officials who are not formally accountable to the electorate, and both the checking and validating functions of the traditional model are impaired."
However, Congress cannot police the many hidden value judgments inherent in the actual conduct of risk analyses. Alternatively, we might consider an extension of Kantrowitz's concept of a "science court", in which scientists represent each side of an issue. One might expand the court by a "lay jury" composed of informed representatives from all branches of the public sector, which, after hearing all arguments, would set regulatory standards for the toxicant in question. The feasibility of such a plan rests heavily on the development of an informed citizenry. We need new methods for communicating technical facts and issues to nontechnically oriented people.

The issues discussed in this paper have placed the scientist in the spotlight. Some argue that scientific panels are no more qualified than any other group of citizens to judge, explicitly or implicitly, what is wise public policy. They decry the view that "objective" characterizations of risk tempered by experts' judgments are more valid than publicly perceived risks, and claim that this view has fostered hostility and distrust between experts and the public. Others maintain that scientists cannot possibly convey information without offering their judgment concerning how the information should affect public policy; indeed it is their responsibility to do so. Thus as noted by Polsby, it appears that scientists are damned if they do pronounce on the wisdom of public policy, and damned if they do not.

The difficulty in separating facts and values guarantees that scientists' values will continue to affect public policy. How can this increasing role be reconciled with traditional democratic ideals? Lowrance has suggested the following guidelines for scientists:

"Recognizing that they are making value judgments for the public, scientists can take several measures toward converting an 'arrogation of wisdom' into a 'stewardship of wisdom'. First, they can leaven their discussions by including critical, articulate laymen in their
group...Second, they can place on record their sources of bias and potential conflicts of interest, perhaps even stating their previous public positions on the issue. Third, they can identify the components of their decisions as being either scientific facts or matters of value judgment. Fourth, they can disclose in detail the specific bases upon which their assessments and appraisals are made. Fifth, they can reveal the degree of certainty with which the various parts of the decision are known. And sixth, they can express their findings in clear, jargon-free terms, in supplementary nontechnical presentations if not in the main report itself."

Implementation of these guidelines may lead to sounder, more accepted decisions. But the guidelines should not lull us into complacency about important inconsistencies and anomalies in our existing regulatory and decision-making procedures.
REFERENCES


<table>
<thead>
<tr>
<th>Source</th>
<th>Description</th>
<th>No. Exposed</th>
<th>Exposure level</th>
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<tbody>
<tr>
<td>Production and use as fumigant</td>
<td>Workers</td>
<td>875,000</td>
<td>0-20 ppm</td>
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<td>Leaded gasoline</td>
<td>Workers</td>
<td>108,000</td>
<td>? Very low</td>
</tr>
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<td>Fresh produce consumption</td>
<td>Population eating Less than</td>
<td>200 x 10^6</td>
<td>? Very low</td>
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<td></td>
<td>fresh, nonlocal product</td>
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Reference: National Institute for Occupational Safety and Health (3).
Table 2. Estimated Lifetime Risk of Nasal Sinus Cavity Tumor Among Male F344 Rats Exposed to Ethylene Dibromide (EDB) at 0.015 ppm

<table>
<thead>
<tr>
<th>Dose-response Model</th>
<th>Lifetime cases per $10^3$ exposed</th>
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<tbody>
<tr>
<td>Multihit</td>
<td>395</td>
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<tr>
<td>Probit</td>
<td>551</td>
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<td>Multistage</td>
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Table 3. Estimated Numbers of Chemicals Tested for Carcinogenicity in Animals, Found Positive, and Regulated

<table>
<thead>
<tr>
<th>Category</th>
<th>Estimated Number</th>
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<tr>
<td>Known Chemicals of Potential Toxicity</td>
<td>more than 100,000</td>
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<td>Chemicals Tested for Carcinogenicity in Animals</td>
<td>~6,000</td>
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<tr>
<td>Chemicals with Some Evidence of Animal Carcinogenicity</td>
<td>~800</td>
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<tr>
<td>Chemicals Regulated as Carcinogens</td>
<td>102</td>
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</table>

References: Office of Technology Assessment (4); Task Force on Environmental Cancer, Heart and Lung Disease, (31).
<table>
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<tr>
<th>Table 4. Hazards Ranked in Study of Risk Perceptions</th>
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<tr>
<td>Home Gas Furnaces</td>
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<td>Home Appliances</td>
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<td>Home Power Tools</td>
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<tr>
<td>Microwave Ovens</td>
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<td>Power Lawn Mowers</td>
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<td>Handguns</td>
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<tr>
<td>Terrorism</td>
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<td>Crime</td>
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<td>Nerve Gas</td>
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<tr>
<td>Nuclear Weapons</td>
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<td>National Defense</td>
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<tr>
<td>Warfare</td>
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<td>Bicycles</td>
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<td>Motorcycles</td>
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<td>Alcoholic Beverages</td>
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<tr>
<td>Caffein</td>
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<td>Water Fluoridation</td>
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Reference: Slovic et al., (10).
Caption for Figure 1. Multistage (-----), multihit (....), and probit (-----) dose response curves for tumors of the nasal sinus cavity among male F344 rats exposed to ethylene dibromide (EDB). Data points at 0, 10, and 40 ppm from (4). Data point at 20 ppm from (32).