*For both scientists and legislators, determining "safe" levels for most pollutants is a tortuous and nearly impossible task*

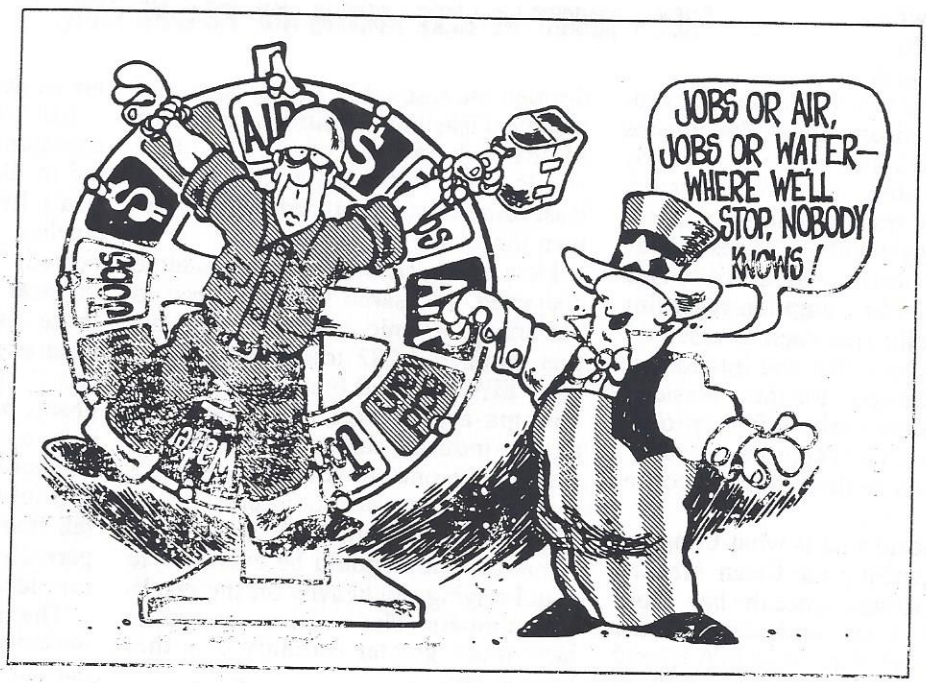
# WHAT IS AN ACCEPTABLE RISK?

By Daniel S. Greenberg
Illustrations by Mark Taylor

A GRIMY relic of turn-of-the-century technology, the vast industrial plant sprawls over 80 bayfront acres in an otherwise appealing residential area of Tacoma, Washington. It is a smelter owned by Asarco, Inc., a giant metals company, and it has three notable products: 1. copper, produced in huge quantities from Philippine ore that also contains traces of arsenic; 2. a $35-million-annual payroll dispensed to 600 workers in a downbeat local economy; and 3. more than 100 tons of cancer-causing arsenic fumes that annually pour into the air from a 565-foot smokestack and leak from the ground-level smelting furnaces.

For insights into economics and metallurgy, the aged Asarco plant has little to offer. But it does provide an instructive example of the tortuous governmental process of risk assessment — the search for elusive answers to such questions as: What is an acceptable risk? Who determines it? And how do they do it?

In Tacoma, those public policy questions are linked to harsh reality. Arsenic levels at least double the normal range have been found in the hair and urine of children in the neighborhood of the Asarco smelter. Is the contamination of Tacoma's atmosphere by arsenic fumes "acceptable?" Mathematical formulations suggest that the risk is trivial compared with the dangers that people accept voluntarily, such as smoking or driving. But what does that mean to families that live within a mile of the controversial smelter? Voicing a hopeful but impractical aim, one mother of an infant son recently concluded: "Somehow I'm going to have to provide him with a protected area."




Risk assessment came to Tacoma with an impact heard nationwide in July 1983. At that time, William D. Ruckelshaus, newly installed for his second tour of duty as head of the Environmental Protection Agency, seemed to offer a Faustian deal to area residents. Stirred by a federal court order to speed up control of arsenic emissions, Ruckelshaus acknowledged that arsenic — which studies have linked to human skin and

lung cancer — is considered carcinogenic "at any level of exposure." Though the federal Clear Air Act does not direct EPA to consider the dollar and job costs of controlling cancer-producing substances, Ruckelshaus apparently felt those issues could not be ignored in Tacoma.

Asarco had hinted that it might close the plant if ordered to improve a limited emissions-control project. Ruckelshaus decided that area residents "will have an opportunity to share with EPA their reactions to managing the risks involved. We must ask them if they are willing to accept certain risk associated with exposures to low levels of the arsenic."

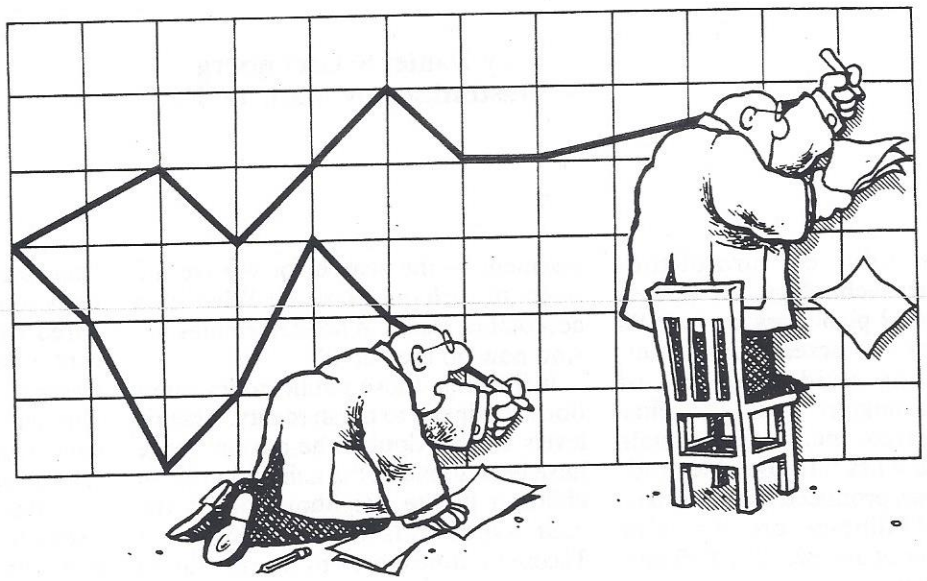
"Tacoma will get a 'vote' on arsenic peril," read one local headline. Typical of many national publications, *Time* magazine headlined its account, "Tough Decision for Tacoma. The EPA poses a choice between cancer risks and jobs."

Confronted with what was widely and reasonably interpreted as a choice between cancer and jobs — posed by the principal federal agency responsible for protecting the environment — the citizens of Tacoma were then treated to a nearly incomprehensible, often contradictory discussion of arsenic, risk assessment and risk management at a series of public meetings initiated by EPA. "Given the no-threshold assumption regarding risks from pollutants such as arsenic," said an EPA paper that was intended to provide background for these sessions, "the only absolutely safe approach would be to reduce exposures to zero," without regard to the economic consequences.

It would seem that is what Congress intended in writing the Clean Air Act, EPA acknowledged, since the law "does not mention costs, and some people would therefore argue that EPA should not consider costs. However, such an approach," EPA pointed out, "makes it impossible to avoid automatic closures since for no-threshold pollutants, such as arsenic, it is presumed that there is some risk even at very low levels and there is no reason other than cost not to eliminate all of these risks."

But zero emission of arsenic is technically unattainable at any practical cost, the paper continued. Rather than forcing the closing of plants, EPA said, the agency aims to control carcinogenic pollutants "at least to the level that reflects the best available technology and to a more stringent level if necessary to prevent public health risks which are deemed unreasonable, taking costs and technical feasibility of further reduction of the risk into account." In other words, EPA was willing to accept at least some arsenic-induced cancer in return for jobs.

How many cancers? Here the muddle deepened. If Asarco were required to cut annual arsenic emissions from the then-estimated 282 tons down to 172 tons, EPA surmised that the number of Tacoma-area residents dying from arsenic-induced cancer would decline from five to one per year. Though these forecasts conveyed an impression of scientific precision, EPA stated that "much caution should be exercised to avoid relying too heavily on the resulting numbers. The numbers appear to have much greater certainty than they have in fact."



"HEY, I THOUGHT WE WERE WORKING WITH THE SAME DATA..."

That caution was seconded by the head of the Tacoma-Pierce County Health Department, Dr. Bud Niccola. Said he: "No one really knows what the risk of cancer is in the community. The EPA used a theoretical model to predict that, and the model's assumptions may not be accurate."

Niccola's warning was vindicated a few months later; after further monitoring of the plant, EPA concluded that total emissions of arsenic fumes were only 115 tons — about 60 percent less than previous measurements had indicated. But that favorable finding was accompanied by bad news: so-called "fugitive emissions" of fumes from Asarco's ground-level furnaces were found to total 24 tons — about two-thirds more than the previous figure. These fumes were considered to be especially menacing because — unlike the fumes that winds carried away from the high smokestack — they hit the surrounding area in concentrated form. In fact, these earth-hugging fumes are blamed for an odd taste in Tacoma's air on numerous windless days.

Just weeks after Ruckelshaus invited community opinion, poll results trickled in. Based on a survey of 503 residents living within 12.5 miles of the smelter, *The Tacoma News Tribune* reported: "Some 72 percent of those living near the smelter and 67 percent of those living farther away believe the smelter poses an environmental health risk." In the 18- to 34-year-old age group, 53 percent favored stricter emission controls, "even if it means the smelter would have to close and eliminate jobs." Support for that proposition fell sharply among people over 55, apparently reflecting the poor job market for older workers.

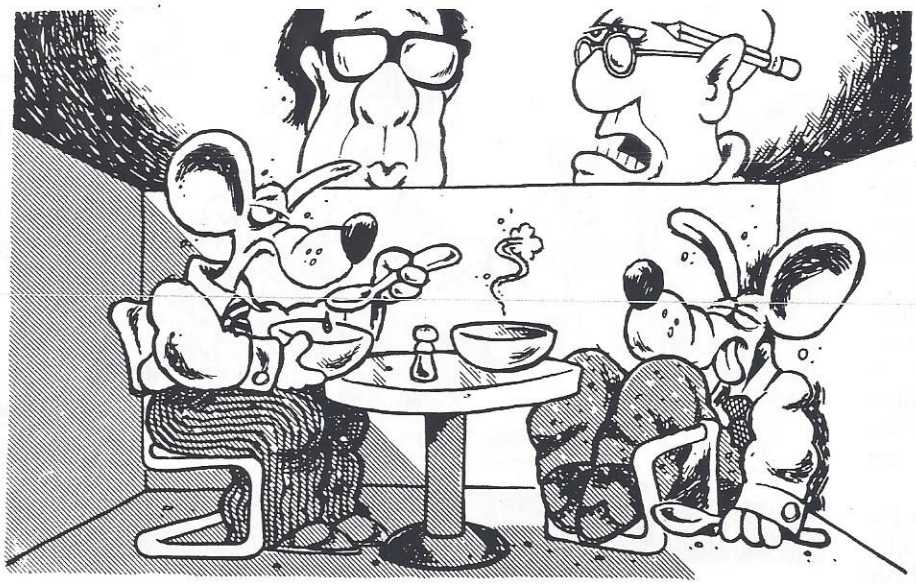
The message sent to EPA was that a majority of the citizens of Tacoma regarded the Asarco smelter as a health

risk, but the community was divided on whether or not the risk was an acceptable one.

Meanwhile, Ruckelshaus — editorially assailed in *The New York Times* and elsewhere for having asked Tacoma's citizens "if they are willing to accept certain risks associated with exposures to low levels of arsenic"—insisted six months later that he had been misunderstood. In response to critics, Ruckelshaus clarified his stand. "Some inferred that I was abdicating my responsibility for this decision, or that somehow the Tacoma people were going to vote on whether they wanted jobs or health. After some initial confusion on this score," the EPA Administrator said, "we made it clear that it was entirely my decision, and that while I wanted to hear, I was not committed to heed."

Characteristic of many cases of risk assessment, EPA's issuance of the long-awaited arsenic standard for Tacoma has been delayed many months beyond the original schedule. The initial timetable called for publication of a new arsenic standard in the spring of 1984. The expected date is now this fall. The reasons are plausible: the need to evaluate new data on emissions and also to study public comments. But no matter how capably those tasks are carried out, the essential fact is that risk assessment — whether by hard sciences like biochemistry or the polling techniques of social science — is a frail tool that's being called upon for mighty tasks. What is risk assessment supposed to do, what ails it, and how might it be improved?

The prestigious, non-partisan National Academy of Sciences considers risk assessment as the use of factual evidence "to define the health effects of exposure of individuals or populations to hazardous materials and situations." But as the citizens of Tacoma have learned over the past year, little or nothing is exact in risk assessment, least of all the "health effects" and the definition of "exposure," regardless of federal laws that seek to shield the environment from harmful substances. Add in legitimate scientific uncertainties, politics, intransigence by self-interested parties, and a short dash of dubious professional competence, and there's little wonder that risk assessment is a muddle. In the words of Marvin Schneiderman, a leading biostatistician and former associate director of the National Cancer Institute, "Neither the art nor science in risk analysis is very good today. We're sort of in the cave-painting era in terms of what we know."



"SURE, IT HURTS MICE... BUT I'M NOT A MOUSE!"

At a time when chemical inventiveness is adding an estimated 1,000 new compounds each year to the approximately 63,000 in common use, a recent study by the National Academy of Sciences concluded that "of tens of thousands of commercially important chemicals, only a few have been subjected to extensive toxicity testing and most have scarcely been tested at all." Then too, test results that reveal no hazard can be insufficient. Michael Gough, a molecular biologist who directed a study of risk assessment for the Congressional Office of Technology Assessment, points out: "Animal tests take two years and cost at least $300,000. When you're finished, you get liver slices from mice, and you're confronted with the question of what they mean."

There's also profound uncertaintly about the "threshold" question that is central to the Asarco controversy and innumerable other environmental issues: is there *any* level of toxicity so low as to be harmless to humans?

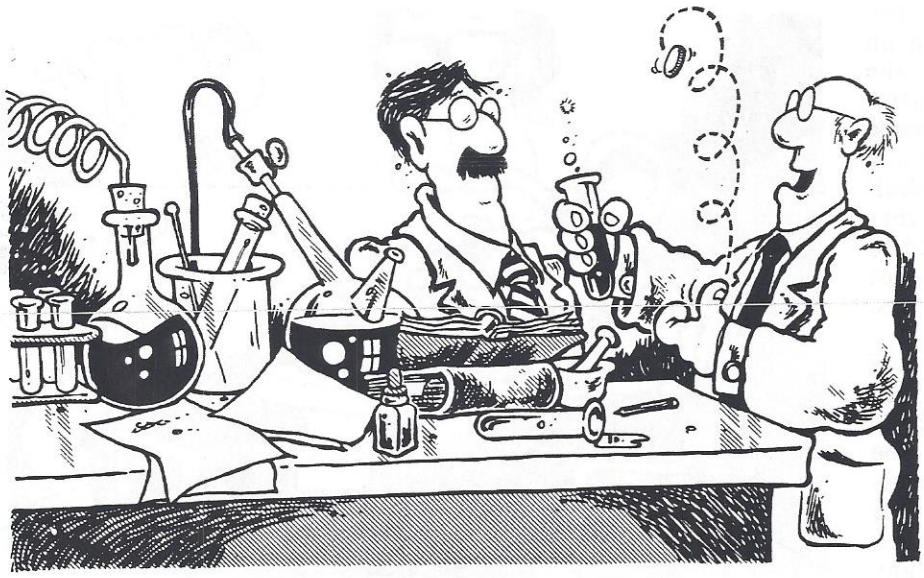
In regard to food, the law says no. The Delaney Amendment to the Food, Drug and Cosmetic Act assumes that carcinogens are dangerous at any level, and therefore forbids human consumption of any food additive known to cause cancer in animals. In contrast, the Clean Air Act, which governs the EPA, merely calls for "an ample margin of safety to protect the public health."

The fundamental scientific problem is that the risks of substances known to be harmful at very low levels often are extremely difficult to prove. Benzene, for example, is a known carcinogen, but when the Occupational Safety and Health Administration (OSHA) sought to ban it from the workplace in quantities in excess of one part per million, the Supreme Court ruled that OSHA hadn't produced evidence that that level constituted a risk.

Then there are uncertainties of extrapolating from test animals to humans. Tests on laboratory animals have clearly demonstrated that the pesticide ethylene dibromide (EDB) is a powerful carcinogen. "EDB is so poisonous that it has produced tumors in every test animal," Francesca Lyman, of Environmental Action, Inc. wrote in *The New York Times*. EPA's Ruckelshaus confirms that observation, but contends that "we don't have any evidence that it has harmed anyone, nor do we have any that it hasn't." Nonetheless, under public pressure, Ruckelshaus banned further use of EDB and set limits in existing food stuffs at 30 parts per bil-

lion for ready-to-eat products and 150 parts per billion for processed grain products. Many states, however, rejected those levels as dangerously high, and set levels far below, on the prudent rule that it is better to be safe than sorry. However—and this is the important point in terms of the scientific immaturity of present-day risk assessment—it is impossible to demonstrate scientifically that, at very low levels, less EDB is safer than more EDB.

Scientific uncertainties constitute formidable problems for honest attempts at risk assessment. But in recent years, there have been situations in which solid scientific work has been undercut by the politicization of the federal agencies responsible for protecting the environment. In 1980, a highly respected scientific panel of the federal National Toxicology Program — which orchestrates work by government agencies responsible for identifying dangerous substances in the environment — concluded that the widely used chemical formaldehyde causes cancer in test animals. The Consumer Product Safety Commission promptly banned the use of building insulation containing the product because of the fumes that it emits. EPA declined to act; three years later, after Ruckelshaus' return, the agency decided to reexamine its decision.



"OKAY, THEN—HEADS, IT'S SAFE; TAILS, IT'S NOT!"

Better testing methods are obviously the solution to the technical shortcomings of risk assessment. And there are some promising developments in that regard. Scientifically, progress is being made on the important questions of the reliability of animal tests as indicators of human hazards. Since direct tests on humans are ethically impermissible, the relationship has been hard to establish. But on the basis of studies of humans who have suffered long exposure to substances later identified as carcinogens, it has been found that laboratory mice are reliable stand-ins for six carcinogens, including cigarettes, vinyl chloride and aflatoxin — a mold found in peanuts and some grain products.

The National Institute of Enrivonmental Health Science has pioneered in the development of rapid tests for determining whether toxic substances become bound to the basic genetic materials of cells — an important warning signal that scientists heed in looking further for carcinogenicity.

Thus, good scientific research, and lots more of it, is a way out of the uncertainties that afflict risk assessment. Is the scientific effort going forward at a vigorous pace? The answer, unfortunately, is no. More than a year after EPA's top leadership was ousted in scandals over mismanagement of the federal Superfund for dealing with toxic wastes, the research effort that underpins the federal environmental program is still suffering from constant battering by the administration's anti-regulation proponents. As a result, EPA's overall program of risk-assessment research may now be only half of what it was in 1981.

Does that mean that important research is going undone? The answer is yes, though, as many scientists point out, scientific conservatism and caution often combine with skimpy budgets to slow investigation. For example, the study of toxic effects on human reproduction is "extremely unplowed territory," according to Ellen Silbergeld, who directs the Toxic Chemicals Program at the Environmental Defense Fund. Silbergeld was formerly chief of neurotoxicology at the National Institute of Child Health and Development, and still conducts a research program there. "EPA," she points out, "does little reproductive toxicology." She adds that the subject is now receiving some long-overdue attention as interest in toxic effects expands beyond fertility to "the quality of reproduction."

Silbergeld expresses confidence in the reliability of animal tests for assessing risks to humans, but she points out something that is not generally realized, "Risk assessment models have been developed only for cancer." In other words, a huge amount of scientific work remains to be done.

Until more scientific findings trickle in, the rock-bottom political question is, what is to be done in the meantime?

Patrick A. Parenteau, Vice President for Resources Conservation of the National Wildlife Federation, reflects the mainstream philosophy of the environmental movement when he argues, "No one says, 'Let's regulate on the basis of bad science.' The issue is, what do we do while we're waiting for an improved science base? We should recognize," says Parenteau, "that the costs of environmental protection are always easier to see than the benefits. You can state how much it's going to cost to clean up a toxic dump, but how do you put a cost on saving a life? Or on the question of how many cancers are 'acceptable'? Economists don't have the answers. Economics can inform but it should not be permitted to dictate." ▣

---

*Syndicated newspaper columnist Daniel S. Greenberg is a longtime observer of science and health issues in Washington, D.C. A former news editor at* Science *magazine, he is now editor and publisher of* Science and Government Report.