

Health

THE CANCER SAFETY CONTROVERSY

More and more, scientific findings clash with cost-benefit considerations when 'acceptable' human risk levels for carcinogens are being formulated.



Masks protect workers from asbestos, a suspected carcinogen.

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be thrown out of work and the country will go to the dogs. The strong suggestion is that eating, drinking and breathing a certain amount of toxins is the inevitable price of progress. We are, in effect, being conditioned to accept man-made poisons in our air, food and water as being normal.

The vast majority of people, however, never think of challenging these choices until a Love Canal starts bubbling under their feet or a James River is closed to fishing. Then they react with outrage; not because it happens, but because it happens to them.

Lawyers play key roles in level setting because the process is not so much an on-going clash of opposing scientific truths as one between conflicting social and economic priorities. Regulatory agencies have a real fear of being sued by industry, according to Dr. Sidney Wolfe, a physician who was on the staff of the National Institutes of Health before becoming director of Ralph Nader's Health Research Group in Washington. "In order to keep the agency out of court, they act only when they have the most open-and-shut case," he claims. "When we go into a hearing, we not only see lawyers from industry, but Wall Street analysts, too. There's big money at stake."

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What's acceptable and what isn't is most often associated with something called cost-benefit, or risk-benefit, analysis. Deceptively simple in theory, it weighs pluses and minuses. The benefits of, say, asbestos are added: fire-resistant homes, schools and offices, plus jobs for asbestos workers, and their combined effect on the economy. The minuses are also totaled: the sharply increasing numbers of people dying from lung cancer, and the cost of caring for the ill and supporting the survivors.

If benefits clearly outweigh costs, it is full speed ahead. If costs far outweigh benefits, the product either never sees the light of day or, if already on the market, is canceled. There are generally no clear-cut imbalances, however, so some level thought to be acceptable is invented.

This raises a fundamental question: To whom, exactly, is the level acceptable? When a newscaster says that "the quality of air today is acceptable," to whom is he or she referring? What is acceptable to the taxi driver who must earn a living with his automobile is not necessarily acceptable to the asthmatic breathing the fumes — except at the moment when the asthmatic, having a seizure, needs the taxi in order to get to a hospi-

tal; then the taxi and its wake of noxious vapors become eminently acceptable to driver and passenger alike.

Although corporate lawyers and economists, as well as many in the public sector, maintain that it is perfectly fair to make production decisions and set acceptable levels after a careful weighing of all likely costs and benefits, others are beginning to challenge the concept on two grounds.

First, cost-benefit tries to equate what is economically, let alone morally, unequatable: kilowatt-hours of electricity produced by a nuclear power plant versus the number of cancer deaths caused by a slow radiation leak at the site where the spent fuel is stored, for example. This kind of equation makes no sense unless we can decide how many kilowatt-hours of electricity a human life is worth.

Second, those who pay the costs and those who derive the benefits are not necessarily the same. Men who dig coal pay a heavy cost in terms of cave-ins, poisoned air and black lung, yet their monetary benefit is not commensurate with those risks.

Before a meaningful scientific basis can be established for setting truly acceptable levels, a deeply important question needs to be answered: Exactly how much of a given substance does it take to cause a human cell to turn cancerous? If no one knows, then every person who believes that there is some magic formula that constitutes a boundary between safety and death is seriously misguided. If there are bound-

SPREADING THE RISK

There are about 100,000 known natural chemical entities, 1 to 5 percent of which are thought to be carcinogenic, according to Dr. W. Gary Flamm, a toxicologist in the Food and Drug Administration's Bureau of Foods. So, what do toxicologists eat?

"Everything," he says. "My philosophy is to spread the risk. If I ate one thing [in excess] I'd be in trouble."

Most grains, including corn, and peanuts develop a mold called *Aspergillus flavus* which, in turn, produces aflatoxin B, a known carcinogen. Peanut butter contains an almost infinitesimal level of aflatoxin B, says Dr. Flamm. But he adds, "This doesn't mean that you shouldn't eat peanut butter. All it means is that you'd be smart not to eat peanut butter, or anything else, exclusively." —W. E. B.

aries, they stand not so much between health and illness as between profit and loss.

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The vast majority of those in cancer research think that environmentally caused cancer is the result of something called a dose-response relationship. This means that there is most likely some kind of direct relationship between the amount of the cancer-causing chemical a person is exposed to and the length of time it takes to contract the disease. A dose-response chart would have a line going from zero to maximum dose, with the risk accelerating and the time span shortening in proportion to the increasing dose.

The big question, though, is this: At precisely what point along that line will someone contract cancer? Given the fact that individuals vary, that there are long latency periods for most cancer-causing substances, and that combinations of chemicals are undoubtedly worse than the simple sum of their elements, it becomes impossible to pick a point on that line and say with certainty that it represents the start of a malignancy. That is what Leo Hetling meant when he asked about the number of cigarettes that can be safely smoked. No cigarette can be safely smoked, but it is impossible to tell which of the thousands upon thousands will be the one that begins the process of wild cellular growth that is cancer.

There are currently two principal ways in which scientists try to determine what causes cancer and how much of it is too much: studying groups of humans and testing animals. Neither method is wholly satisfactory. Epidemiology compares groups that are exposed to certain kinds of chemicals and radiation with control groups that are not exposed. It has some serious shortcomings, however. For one thing, it is impossible to isolate people, like laboratory animals, for most or all of their lives, so it is impossible to know about everything they eat, drink and breathe. Further, the cause and effect relationship in epidemiological studies is often weak. Asbestos workers do have a higher percentage of lung cancer than does the general public, but that does not necessarily mean the asbestos causes the cancer; it may mean that asbestos fibers in the lungs trigger something else that causes the cancer. Finally, epidemiologists are hampered by usually small groups, individual resistance to participation and, in a society as mobile as this one, the difficulty of access to good records.

Animal experiments, generally with rodents, have for the most part been very effective

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By William E. Burrows

Sometimes a simple question put by a layman can get to the heart of a complex scientific problem more surely than expert interrogation. So it was at the New York Academy of Sciences' International Conference on Public Control of Environmental Health Hazards last year. Peter A. A. Berle, then New York State's Environmental Conservation Commissioner, had just unveiled a plan for dredging heavily contaminated "hot spots" along the upper Hudson River of 340,000 pounds of the PCB's that had been dumped into the waterway by the General Electric Company. A succession of health officials, scientists and corporate representatives rose to question Mr. Berle about the details of removing the PCB's (polychlorinated biphenyls — heat-resistant chemicals used for insulating transformers and capacitors), which have been shown to cause birth defects, reproductive failure and cancer in animals, and are strongly suspected of being carcinogenic to man.

When her turn came, Carolyn Cunningham, the head of the Conservation Advisory Council for Rye, N. Y., whose "Tuesday Only" tag indicated her limited status at the meeting, stepped to the microphone and asked a question so elementary that none of the experts in the room would have dreamed of raising it. Yet the answer to it continues to elude and confound them all: "The acceptable level for PCB's has been set at 5 parts per million. Is that level safe?"

Mr. Berle deferred to Leo Hetling, then his director of pure-waters research, who answered: "That's like asking how many cigarettes can one safely smoke. The Food and Drug Administration considers it safe for eating fish."

Mrs. Cunningham was not satisfied with Mr. Hetling's evasive reply. But his smoking analogy amounted to the plain truth. No one knows exactly how many PCB's the human body can safely assimilate, so setting "acceptable" levels for them, as well as for thousands of other dangerous chemicals, including saccharin, is scientifically absurd.

Saccharin, in fact, is currently the object of a bitter controversy over whether it should be banned in the United States, as it is in Canada. Repeated laboratory tests have showed that the artificial sweetener causes cancer in animals and almost without question can do the same in humans. While acknowledging that saccharin can be lethal, a National Academy of Sciences panel recommended to Congress on Feb. 28 that the additive be restricted but not banned entirely, since it is considered necessary for those who must restrict their sugar intake. There were 12 vigorous dissenters among the 37 panel members, however. Some of them went so far as to contend that there is really no scientific basis for setting human risk levels for carcinogens and that dividing additives into risk categories is, therefore, senseless.

Meanwhile, the House Subcommittee on Health and the Environment has scheduled hearings on saccharin this spring amid what is one of the fiercest lobbying battles in memory.

Levels of acceptability — the doses of chemicals and radiation people may safely absorb — are becoming critically important now that so many cancers are thought to be environmentally caused. And since most cancer-causing chemicals have long latency periods, the real effects of the petrochemical explosion of the 40's, 50's and 60's are only just beginning to be felt. An estimated 400,000 Americans will die of cancer this year and it is thought that 20 percent of all Americans now living — perhaps one out of every five reading this — are going to die of some form of cancer unless something is done about it, and quickly.

Yet none of the public-health officials who set acceptable levels for the thousands of chemicals we eat, drink and breathe can be absolutely sure that those levels adequately protect the public from serious illness or deadly disease. Any dose of a toxin, however low, involves some risk. But trying to calculate the precise degree of risk is incredibly difficult.

To make matters worse, the entire level-setting process takes place in a regulatory morass involving several Federal agencies and a dozen laws (each of which is to some extent vague, inconsistent or contradictory), state and local agencies, the courts, Congress, business interests, environmentalists, "independent" testing laboratories, the National Academy of Sciences, hospitals and universities, a legion of lobbyists, and a growing number of health functionaries on virtually all levels of government. The result is pandemonium.

In the end, economic, not scientific, factors frequently prevail. Often these are incorporated into law. The Toxic Substances Control Act, for example, stipulates that health risks be balanced against economic factors and other "public impacts." It is the scientists and statisticians, however, on whom we must depend to apply data from cellular and animal experiments in an effort to figure out how much of which poison, individually and in combination, the human body can tolerate. But E. Cuyler Hammond, a vice president of the American Cancer Society and an expert statistician, says that the process, though seemingly sound, is basically "by guess and by God."

Yet industrialists, lawyers, politicians and economists in essence take these numbers, imprecise as they are, and present the public with difficult choices: How much of these poisons are you willing to live with? If you don't swallow a little poison every day — a level we agree is acceptable — you will

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in determining whether a given chemical is carcinogenic. But there are many scientists who argue that applying such data to humans, which is called extrapolation, can be misleading. "There is no reason to believe that what causes cancer in animals will do it in human beings, and vice versa," says Dr. Irving J. Selikoff, director of the Environmental Sciences Laboratory in the Mount Sinai School of Medicine in New York. "If you can't extrapolate from a mouse to a rat, how can you do it from a mouse to a man?" he asks. Dr. Selikoff does not question the value of animal experiments, but only maintains that biological systems and responses vary even between different species of rodents, so precise relationships between rodents and humans are just that much more difficult to establish. Furthermore, a typical animal experiment involves 100 or fewer test animals, yet it costs upward of \$250,000.

Since the regulatory agencies are not funded to perform anywhere near the number of necessary experiments (there are about 35,000 different pesticide formulations alone), the chemical manufacturers themselves, incredibly, assume that responsibility. Testing is either done in-house or, more often, is farmed out to "independent" laboratories. In that chemical and drug companies are in business to sell their wares, not to see them squelched in laboratories for being dangerous to human health, it is not too far-fetched to suggest that these labs give their clients concoctions every reasonable doubt.

In mid-1977, the Environmental Protection Agency and the Food and Drug Administration began joint audits of 100 laboratories. Only three, Industrial Bio-Test Laboratories of Northbrook, Ill., and two other labs doing far less testing, have been found to have deficiencies, according to Fred T. Arnold, chief regulatory analyst for pesticides at the E.P.A. And deficiencies, he adds, are not necessarily deliberately caused. Until the aftermath of that audit, Industrial Bio-Test was one of the biggest of the "independents" and did about 4,300 pesticide tests for such companies as American Cyanamid, Chevron, Ciba-Geigy, Dow, Gulf, 3M, Monsanto, Shell and Veisicol, plus the United States Department of Agriculture and the F.D.A. itself.

According to Mr. Arnold, his agency has no direct authority to regulate laboratories, but it can require that manufacturers undertake "stringent" testing of pesticides by whatever means are necessary. If the tests are judged inadequate or distorted, the

E.P.A. can order them repeated, which is what is now happening in the Industrial Bio-Test case. But, Mr. Arnold says, what with redosing and reanalyzing, it will be two years before the various toxicity levels are fully determined. Meanwhile, some of the 123 pesticides in question, among them several of the most heavily used in the world, remain in mass production.

Toxic chemicals, including those that can cause cancer, are supposed to be regulated directly by four Federal agencies:

- The Environmental Protection Agency, the largest of the regulators, which is responsible for protecting the overall environment.

- The Food and Drug Administration, operating under the Department of Health, Education and Welfare, which is responsible for drugs, food, cosmetics, medical devices, television sets and microwave ovens.

- The Consumer Product Safety Commission, an independent agency, which monitors such consumer items as children's clothing, patching compound, and aerosol sprays.

- The Occupational Safety and Health Administration (OSHA), part of the Department of Labor, which tries to control "hazards in the workplace," from asbestos particles in the air to the number of fire exits.

Although these agencies are required by law to do the actual regulating, they are merely the most visible part of a much larger mechanism. In addition to coming from industry and universities, many of the data used for decision making come from the National Cancer Institute, the National Institute of Environmental Health Science and the National Institute for Occupational Safety and Health. Then there are all of the other agencies, large and small, with primary responsibilities elsewhere which nonetheless become involved in toxic substances research and regulation.

In August 1977, the four main regulatory agencies spawned something called the Interagency Regulatory Liaison Group (I.R.L.G.), which is supposed to facilitate cooperation among them. An I.R.L.G. risk-assessment group announced on Feb. 7 that it has come up with methods for deciding whether something is carcinogenic and, if so, on the extent of the risk it poses. The report will now be submitted for peer review and public comment.

The situation has been so

confused that when the E.P.A. recently asked the National Academy of Sciences to evaluate two pesticides — heptachlor and chlordane — one academy committee came up with a risk assessment, while another reported that it hadn't enough information to do so with reliability. The discrepancy came less from disagreement over the validity of extrapolating animal test data than from ambiguities in the law.

What is acceptable and what is not is terribly complicated by the 12 laws, each of which came out of a different Congressional committee, under which the four major agencies function. The Clean Air Act, Water Pollution Control Act, Safe Drinking Water Act and Federal Insecticide, Fungicide and Rodenticide Act, all administered by the E.P.A., permit cost-benefit analysis for setting acceptable levels, but do not require it. The Food, Drug and Cosmetic Act (F.D.C.A.), demands cost-benefit analysis in some instances and prohibits it in others. The F.D.C.A.'s controversial "Delaney clause" forbids carcinogenic additives from being put into food, but since PCB's (as one example) are environmental rather than an additive, they are not covered by the clause.

The elasticity of the Clean Air Act is likely to have prompted Charles L. Schultze, chairman of the Council of Economic Advisers, to warn E.P.A. Administrator Douglas Costle last May that his agency's broad new proposals to control air pollution would "impose substantially higher costs on business than is necessary." The E.P.A., bending to such pressure, last fall weakened a proposed smog regulation for the first time in its history. More recently, a memorandum from Mr. Schultze and Alfred E. Kahn, the President's chief adviser on inflation, said that E.P.A.'s pending water-pollution regulations could be "prohibitively expensive" and that the whole program should be re-examined to relate the costs to the benefits. Here, laid bare, is the nub of the antiregulatory argument and the basis for most of the courtroom action: Following all of the rules and regulations is economically crippling and dangerously inflationary.

It is Mr. Schultze's use of the word "necessary" in the air-pollution warning that would send economists and ecologists going for one another's throats. How necessary is clean air and how clean should it be in order to be acceptable? What if requirements for super-duper clean air so constrict business that companies collapse and thousands are thrown out of work? Would those unemployed workers rather have perfect air,

inflation and no jobs, or not-so-perfect air, a healthy economy and work? This is the essence of industry's argument.

Although existing law stipulates that 5 parts per million is the allowable level in fish, as Leon Helling told Carolyn Cunningham, the F.D.A. in fact proposed in April 1977 to lower that level to 2 parts per million, as Canada had already done. As required by law, the proposal appeared in the Federal Register. Interested parties were given 30 days to file objections and request a hearing.

Robert G. Martin, assistant vice president of the Sport Fishing Institute, an organization representing the multibillion-dollar sport-fishing industry, maintains that he has yet to see studies "implicating PCB's with human health. You really can't be against public health," he says, "but I find it difficult to see where human health has been involved." In checking his files, Mr. Martin adds, "I could find no reference to the institute officially commenting on a proposal to lower allowable limits of PCB's from 5 to 2 parts per million." F.D.A. records, however, tell a different story. They show that Gilbert C. Radonski, executive secretary of the institute, sent a letter to the agency on May 23, 1977, which said that it "has not been demonstrated that an eminent health hazard exists that would justify a reduction in the total of PCB's in fish from 5 parts per million to 2 parts per million." The letter also called for more research on PCB's and for the issuance of "guide-

lines" on the best ways to prepare and cook fish contaminated by the chemicals. (The institute's motto is: "The Quality of Fishing Reflects the Quality of Living.")

Other fishing organizations, such as the Midwest Federated Fisheries Council and the National Fisheries Institute, and even the New York State Legislature, came out for delaying a lowering of the PCB tolerance level in fish "pending further studies on the drastic and possibly tragic economic implications any change would instigate." This position prompted one member of the New York PCB Settlement Advisory Committee to say privately, "What they want, at bottom, is a body count [before they believe that PCB's are carcinogenic to humans]." Meanwhile, the proposal to drop the PCB level, a classic victim of cost-benefit analysis, seems economically unacceptable and is now in limbo.

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After years of notable victories by environmentalists, the economics-versus-ecology battle looks as though it is beginning to tilt the other way, in part because of persistent inflation and also because of an equally persistent mistrust of big government and its sluggish and meddling bureaucracy. Some observers even sense a growing backlash among citizens who feel that good old American enterprise is choking to death on hopelessly snarled red tape and ridiculous regulations. They feel, and with some justification, that they are overregulated and underprotected. (Given the President's recent announcement that OSHA was eliminating 928 "unnecessary" regulations, this sentiment seems at least partly shared by the Administration.)

But because of the long latency period it is vital to work now to prevent as much cancer as possible in the year 2000, warns Dr. Irving Selikoff of Mount Sinai. "How much risk can you live with? That's the nature of the debate over the word 'acceptable,' and it must be decided by society, not by scientists." ■