other countries, air pollution continues to increase, particularly in the coal-rich regions of eastern Europe and China. The incidence of respiratory and cardiac disease is growing rapidly in these areas, as is damage to lakes and forests.

**Avoiding havoc**

A recent study by the Environmental Defense Fund shows that power plants, industry, and automobiles are leading sources of the nitrogen pollution that wreaks havoc on coastal ecosystems. Explosive blooms of algae nourished by nitrogen suffocate fish and shellfish populations and invade swimming beaches. Scrubbers on smokestacks designed to trap sulfur do not control nitrogen, but energy efficiency reduces both.

Energy efficiency can be a new weapon in the air pollution wars, complementing scrubbers and catalytic converters. Czechoslovakia, East Germany, Poland, and others could stem the damage to their forests by improving their industrial energy efficiency. Rome could attack the cause of much of the population's respiratory disease and slow the deterioration of its ancient ruins by doubling the fuel efficiency of its cars. A 1987 study by the American Council for an Energy-Efficient Economy concluded that increased efficiency could help widen the scope and improve the cost effectiveness of proposed acid rain control programs.

The ultimate environmental problem may be carbon dioxide accumulating in the Earth's atmosphere—threatening to irrevocably alter the world's climate. Already, the average temperature worldwide has increased by 1 °F in the last 100 years. This "greenhouse effect" could well make the world warmer 50 years from now than it has been at any time in human history. The main cause of this phenomenon is fossil fuel combustion, which adds 5.4 billion tons of carbon to the atmosphere each year—more than one ton for each person on the planet.

The full implications of such a warming are not fully understood, but they could well include more frequent droughts, serious disruptions in agriculture, and the flooding of densely populated coastal areas. Governments throughout the world not only have been slow to respond to the climate problem and other environmental threats but also are actively pursuing energy policies that aggravate them.

Sustained improvement in energy efficiency must be the central component of any viable strategy to limit global climate change. No other strategy can be developed quickly enough to slow global warming significantly in the next few critical decades. A demanding but achievable goal is an annual 2% gain in energy efficiency.

The energy crisis of the seventies has receded for the time being, but the environmental limits on energy growth continue to press closer. Fuel prices are low, but the environmental costs of energy profligacy are mounting rapidly. Energy efficiency is an economic opportunity, but it is fast becoming an environmental necessity.

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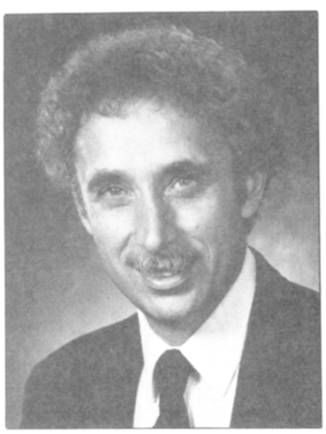
# Determining an acceptable level of risk

*By Curtis C. Travis and Holly A. Hattemer-Frey*



*Curtis C. Travis*

*Holly A. Hattemer-Frey*

In a recent decision involving vinyl chloride (*1*), the U.S. Circuit Court of Appeals for the District of Columbia mandated that EPA identify "an acceptable level of risk" for human exposure to chemical carcinogens regulated under Section 112 of the Clean Air Act. The court proposed a two-step process for regulating chemical carcinogens under the act. EPA must first establish a "safe" level of emissions that will result in "acceptable" exposure without regard to cost or technical feasibility (i.e., the determination must be based solely on human health risks).

Judge Robert Bork of the U.S. Court of Appeals wrote "The (EPA) administrator cannot under any circumstances consider cost and technological feasibility at this stage of the analysis. The latter factors have no relevance to the preliminary determination of what is safe." Once a "safe" risk level has been set, EPA may then consider other factors, such as cost and technological feasibility, to define the level that provides an "ample margin of safety to protect public health." (The "margin of safety" is intended to account for the scientific uncertainty in estimating human health risks associated with exposure to environmental carcinogens.)

Several approaches have been suggested for establishing a single, acceptable risk level for exposure to chemical carcinogens (*2*). The court, for example, suggested that an acceptable risk level could be determined by examining risks associated with normal, everyday activities. The court noted

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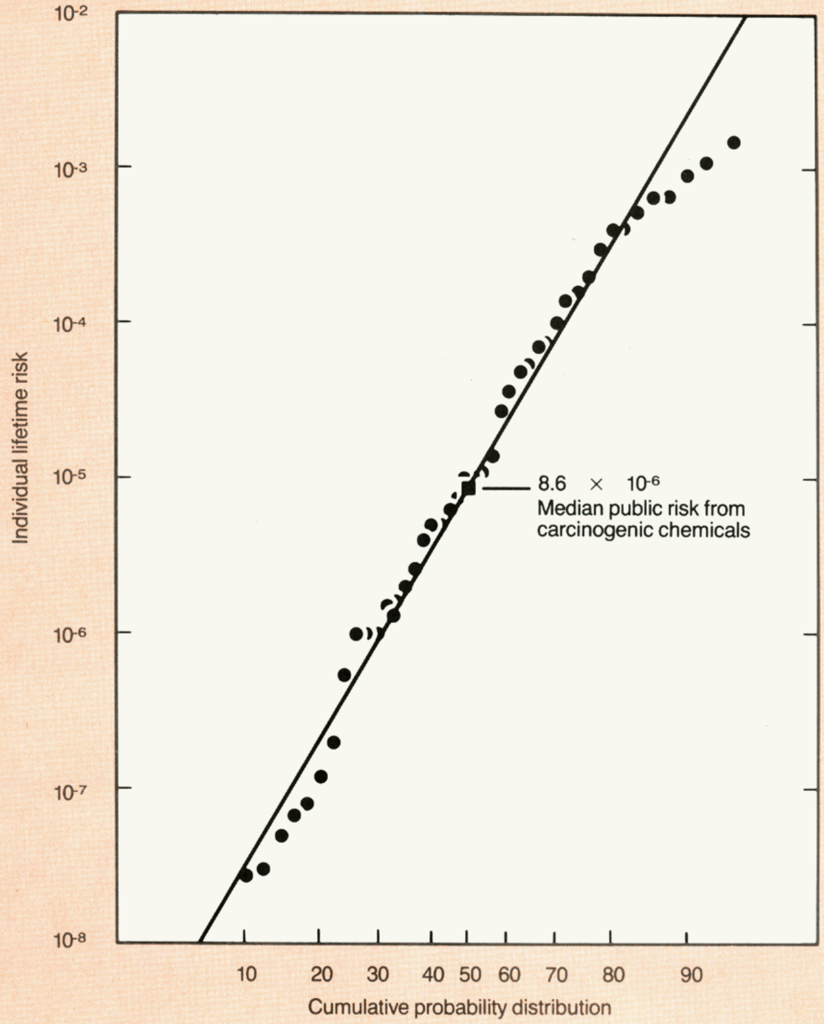
that although many everyday activities, such as driving a car, involve certain risks, few people perceive such risks as unacceptable. (The lifetime risk of fatality from motor vehicles is $2 \times 10^{-2}$, i.e., the lifetime probability of dying in a car accident is 2 in 100 [*3*]). We believe that the court, in its interpretation of Section 112 of the Clean Air Act, was indirectly advocating use of a *de manifestis* level (i.e., a ceiling above which events are inherently unsafe and should be regulated without regard for cost) to establish an acceptable level of risk.

Travis et al. (*4*) reviewed 132 federal regulatory decisions concerning environmental carcinogens to determine the level of risk that led to agency action. The results showed that for small populations, every chemical with an individual lifetime cancer risk above about $10^{-3}$ historically has been regulated. For large populations, the *de manifestis* level drops to $10^{-4}$. (Both *de manifestis* levels are substantially lower than the individual lifetime probability of developing cancer from background sources, $2.5 \times 10^{-1}$). We believe that such a population-based *de manifestis* level is an appropriate method for establishing an acceptable risk level, because it represents the level of risk that regulatory agencies have deemed acceptable in the past; consequently, it represents a working consensus on the value of human life. We recommend that a population-based *de manifestis* level be adopted to establish the level above which cancer risks should be considered inherently unsafe and regulated—no matter what the cost.

The EPA administrator rejects the opinion that the EPA can establish a universal "acceptable level of risk" that should never be exceeded under any circumstances (*5*). The administrator also maintains that, because of the unprecedented provisions of the Clean Air Act, acceptable risk levels established under the act have little value for making risk determinations under other statutes (*5*). We submit, however, that using a population-based *de manifestis* level provides an equitable method of establishing acceptable risk levels that can be applied to other regulatory decisions.

FIGURE 1
**Individual lifetime public risks from carcinogenic chemicals**




### The benzene case

Benzene was the first chemical carcinogen to be regulated under the Clean Air Act after the vinyl chloride decision (*5*). EPA proposed the following four values as representative of an "acceptable level of risk" that protects public health with an ample margin of safety:

- $2 \times 10^{-5}$ for ethylbenzene and styrene process vents;
- $4 \times 10^{-4}$ for benzene storage tanks;
- $1 \times 10^{-3}$ for benzene equipment leaks; and
- $6 \times 10^{-3}$ for coke by-product plant emissions.

After establishing "acceptable" baseline risk levels, EPA decided the costs of regulation greatly exceeded potential health risk reductions for process vents, storage tanks, and equipment leaks and that baseline risk levels protected public health with an ample margin of safety (i.e., no additional controls were required) (*5*).

For coke by-product plants, however, EPA decided that the maximum individual risk could be reduced to $10^{-4}$ at a reasonable cost ($1 million to $30 million per year) and proposed that regulatory action be implemented (*5*). In arguing that the acceptable risk level established for benzene equipment leaks ($1 \times 10^{-3}$) protected public health with an ample margin of safety, EPA noted that the estimated cancer incidence is 0.3 cases per year. Only 0.02 cancer cases are associated with a $10^{-5}$ risk level, and only 0.009 cases per year are associated with risks of $1 \times 10^{-4}$ and greater. Conversely, for coke by-product plants, the estimated cancer

**"Past regulatory decisions indicate that in many circumstances risks greater than $10^{-4}$ are in fact tolerated."**

incidence associated with the baseline risk value ($6 \times 10^{-3}$) is 3 cases per year, and 1.4 cases occur in populations exposed at lifetime risks of $1 \times 10^{-5}$ or higher.

In these decisions EPA explicitly acknowledges that total cancer incidence, and not just maximum lifetime individual risk, is important in establishing an acceptable level of risk—a position that is consistent with previous EPA decisions (*5*) and our proposal. We point out, however, that the proposed $6 \times 10^{-3}$ acceptable risk level for coke by-product plants is above the historical *de manifestis* level.

Some environmentalists and state regulatory agencies may find our proposal (as well as EPA's decision for benzene) to be nonprotective of human health, for some of these groups hold that *all* risks above $10^{-6}$ are significant and should be reduced regardless of cost. For example, the South Coast Air Quality Management District in southern California recently adopted a rule that denies permits for any proposed project with an estimated risk greater than $10^{-6}$ (*6*). A review of previous regulatory decisions, however, indicates that this position is not consistent with actual regulatory practice.

### What is acceptable?

Table 1 lists upper bound risk levels *after regulation* for public exposure to 36 chemical carcinogens. These risk levels were published in the *Federal Register* or computed using EPA's carcinogen potency data (see Table 1 for individual sources). These upper bound estimates are based on the assumption that an individual is exposed to a chemical at the maximum level allowed by federal standards over a public lifetime (70 years).

Figure 1 shows the cumulative probability distribution of cancer risks associated with current standards for public exposures. The figure indicates that about 70% of chemical carcinogens have a postregulatory lifetime public risk greater than $10^{-6}$, whereas about 30% have a postregulatory lifetime public risk greater than $10^{-4}$. Thus past regulatory decisions explicitly acknowledge that some risks (i.e., risks in the range of $10^{-6}$ to $10^{-3}$) are acceptable in modern society.

Regulatory agencies have an obligation to limit human exposure to chemical carcinogens to levels that are both acceptable and as low as reasonably

TABLE 1

**Postregulatory risk levels for chemical carcinogens (public exposure)**

| Chemical | Lifetime risk (per 100,000) | Reference |
|---|---|---|
| Acrylonitrile | 0.012 | 49-FR-36635 |
| Aflatoxins | | FDA Docket No. |
| Southeast | 66.4 | 78N-0048 |
| Entire United States | 2 | " |
| Aluminum tris | 0.0027 | 48-FR-50532 |
| Ambien | 0.001 | 46-FR-17229 |
| Amitraz | 0.1 | 44-FR-2678 |
| Arsenic | | |
| High-copper smelters | 9,200 | 48-FR-33112 |
| Low-copper smelters | 150 | " |
| Glass manufacturing | 15.6 | " |
| Lead smelters | 0.7–11 | " |
| Zinc Smelters | 0.1–2.2 | " |
| Zinc oxide plants | 17–280 | " |
| Chemical plants | 4–64 | " |
| 2nd. lead smelters | 21–340 | " |
| Wood preservatives | 10 | 49-FR-28666 |
| Water | 2,100 | EPA 440/5-84-033[a] |
| Benomyl | 7 | 49-FR-1402 |
| Benzene | | |
| MAPV | 7.6 | 49-FR-8386 |
| EBSP | 14 | " |
| BSV | 3.6 | " |
| Coke by-product | 30 | 49-FR-23522 |
| Equipment leaks | 45 | 49-FR-23498 |
| Paint strippers | 0.62 | 43-FR-21838 |
| C.I. vat orange 1 | 0.000003 | 50-FR-20405 |
| Cadmium (water) | 220 | EPA 440/5-81-032[a] |
| 2-Chloroallyldithio-carbamate | 0.2 | 46-FR-27973 |
| Chlorobenzilate | | |
| Entire United States | 0.26 | 44-FR9548 |
| Florida residents | 0.7 | " |
| Chlorothalonil | 0.01 | 50-FR-26592 |
| Chromium (water) | 5,900 | EPA 440/5-84-029[a] |
| Cypermethrin | 1 | 50-FR-1112 |
| Cyromazine | 0.1 | 49-FR-18120 |
| Dimethylnitrosamine | 0.0005 | 50-FR-4643 |
| Epichlorohydrin | | |
| Dimethylnitrosamine | 0.0000002 | 49-FR-13817 |
| Polyamide | 0.0013 | 49-FR-13821 |
| Ambient air | 1.1 | 50-FR-24575 |
| Ethalfluralin | 0.38 | 49-FR-511 |
| FD&C Yellow No. 5 | 0.04 | 50-FR-35774 |
| Hexachlorodibenzo-*p*-dioxin | 1 | 49-FR-28666 |
| Lead acetate | 0.02 | 45-FR-72112 |
| Lindane | | |
| Air | 0.5 | 48-FR-48512 |
| Water | 15 | 40-FR-1990[a] |
| Methoxychlor | 0.005 | 45-FR-49117 |
| Methylene chloride | | |
| Decaffeinated coffee | 0.1 | 50-FR-51551 |
| Metolachlor | 0.1 | 47-FR-23932 |
| Oryzalin | 0.51 | 49-FR-45854 |
| 2,2′ Oxamidobis | 0.007 | 48-FR-37616 |
| PCBs (in fish) | 100 | 49-FR-21514[a] |
| Perchloroethylene | 0.1 | 47-FR-27118 |
| POMs | 21 | 49-FR-31680 |
| Saccharin | 40 | 42-FR-19996 |
| *p*-Toluidine | | |
| (D&C Green No. 5) | 0.003 | 47-FR-24278 |
| (D&C Green No. 6) | 0.0067 | 47-FR-14138 |
| (D&C Red, No. 6, 7) | 0.002 | 47-FR-57681 |
| Diet | 0.0067 | 47-FR-14138 |
| Contact lenses | 0.00001 | 48-FR-13020 |
| Toxaphene | 1600 | EPA 440/5-80-076[a] |
| Trifluralin | 0.053 | PD#4 (OTS, 1982) |
| Trihalomethanes | 10 | 43-FR-5756 |
| Vinyl Chloride | | |
| EDC-VCM plants | 21 | 50-FR-1182 |
| PVC plants | 59 | " |
| Food | 0.01 | 51-FR-4177 |

[a]Risk estimates calculated using concentration allowed by standard and carcinogen potency data published by EPA's Carcinogen Assessment Group (November 1984), representing extreme upper bound risks.

achievable. However, the view that *all* risks greater than $10^{-6}$ are unacceptable and should be regulated no matter what the cost is economically unrealistic and is not compatible with past regulatory practice. Although it may seem barbaric to argue that some risks are acceptable and therefore must be endured by society, past regulatory decisions indicate that in many circumstances risks greater than $10^{-4}$ are in fact tolerated.

The current EPA benzene proposal indicates that maximum individual risks as high as $10^{-3}$ are tolerable if reduction of exposures would not appreciably reduce total population cancer incidence. EPA has argued similar positions in the past (i.e., the risk associated with zinc oxide plants is $3 \times 10^{-3}$ [*7*]; secondary lead smelters, $3 \times 10^{-3}$ [*7*]; elemental phosphorus plants, $1 \times 10^{-3}$ [*8*]; vinylidine chloride, $8 \times 10^{-4}$ [*9*]; radionuclides from Department of Energy facilities, $7 \times 10^{-4}$ [*8*]; and radon from uranium mill tailings, $5 \times 10^{-4}$ [*10*]). The existence of a population-based *de manifestis* level in the range of $10^{-3}$ to $10^{-4}$ is a regulatory fact. Explicit adoption of this level would maintain consistency with past decisions and simplify regulatory decision making.

## References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(4) Travis, C. C. et al. *Environ. Sci. Technol.* **1987,** *21,* 415–20.
(5) U.S. Environmental Protection Agency; Proposed Benzene NESHAP Decisions and Limitations of Issue to Section 112 of the Clean Air Act, Memorandum from the Office of the Administrator, April 1988.
(6) Broiles, S. A. *Risk Analysis,* in press.
(7) *Fed. Regist.* **1983,** *48,* 33112.
(8) *Fed. Regist.* **1985,** *50,* 5190.
(9) *Fed. Regist.* **1985,** *50,* 32632.
(10) *Fed. Regist.* **1986,** *51,* 6382.



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