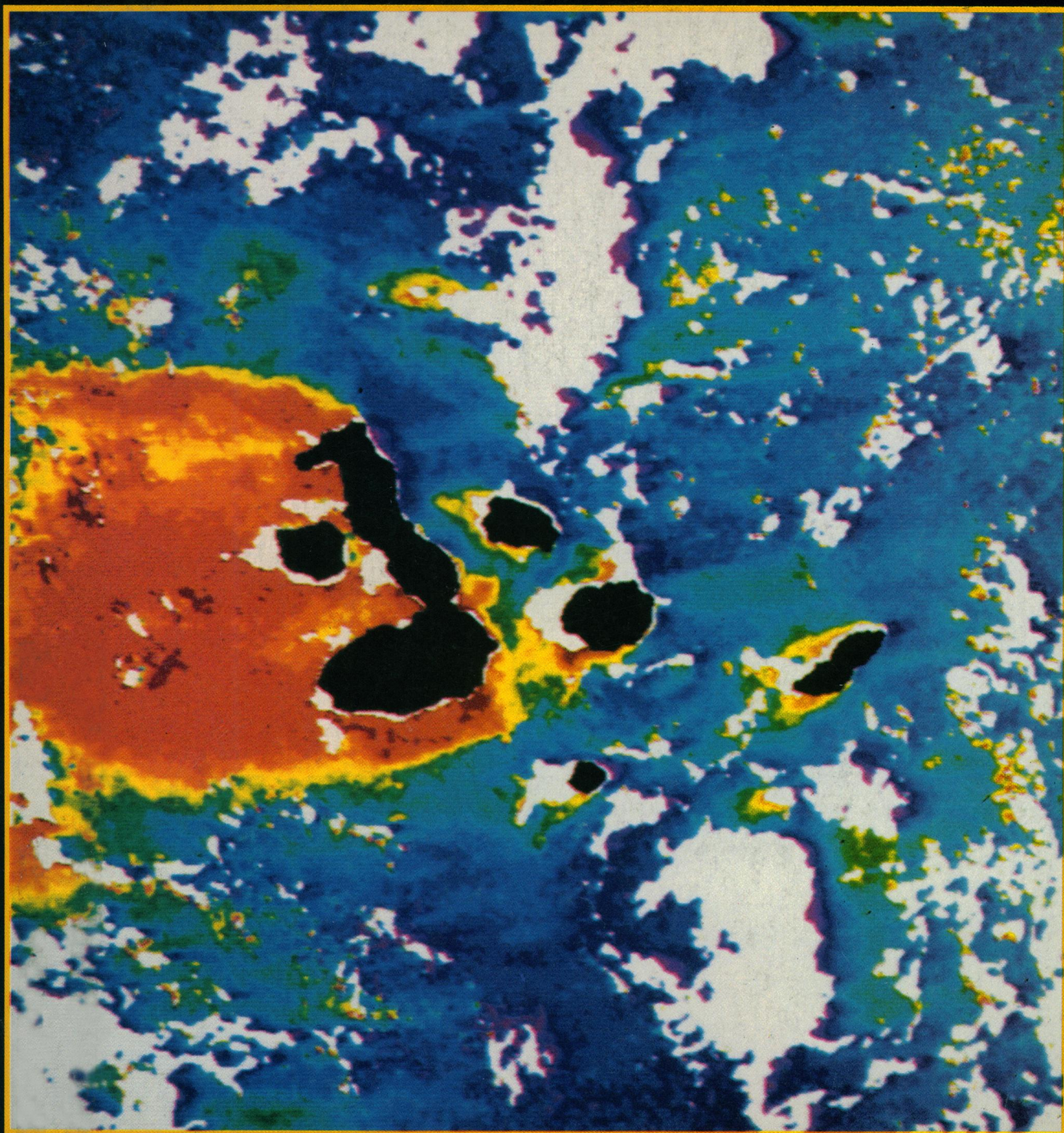


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Satellite ocean color image showing the distribution of phytoplankton pigments around the Galápagos Islands during El Niño. This computer-processed image, color-coded according to concentration range, was produced from data collected on 1 February 1983 using the Coastal Zone Color Scanner aboard NASA's Nimbus-7 satellite. Regions of high concentrations (above 1 milligram per cubic meter) are orange; intermediate levels, yellow and green; lowest levels (less than 0.2 milligram per cubic meter), blue. Major islands are black and clouds white. North is at the top; equator lies horizontally just above the center of the image. See page 1069. [G. Feldman, State University of New York, Stony Brook 11794; D. Clark, National Oceanic and Atmospheric Administration, Washington, D.C. 20233; and D. Halpern, National Oceanic and Atmospheric Administration, Seattle, Washington 98115]

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LETTERS

Models of Carcinogenesis

Nicholas A. Ashford *et al.*, in their response to comments on their article (Letters, 11 May, p. 554), raise several important issues about low-dose extrapolation models for carcinogens. I would like to comment on an additional and critical element of no-threshold models, using the one-hit, no-threshold model as an example.

The one-hit, no-threshold model for low-dose extrapolation of the dose-response relationship for carcinogens predicts a finite probability that a single molecule can evade the body's defenses and produce an event that triggers cancer. A toxicological threshold is a dosage at or below which no adverse response is observed.

This "no-threshold" concept has received widespread publicity in both the popular and scientific literature and has served as a focal point for criticism of the model. Reduction of this argument ad absurdum has resulted in legislation such as the Delaney clause of the Federal Food, Drug, and Cosmetic Act (1). This clause requires that any substance used as a food additive and demonstrated to be a carcinogen in either an animal bioassay or human study must be banned from all food products.

It is critical that the one-hit, no-threshold model be placed in the context of the stochastic (probabilistic) relationship in which it was developed. Although it is theoretically possible that a single molecule of a carcinogen could induce cancer, the probability of this occurrence is vanishingly small. The carcinogenic potential of a chemical substance is a function of both potency and dose. According to the one-hit theory, both of these variables directly and proportionally affect the derived probability that a carcinogenic event will occur. Carcinogens vary in potency by approximately 12 orders of magnitude, and hence there is a wide range of carcinogenic probabilities for any specified dosage of different carcinogens.

For example, benzene is a moderately potent, proven human and animal carcinogen. Low-dose extrapolation from occupational studies using the one-hit, no-threshold model suggests that persons drinking water containing 1 part per billion (weight to volume) (1.0 microgram per liter) of benzene throughout their lives might have an added risk of cancer (excess cancer risk) as high as approxi-

mately 2×10^{-6} (2) (two additional cases of cancer for every million people so exposed).

The probability of cancer from a single molecule of benzene per liter of drinking water is readily calculable by using this model. If one assumes that the average person weighs 70 kilograms and drinks 2 liters of water per day for a lifetime, the excess carcinogenic risk of drinking water contaminated with one molecule of benzene per liter, a lifetime consumption of about 51,000 molecules of benzene, is approximately 10^{-22} . This risk is more than 16 orders of magnitude smaller than the most stringent state or federal regulatory standard for an allowable risk level of 1×10^{-6} (one in a million excess lifetime risk of cancer). Assuming that the present total world population is 5 billion people and that it consumes this "contaminated" water, one would not expect even one additional case of cancer from this contaminated water, since the probability of one excess case of cancer's occurring in the world's population is 5×10^{-13} .

The fact is that both factions in this argument are correct. According to the no-threshold, one-hit model, there is a finite probability that one molecule of a carcinogen could cause cancer; however, the opponents of this theory are also correct in expressing their incredulity at this possibility. For all practical purposes, the probability of this occurring is so slight as to make this skepticism reasonable. The fact that this model allows for the possibility that one molecule of a carcinogen can induce cancer does not invalidate the model. On the contrary, because the model itself predicts that the occurrence of even a single cancer case from a single molecule of a carcinogen is highly unlikely, the model is able to reflect the known pharmacokinetics and enzymology at extremely low doses rather than totally dismissing this carcinogenic potential by assuming an absolute threshold.

NORMAN GRAVITZ

Epidemiological Study Section,
California Department of Health
Services, 2151 Berkeley Way,
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References and Notes

1. Public Law 85-929, 72 Stat. 1784 (1958).
2. Environmental Protection Agency value for the low-dose slope of 0.052 (milligrams per kilogram per day)⁻¹ based on R. A. Rinsky, R. J. Young, and A. B. Smith ["Leukemia in benzene workers," *Am. J. Ind. Med.* 2, 217 (1981)] and provided in *Health Assessment Document for Acrylonitrile* [(EPA-600/8-82-007, Environmental Protection Agency, Washington, D.C., 1983), p. 13-165].

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Environmental Risk Management

Although the Environmental Protection Agency has compiled a reasonably good record during its 13-year history, its prestige has never matched its accomplishments. When the agency began its operations, municipal sewers were discharging large quantities of untreated waste into streams. Industrial stacks were emitting millions of tons of particulates. Automobiles were discharging ten times as much pollution per mile of travel as they do now. Today the water in Lake Erie is said to be drinkable, and fish have returned to formerly polluted rivers.

However, these accomplishments are ignored and EPA finds itself in a virtually untenable position as it seeks to deal with concerns about toxic chemicals. In part, the problem stems from lack of information concerning the toxicities of the over 65,000 different industrial chemicals listed as having been in commercial production since 1945. Contributing heavily to EPA management problems is the fact that it operates under eight different federal environmental statutes, each dealing with a different aspect of environmental protection and each carried out in different branches of EPA. Some of the eight statutes require or allow EPA to base its regulatory decision directly on risk reduction regardless of cost. Other regulatory decisions, such as control of toxic pollutants in the Clean Water Act Effluent Guidelines Regulations, are to be based on available technology and cost instead of risk reduction. As a result of such differing mandates, program integration has been a continuing problem for the leadership of EPA. Failure to coordinate has led to duplicative research and uncoordinated regulation of the same industry or same substance by different programs.

The combination of lack of knowledge of the toxicities of chemicals and internal inconsistencies in EPA has left the agency vulnerable when confronted with unfounded claims of great hazards to the public. The media are seemingly uncritical in their treatment of so-called deadly chemicals. In recent scares about dioxin they have roused sufficient public anxiety to force the agency to give a minor matter top attention at the expense of more important risks to the public.

The EPA has been moving toward a more surefooted and internally consistent approach that is set forth in a report on risk assessment and risk management.* Emphasis is being placed on identifying and reducing major risks. This is to be accomplished by a two-step process—risk assessment followed by risk management. Risk assessment takes into account such evidence as is available about toxicity. More important, it factors in the degree and extent of exposure of the populace to the agent. When such an analysis was performed with respect to a proposed regulation of benzene emissions from maleic anhydride and ethylbenzene plants and benzene storage plants, the regulation was subsequently withdrawn. It was found that the total expected incidence of leukemia arising from such emissions was one case in 13 years. In the same period more than 4 million deaths would occur from cigarette-induced cancer.

Risk assessment of toxic chemicals will remain controversial. Most studies are performed on animals whose sensitivity is well known to differ in unpredictable ways from that of humans. The assumption of a no-threshold effect for carcinogens is also unproved. However, it is the intention at EPA to arrive at internal consistency in risk assessment and then to make public the basis for its assessment. Risk management will then occur with procedures and decisions dictated by the relevant federal statutes.

The EPA is to be commended for arriving at a sensible policy for identifying and managing environmental risks. When the public understands what is being done, the agency should encounter less capricious buffeting and should be more free to formulate an appropriate set of priorities to its tasks of improving the environment.—PHILIP H. ABELSON

*Environmental Protection Agency, *Risk Assessment and Risk Management: Framework for Decisionmaking* (Washington, D.C., in press).

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Contact: Dr. Alexandra H. Filipovich
Immunodeficiency—Cancer Registry
Box 610 Mayo
University of Minnesota
Minneapolis, MN 55455
(612) 376-2174
Citing Contract #N01-CP3-1011

Chemical Resources

Chemical Carcinogen Reference Standard Repository: Reference Quantities of nearly 700 com-
pounds are available. Included are numerous representatives of the following classes: poly-
nuclear aromatic hydrocarbons, PAH metabolites, radiolabeled PAH metabolites, nitrogen het-
erocycles, nitrosamines/nitrosamides, aromatic amines, aromatic amine metabolites,
radiolabeled retinoids, azo/azoxy aromatics, inorganics, nitroaromatics, pesticides, pharmaceu-
ticals, natural products, dyes, dioxins, chlorinated aliphatics and miscellaneous groups. Data
sheets provided with the compounds, include chemical and physical properties, analytical data,
hazards, storage, and handling information. Catalog available upon request.

Contact: Coordinator for Chemical Research Resources
Chemical and Physical Carcinogenesis Branch, DCE, NCI
Landow Bldg./Rm 9B01
Bethesda, MD 20205
(301) 496-5471

Cost: Subject to chemical class code and quantity (see catalog)

The Tumor Virus Epidemiology Repository
(TVER) contains sera and other biological
samples from more than 13,000 patients and
controls obtained in 12 different countries. The
TVER was established primarily to support
collaborative research on the role of Epstein-
Barr virus (EBV) in Burkitt's lymphoma,
nasopharyngeal carcinoma, and related dis-
eases. Part of the collection includes sera that
were obtained from nonhuman primates inocu-
lated with EBV.

The TVER is able to adjust its collection to fa-
cilitate the development of new collaborative
studies. In addition, some samples are avail-
able for reagents and independent research.
The most extensive collections are serum
samples from patients with Burkitt's lymphoma
(sera from more than 1000 patients).

Contact: Dr. Paul H. Levine
Clinical Epidemiology
Branch, DCE, NCI, NIH
Landow Building, Room 8C41
Bethesda, MD 20205
(301) 496-5067

Cost: Free To Collaborating Investigators;
Others—Shipping Charges Only