Maurice A. Deane School of Law at Hofstra University
Scholarly Commons at Hofstra Law

Hofstra Law Faculty Scholarship

1985

Carcinogens in Air: A Crisis in Regulation

Leonard A. Miller

Vern R. Walker
Maurice A. Deane School of Law at Hofstra University

Lydia N. Wegman

Follow this and additional works at: http://scholarlycommons.law.hofstra.edu/faculty_scholarship

Recommended Citation
Leonard A. Miller, Vern R. Walker, and Lydia N. Wegman, *Carcinogens in Air: A Crisis in Regulation*, 3 Environmental Forum 44 (1985)
Available at: http://scholarlycommons.law.hofstra.edu/faculty_scholarship/759

This Article is brought to you for free and open access by Scholarly Commons at Hofstra Law. It has been accepted for inclusion in Hofstra Law Faculty Scholarship by an authorized administrator of Scholarly Commons at Hofstra Law. For more information, please contact lawcls@hofstra.edu.

Carcinogens in Air: A Crisis in Regulation

This may be EPA's most productive year ever in terms of making hazardous air pollutant decisions. A major challenge involves integration of that program with counterpart water and pesticide programs.

by Leonard A. Miller,
Vern R. Walker,
and Lydia N. Wegman

Throughout 1984, and particularly in the past six or seven months, it has become increasingly clear that the U.S. Environmental Protection Agency has been accelerating its research and regulatory efforts in the area of hazardous air pollutants under Section 112 of the Clean Air Act. The flurry of agency activity has included statements before congressional committees and several regulatory actions.[1] This work is quickly approaching a regulatory crisis. Congress, moreover, undoubtedly will address Section 112 issues as part of any reauthorization of the Air Act. As evidence of Congress's continuing concern, Rep. John D. Dingell (D-Mi.), chairman of the House Energy and Commerce Committee, introduced a bill in the closing week of the last Congress to amend Section 112 by providing EPA with increased regulatory flexibility.

The intense regulatory efforts and legislative interest are symptoms of an underlying crisis faced by EPA due to the current language in Section 112. The section requires the Administrator to list as hazardous those pollutants which, in his judgment, cause or contribute to air pollution that may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness. The listing of a pollutant triggers the Administrator's responsibility to develop emission standards that will protect public health with an ample margin of safety.

The crisis faced by the agency is being produced by a forced confluence of two regulatory policies developed in isolation from each other and designed separately in such a way that they do not produce reasonable results when they are merely joined together. These regulatory policies derive from the air dispersion modeling efforts in the air program and the hazard evaluation techniques for cancer in the water and pesticide regulatory areas.

A forced confluence of two policies developed in isolation from each other.

Over the past decade, EPA's air program has devoted significant resources to, and has based its reputation on, air quality dispersion modeling. The regulatory program to prevent significant deterioration of air quality in clean air areas, for example—the "PSD" program—is premised on the agency's ability to use mathematical models to predict concentrations of particulate matter and sulfur dioxide. Likewise, regulatory efforts to attain national ambient air quality standards are also based in large part on mathematical modeling. EPA's reliance on such models has been tested in court, and the agency's authority to use its models has been upheld.[2] In

All three authors practice environmental law concerning air, water, and pesticide regulation with the firm of Swidler, Berlin & Strelow, Chartered. Miller was with EPA from 1967 to 1980. He started in the air program, worked in Region X, Seattle, as Enforcement Division Director, and headed the Water Permit and Enforcement Program at EPA headquarters. Walker did his doctoral and postdoctoral work in logic, scientific methodology, and artificial intelligence, and has concentrated in his legal career on issues involving the use of scientific evidence, particularly modeling and toxicology, in environmental disputes. Wegman, with EPA from 1977 to 1982, served as a lead attorney in air pollution matters.

essence, the courts have recognized that EPA's air program must be permitted to operate in spite of the uncertainties in predictions that such models introduce. In deference to the agency's expertise, the courts have given EPA the latitude to regulate within the limits of the best available tools. Thus, on the air side of EPA, the ability to predict the exposure of people to pollutant concentrations has been an essential element in establishing EPA's regulatory program.

Dingell's 1984 hazardous air pollutant amendments would give EPA more flexibility, but any Section 112 revisions are certain to be controversial.

In contrast, on the water side of EPA under the Clean Water Act, as also in the pesticide program under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), agency concerns have long focused on toxicity or hazard. The traditional approach has been to regulate on the basis of the dose level at which there is no effect on animals or man—the no-observable-effect level, or "NOEL." EPA has regulated using a no-observable-effect level for acute hazards, and for such hazards as teratogenicity (the ability to cause developmental malformations in a fetus) and other effects on reproduction.

This approach is not applied to carcinogens, however, because the agency takes the position that it is not possible to establish any "safe" threshold exposure for a carcinogen.[3] The agency's view is shared by other federal agencies and some members of the scientific community. This view holds that a reduction in the dose of a carcinogen produces a diminished, but no less real, risk of cancer—a risk that is never zero so long as some dose is received. If carcinogens have the potential to cause cancer at any arbitrarily small dose, then a primary regulatory issue is this: How much risk of exposure to cancer is the agency permitted to allow under the law, or willing to allow as a matter of policy?

Empirical data on thresholds and on a dose-response relationship for cancer are generally hard to obtain. Epidemiological data for carcinogens are very limited. Only a handful of chemicals have longitudinal studies of worker data, and even those studies often are considered to involve too few people, or a group of people not representative of the general population. Data from occupational epidemiological studies, moreover, are seldom directly applicable to the general population, given, for example, the larger number of confounding variables in the ambient environment, the extreme variability of exposure, and the lack of medical data.[4] Therefore, the agency is forced to rely on chronic bioassays in which animals are dosed with the test chemical at levels high enough to produce effects—doses so high that the highest dose often produces acute effects. The agency then extrapolates low-dose risks for humans based upon the response in highly dosed animals.

This approach to assessing carcinogenicity has been developed in the water program—as can be seen, for example, from a review of the criteria documents for toxic water pollutants published in 1980 and of the agency's more recent proposal for regulating volatile synthetic organic chemicals in drinking water.[5] Moreover, under FIFRA, EPA has developed risk assessment techniques for carcinogenicity in developing regulations on pesticide registrations and the restriction of pesticide use.

EPA's approach to cancer assessment under these two programs has been quite conservative. At least two facts, however, have enabled the agency to avoid having an extremely conservative approach to modeling carcinogenicity result in a similarly conservative regulatory structure. First, FIFRA is basically a balancing statute, under which EPA must balance risks against the benefits of pesticide use. Second, in some cases, the agency has not had adequate exposure data on pollutant residues in food or water or on the numbers of people exposed to any given compound. The absence of such data can give the

agency flexibility in designing its ultimate regulatory program.

In view of the agency's conservative methodology in other programs, why is a more serious regulatory concern posed by Section 112 of the Clean Air Act? The reason, in part, is that the air program, with its strong legal precedents backing use of air quality dispersion modeling, its significant technical work on performing such exposure modeling, and its reputation for professing an ability to predict levels of exposure, now is focusing on carcinogenic air pollutants. It appears unavoidable that the entrenched and conservative air dispersion modeling techniques will now be harnessed to the equally entrenched and conservative paradigm for assessing carcinogenic potential. It is clear too that this will occur under a statutory provision lacking FIFRA's risk-benefit balancing characteristics. Consequently, the next year or two may find the fusion at EPA of 1) the health-based Clean Air Act, a statute requiring standards for hazardous air pollutants to provide an ample margin of safety; 2) a judicially approved methodology for assessing pollutant concentrations in air; and 3) a strong precedent for assessing the carcinogenicity of chemicals.

Even under an Administrator who seeks to exercise reasonable judgment in regulating under Section 112, it will be extremely difficult for the agency to explain why it should not promulgate stringent standards for hazardous air pollutant emissions on the basis of possible carcinogenic effects.

EPA so far has attempted to mitigate potentially harsh results under Section 112 by developing a two-step regulatory process for selecting appropriate control levels for sources emitting pollutants designated as hazardous. First, the agency defines the best available technology (BAT) as the minimum level of control that must be implemented. BAT for new and existing sources is the technology that the Administrator judges to be the most advanced level of control when one takes into account economic, energy and environmental impacts, and any technological problems connected with retrofitting existing sources.

The second step involves assessing the residual risk remaining even after application of BAT. To make this assessment, EPA identifies a level of control more stringent than BAT and evaluates the incremental reductions in health risks that can be secured against the incremental costs and economic impacts the agency estimates will result from use of the more stringent controls. The results of comparing costs and economic impacts of control with the benefits of further risk reduction are used in determining whether the residual risks that remain after application of BAT are unreasonable. If the residual risks are unreasonable, then the Administrator presumably would require further controls. In other words, although environmentalists have argued that a cost-benefit analysis is not permissible under the Clean Air Act, the agency has interpreted the statutory language as allowing room for economic and political realities.[6]

An illustration of the agency's attempt to elude the statute's rigidity is found in its decision to withdraw proposed standards for three categories of sources which emit benzene.[7] In that action, EPA concluded that the health risks to the public from benzene emissions from the source catgories and the potential reductions in health risks that could be achieved with available control techniques were too small to warrant federal regulation under Section 112. In essence, EPA determined that the health risks from these sources were not significant enough to justify the expense of control technology. Not surprisingly, EPA's decision has been challenged by environmentalists. The case will present the U.S. Court of Appeals with its first opportunity to address squarely the regulatory approach EPA has developed under Section 112.

Health risks 'not significant enough' to justify expense of control technology

The agency's struggle to develop a regulatory approach that properly balances costs and benefits in regulating hazardous air pollutants has not ended. In its proposed standards for wet-coal charged by-product coke oven batteries, EPA indicated it would consider adopting a one-step process that weighed both before-control and after-control risks, health risk reductions, and the economic and societal expense of obtaining those risk reductions. The one-step process would emphasize public health risks rather than emission estimates in selecting controls.[8] While the practical effect of such an approach remains to be seen, the proposal reflects the agency's ongoing effort to accommodate both the statutory mandate and economic realities.

As Congress has focused its attention on EPA's past failures to use its Section 112 authority aggressively, the agency has moved to evaluate the risks posed by a variety of pollutants. EPA has committed to make listing decisions on 20 pollutants by the end of 1986. To meet that commitment, it is developing scientific documents on each of these pollutants. An EPA Office of Air Quality Planning and Standards task force issued a draft report in September 1984 covering the pollutants EPA believes may require regulation under Section 112. The report assigns aggregate cancer risks to 49 pollutants. This so-called "Six-Month Study," officially entitled "The Magnitude and Nature of the Air Toxics Problem in the United States," currently is undergo-

ing external review by scientists and policymakers. Available in draft form from the agency, it identifies several pollutants and source categories that may be important contributors to the incidence of cancer from air toxics, and it suggests the need for improving the toxics database, both in terms of pollutants and source categories.

Coming year could be one of agency's most productive in hazardous air pollutant field.

Although the report's conclusions are preceded by lengthy caveats on the quality of the data relied on in reaching its conclusions, and although the preliminary nature of the report is emphasized repeatedly, it surely will serve as the basis for the agency's research and regulatory efforts in hazardous air pollution during the coming years. Moreover, while it is clear that most states cannot undertake extensive analyses of hazardous air pollutants, aggressive states can use EPA's list of possibly carcinogenic pollutants to determine which pollutants pose the greatest hazards within their own boundaries. They may then act to control emissions of those pollutants. Furthermore, Congress undoubtedly will consider the report, and its conclusions are likely to be reflected in proposed Air Act amendments.

It is highly unlikely that EPA will rest on the laurels of its previous regulatory efforts. Indeed, the "Six-Month Study" indicates that up to 2,000 incidents of cancer are due to the pollutants that had been studied. With data mounting and further studies planned, the coming year could be one of the agency's most productive in the area of hazardous air pollution.

In deciding whether to regulate under Section 112, the agency may be hard pressed to pursue any course other than a tough regulatory approach in the face of pressure from Congress and judicial challenges. Unfortunately, the tough regulatory approach the agency may be forced to take leads to a logical, technical, and legal box probably never contemplated by Congress. The degree of uncertainty in estimating pollutant levels by use of dispersion models (an uncertainty which is acknowledged by the air program) is further compounded by the uncertainty that results from extrapolating human health effects from questionable animal data (an extrapolation which is being debated in the scientific community and in the water and pesticide programs). Whether reasonable regulations can possibly result from such cumulative uncertainty is, at a minimum, open to doubt. Over the next few years, the challenge confronting the agency will be the integration of its own technical and regulatory work in its air, water, and pesticide programs into a single reasonable and acceptable regulatory fabric. □

FOOTNOTES

[1] *In testimony on November 7, 1983, before the Subcommittee on Oversight and Investigation of the House Energy and Commerce Committee, EPA Administrator William Ruckelshaus promised to make decisions on whether to regulate 20 to 25 pollutants as hazardous under Section 112. In June 1984, the agency promulgated standards for benzene emissions from one source category, proposed standards for another category, and withdrew its proposed standard for three other source categories. See 49 Federal Register 23498, 25322, and 23558 (June 6, 1984). In August, EPA announced that it would not regulate polycyclic organic matter as a hazardous pollutant under Section 112, a judgment required under Section 122 of the Act. 49 Federal Register 31680 (August 8, 1984). In September, the agency added coke oven emissions to its list of hazardous air pollutants, setting in motion the regulatory process of proposing emission standards for wet-coal charged by-product coke oven batteries. 49 Federal Register 36560 (September 18, 1984). That same month the agency issued a draft report on the magnitude and nature of the U.S. air toxics problem. At the end of October, EPA announced that it was withdrawing the standards it had previously proposed for radionuclide emissions. 49 Federal Register 43906 (October 31, 1984). Finally, in October it was reported that EPA soon will announce decisions not to list six substances as hazardous under Section 112.*

[2] Cleveland Electric Illuminating Co. v. EPA, *572 F.2d 1150 (6th Cir. 1978)*, cert. denied, *439 U.S. 910 (1978) (8 ELR 20312)*; Cincinnati Gas & Electric v. EPA, *578 F.2d 660 (6th Cir. 1979)*, cert. denied *439 U.S. 1114 (1979)*.

[3] *See*, e.g., *49 Federal Register 23479, col.2, June 6, 1984.*

[4] *See*, e.g., *49 Federal Register 23479, col.1, June 6, 1984.*

[5] *49 Federal Register 24330 (June 12, 1984).*

[6] See *49 Federal Register 23533 (June 6, 1984).*

[7] *49 Federal Register 23558, June 6, 1984.*

[8] *49 Federal Register 23545, cols.1 and 2, June 6, 1984.*

Answers to "Who Said It?"

(see quotations on page 35)

1. *The National Advisory Committee on Oceans and Atmosphere, commenting in its recent report, "Nuclear Waste Management and the Use of the Sea."*
2. *"Ronald Reagan's Second-Term Agenda," Fortune magazine, October 1984, (based on interviews with 40 present and former Administration officials.*
3. *Joel S. Hirshhorn, Senior Associate, Office of Technology Assessment, for the hearing record on September 10, 1984 of the Committee on Environmental and Public Works.*
4. *William D. Ruckelshaus, then EPA Administrator, in a letter to groups endorsing a report critical of EPA.*
5. *Sen. Bill Bradley (D-N.J.), commenting on forest damages (Congressional Record, August 9, 1984).*