

Attachment :

EXECUTIVE SUMMARY

PLAINTIFF'S EXHIBIT

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THE AIR TOXICS PROBLEM IN THE UNITED STATES:
AN ANALYSIS OF CANCER RISKS FOR SELECTED POLLUTANTS

U.S. Environmental Protection Agency
Office of Air and Radiation
Office of Policy, Planning and Evaluation

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PREFACE

This report on the air toxics problem in the United States is a final version of a September 1984 U.S. Environmental Protection Agency draft document entitled "The Magnitude and Nature of the Air Toxics Problem in the United States." Simultaneously with release of the draft report, EPA solicited comments on the analysis from a peer review panel made up of non-EPA experts in fields such as toxicology, air monitoring, and air pollution control. In response to the panel's comments, as well as to unsolicited comments received from several organizations, the authors have substantially revised the Executive Summary and have made changes in other parts of the report. The revised version more clearly delineates the limitations and caveats of the analysis. Also, the title of the report has been revised to recognize the limited scope of the analysis.

In addition, certain of the risk estimates have been changed as new information has become available. In particular, the risk estimates for nickel and ethylene dichloride have been revised substantially downward and methyl chloroform has been dropped from the analysis. The report has not been altered where the Agency is currently considering, but has made no final decision regarding, changes in certain of the data used in this analysis (e.g., potency information) or in the regulatory status of certain chemicals examined.

Several additions were made to the report. A new section has been added that delineates current activities within EPA resulting from the report, including a brief discussion of the national strategy for air toxics. Air quality data have been evaluated for 1970 and the estimated risks compared to those based on 1980 data to provide a more quantitative estimate of progress under programs for criteria pollutants. Finally, data from personal exposure monitoring have been converted to aggregate national risk for several compounds to enhance comparison of the indoor/outdoor air toxics problem.

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Goals

This report summarizes the results of a study which will be used by the U.S. Environmental Protection Agency (EPA) to provide a basis for consideration of strategies to deal with the ambient air toxics problem in the United States. The study attempted to assess the magnitude and nature of the air toxics problem by developing quantitative estimates of the cancer risks posed by selected air pollutants and their sources. Four basic questions were examined:

1. What is the approximate magnitude of the air toxics problem, as measured by the estimated cancer risks, associated with air pollution?
2. What is the nature of the air toxics problem, that is, what pollutants and sources appear to cause the problem and what is their relative importance?
3. Does the problem vary geographically, and if so, in what ways?
4. Are current air toxics data bases adequate? If not, what are the significant data gaps?

Context and Limitations

Readers of this report should fully understand the study's limitations so that its conclusions are interpreted correctly. The analysis was undertaken to orient EPA to the problem of airborne carcinogens, to stimulate policy discussions, and to guide further studies. Despite the fact that quantitative estimates of risk are presented in this report, the study was not initiated to support specific regulatory decisions. Instead,

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its goal was to obtain a quick assessment of the air toxics problem in the United States, and as such should be regarded as a "scoping" study only. Only readily available existing data were used regarding compound potencies, emissions, and ambient levels; no new data were collected. The only health effect examined quantitatively was cancer; health data on such effects as teratogenicity are not extensive enough to permit quantification. Also, acute health effects related to short-term exposures were not included.

Consideration of the limited scope of the study, as well as of the caveats and assumptions that are discussed in the text of the report, is an important responsibility of those reading and using this report. Some of the important caveats to keep in mind are identified later in the Executive Summary under "Sources of Uncertainty."

In summary, the risk estimates presented in this report should be regarded as only rough approximations of total incidence and individual risk, and should be used in a relative sense only. Estimates for individual compounds are highly uncertain and should be used with extreme caution. The reader is cautioned against applying these risk estimates to specific geographic locations, since the relative importance of particular pollutants and sources varies considerably from one place to the next.

As more data become available, these risk estimates will undoubtedly change. As such, the portrait of the air toxics

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problem depicted in this study should be regarded as a snapshot, the form and substance of which will certainly change as new data become available.

Analytical Methods

Three major analyses were undertaken to estimate cancer incidence and individual lifetime risks: each analysis included a separate set of compounds, with considerable overlap. The Ambient Air Quality Study used ambient data for five metals, ten organic compounds, and benzo(a)pyrene (BaP) to assess these risks. Two other analyses--the NESHAP Study and the 35-County Study--used emission estimates and exposure models to estimate incidence and maximum individual risks associated with the pollutants selected. In addition, a "BaP surrogate" approach was used to estimate cancer incidence associated with products of incomplete combustion (PIC): a dose-response coefficient relating lung cancer incidence and PIC was generated from epidemiological studies, and cancer incidence associated with PIC exposure was estimated by applying this dose-response coefficient to current ambient BaP levels. Finally, quantitative risk assessments available from other EPA activities for asbestos, radionuclides, and gasoline marketing were incorporated into the study.

Four additional reports were prepared to assist in interpreting the results of the study. One report reviewed national emissions data for over 90 compounds and provided summaries by source type, geographic location, growth trends, and data quality. Other papers were prepared on the atmospheric trans-

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formation of air pollutants, indoor/outdoor relationships for air toxics, and risk estimates used by other program offices within EPA in regulating selected toxic substances. Further, statistics on annual cancer incidence, cancer deaths, and estimates of the cancer cases associated with other causes (e.g., diet, smoking, indoor exposures) were compiled. The study team also analyzed and summarized the information available on several source categories for which current data are insufficient to perform a quantitative risk assessment. Finally, contacts made with all 50 state air pollution agencies, 33 local air pollution agencies, the Canadian government, and the Commission of European Communities revealed that virtually no other comprehensive studies are available that quantify estimated cancer incidence related to air toxics.

The study examined the magnitude and nature of the air toxics problem using existing data and, where possible, standard EPA techniques for quantitative risk assessment. We did not attempt to evaluate the validity of those techniques; rather, we tried to apply them as comprehensively as possible. For example, we relied on unit risk estimates generated by EPA's Carcinogen Assessment Group (CAG) and by Clement Associates, many of which represent plausible upper-bound estimates of unit risk. These estimates also assume 70 years of continuous exposure to outdoor ambient levels. However, where appropriate, we point out the

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possible effects of considering non-traditional approaches, such as examining the risks associated with indoor exposures to air pollutants.

Conclusions

Given the scope, limitations, methods, and assumptions discussed above, the following conclusions may be drawn from this study:

1. Both point sources (major industrial sources) and area sources (smaller sources that may be widespread across a given area, such as solvent usage and motor vehicles) appear to contribute significantly to the air toxics problem. Large point sources are associated with many high individual risks, while area sources appear to be responsible for the majority of aggregate cancer incidence.
2. While there is considerable uncertainty associated with the risk estimates for some substances, available data indicated that the following pollutants may be important contributors to aggregate cancer incidence from air toxics: metals, especially chromium and arsenic; asbestos; products of incomplete combustion; formaldehyde; benzene; ethylene oxide; gasoline vapors; and chlorinated organic compounds, such as chloroform; carbon tetrachloride; perchloroethylene; trichloroethylene; and vinylidene chloride.
3. A wide variety of sources contributes to individual risk and aggregate incidence from air toxics. These include: road vehicles; combustion of coal and oil; woodstoves; metallurgical industries; chemical production and manufacturing; gasoline marketing; solvent usage; and waste oil disposal. As a broad category of activities, combustion/incineration is probably the largest single source of risk.
4. For those cities with sufficient data for analysis, large city-to-city and neighborhood-to-neighborhood variation in pollutant levels and sources was found. However, our current air toxics data base is inadequate to accurately characterize most local air toxics problems.
5. Three analyses quantified estimated cancer risks due to 15 to 40 toxic air pollutants (the number of pollutants

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examined varied with the different analyses). The estimates from these analyses showed a range of 5 to 7.4 cases of cancer per million people per year (1,300 to 1,700 cases annually nationwide) for the pollutants examined. These are not actual predictions of incidence, but are instead a statistical way to represent the potential health effects of human exposure to airborne carcinogens.

The reader is reminded that these estimates are highly uncertain, and is cautioned that the convergence of the various analyses on a seemingly narrow range (5 to 7.4 cases per million) is somewhat coincidental, given that estimates for individual compounds varied widely among the different analyses.

For perspective, estimated nationwide cancer cases and cancer deaths for 1983 were 850,000 and 440,000, respectively.

6. Maximum lifetime individual risks of 10^{-4} (1 in 10,000) or greater in the vicinity of major point sources were estimated for 21 pollutants, about half of those that were studied. Maximum lifetime individual risks of 10^{-3} (1 in 1,000) or greater were estimated for 13 pollutants.
7. Additive lifetime individual risks in urban areas due to simultaneous exposure to 10 to 15 pollutants ranged from 10^{-3} to 10^{-4} . These risks, which were calculated from monitoring data, did not appear to be related to specific point sources. Instead, they represent a portion of the total risks associated with the complex pollutant mixtures typical of urban ambient air.
8. Some low-production organic chemicals appeared to contribute little to aggregate incidence: 21 organic chemicals were estimated to account for a total of less than 1.0 cancer cases per year nationwide. However, this conclusion may be due in part to the lack of data concerning the emissions and toxicity of these "exotic" chemicals.

Some of these low-production compounds did appear to be associated with high individual risks. For example, the maximum lifetime individual risk for 4,4'-methylene dianiline was estimated at 1.5×10^{-3} .

9. The study indicated that "non-traditional" sources of air toxics--such as publicly owned treatment works (POTWs) and hazardous waste treatment, storage and disposal

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facilities (TSDF's)--may pose important risks in some locations. For instance, preliminary findings suggest that POTW's with industrial indirect discharges may emit volatile organic compounds in excess of 100 kkg/yr. Individual lifetime risks for a single compound at one TSDF were estimated as high as 10^{-5} .

10. EPA's criteria pollutant programs appear to have done more to reduce air toxics levels than have regulatory actions aimed at specific toxic compounds. An analysis of 16 pollutants was completed using both monitoring and emission data in order to evaluate progress made on air toxics between 1970 and 1980. The estimated cancer incidence rate for these air pollutants in 1980 was less than half that for 1970, i.e., 6.8 per million per year in 1980, compared to 17.5 per million in 1970. This seems reasonable considering the diverse array of air toxics sources, the multipollutant nature of the problem, and the relative intensity of EPA's criteria and air toxics programs.
11. Even after regulations are implemented under Section 112 of the Clean Air Act for benzene and arsenic, these pollutants still appear to make significant contributions to aggregate incidence due to air toxics. This seems to demonstrate that the base for the air toxics regulatory programs needs to be broadened to include emissions from small area sources, such as combustion, road vehicles, and solvent use.
12. Major weaknesses and gaps characterize air toxics data bases at the federal, state, and local levels. The few air toxics emission inventories available generally show inconsistencies and anomalies, the air quality data available are often inadequate to develop population exposure estimates, and few compounds have been tested adequately for health effects. The data limitations preclude performing specific comprehensive risk assessments for most urban areas, for many compounds, and for many potentially large sources of air toxics risks (such as incineration, hazardous waste disposal, indoor exposures, atmospheric transformation, and Superfund sites).

Sources of Uncertainty

Many assumptions and extrapolations are necessary to transform ambient or modeled levels of air pollutants into exposure estimates.

Whether such assumptions introduce a high or low bias into the results is difficult to assess. However, it is clear that the use of such assumptions injects a considerable degree of uncertainty into the analyses.

Some of the factors which may have led the analyses to understate the risk of cancer related to air toxics are as follows:

1. Urban ambient air is characterized by the presence of dozens, perhaps hundreds of substances. Risk estimates for most of these could not be calculated due to data limitations.
2. Indoor concentrations of certain pollutants (e.g., radon, tobacco smoke, formaldehyde, and other volatile organic compounds) are commonly several times higher than outdoor concentrations. The estimated cancer incidence associated with indoor exposures to passive smoking (500 to 5,000 annually), radon (1,000 to 20,000 annually), and with 24-hour personal exposures to 5 organic compounds (1,500 annually) indicate that indoor sources make an important contribution to air toxics risks.
3. Risks due to compounds formed in the atmosphere could not be quantified in the analyses using exposure models, but there are indications that these risks may be significant. For example, formaldehyde is formed in the atmosphere by the breakdown of other organic compounds, and some compounds (e.g., toluene) may be converted into toxic substances through photochemical reactions.
4. Although it has been shown that certain combinations of exposures may have synergistic effects (for instance, smoking and asbestos exposure), all risks were assumed to be additive.

Factors which may have caused the analysis to overestimate cancer risks associated with air toxics are as follows:

1. Cancer unit risk values were obtained from EPA's Carcinogen Assessment Group (CAG) and Clement Associates. EPA unit risk values are generally regarded as plausible, upper-bound estimates. That is, the unit risks are not likely to be higher, but could be considerably lower. In many cases, the unit risk values are preliminary.

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2. The weight of evidence of carcinogenicity for the compounds examined varies greatly, from very limited to very substantial. Further, the extent of evaluation and health review performed varies considerably among compounds. For this report, a conservative scenario (i.e., that all compounds included in the report are human carcinogens) was assumed.
3. The risk assessments assume that people living in an area are exposed to the estimated ambient levels for 70 years, 24 hours a day. This especially compromises estimates of maximum lifetime individual risk. Few plants operate for 70 years, most people change their homes several times during their lives, and they also leave their neighborhoods during the day.
4. The degree to which outdoor emissions of many pollutants (e.g., trace metals) penetrate indoors is largely unknown. If emissions of a pollutant from outdoor sources do not penetrate completely indoors and if there are no indoor sources of that pollutant, then we will have over-stated risks, since we have assumed constant exposure to levels equalling those of outdoor air.
5. Although certain combinations of exposures may have antagonistic effects, all risks were assumed to be additive.

Current Activities

This study was completed and a draft was sent by the Agency through peer review late in 1984. Simultaneously, based on the preliminary findings of the analyses, EPA initiated a series of activities designed to examine the need for a new national strategy for air toxics. These included:

1. Formation of an Agency-wide Air Toxics Group to follow up on the study and to guide the development of any needed changes in national strategy.
2. Additional analytical studies to examine in more detail the controllability of the most important pollutants and the impact or risk of the current programs for criteria pollutants from now through 1995.

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3. Discussions of the results of the study and possible new national strategies with all interested groups, including industry, public interest organizations, state and local governments, and legislative staffs.

Although these activities will not be completed until mid-1965, EPA is beginning to explore several changes to its program for air toxics. The focus of direct federal regulation is shifting from an emphasis on isolated large point sources to more complex situations that have greater potential for high national incidence of cancer. Generally, this will mean increased emphasis on area sources and those point sources that emit several potentially toxic pollutants. In addition, several new activities are being considered that will provide for a more comprehensive national program. These include a federal partnership with state and local agencies to evaluate and, if necessary, regulate large point sources with emphasis on reduction of high individual risk situations, and an examination of problems caused by concentrations of sources within cities or industrial regions.

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