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COMMENTS

on the

Proposed Rules of the Environmental Protection Agency

to Establish

Policy and Procedures for Identifying, Assessing,

and Regulating Airborne Substances Posing

A Risk of Cancer

[OAQPS 79-14, 44 Fed. Reg. 58642 (Oct. 10, 1979)]

and on the

Advanced Notice Proposed Rulemaking

for Proposed Generic Standards

[A-79-13, 44 Fed. Reg. 58662 (Oct. 10, 1979)]

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February 21, 1980

INTRODUCTION

The Natural Resources Defense Council and the Environmental Defense Fund submit these comments on the Environmental Protection Agency's proposed policy for regulating airborne carcinogens under Section 112 of the Clean Air Act. We strongly support the adoption and implementation of a policy that will obtain effective control of cancer-causing air pollutants.

One American in four is expected to contract cancer, and one in five to die of it. The vast majority of cancer cases are preventable. Chemical and radioactive substances released into the ambient air from stationary sources are the sole or contributing causes of a substantial fraction of these cases. Controlling these carcinogenic air pollutants is a necessary step in the fight against this disease.

Although Congress gave EPA an urgent mandate to control these chemicals as "hazardous air pollutants" under Section 112 of the Clean Air Act, in ten years the Agency has set only four hazardous air pollutant standards. Yet there are as many as several hundred chemicals emitted from stationary sources that are known or strongly suspected to cause cancer. A quantum leap in EPA action under Section 112 is necessary if the Agency is to protect the public health, as the Clean Air Act requires.

As we detail in these comments, NRDC and EDF strongly support certain conclusions and determinations in the proposed policy. Specifically, we support:

- EPA's conclusion that the public is exposed to many--perhaps several hundred--air pollutants released from stationary sources which may reasonably be anticipated to cause cancer in humans.

- EPA's conclusion that even low levels of exposure to these pollutants increase the number of persons who may reasonably be anticipated to contract cancer and that no safe level of exposure to a carcinogen can be identified.

- EPA's conclusion that airborne carcinogens pose a major public health problem requiring strongly precautionary control of emissions to prevent deaths and serious illnesses.

- EPA's conclusion that positive results in human epidemiological studies and animal toxicological studies each are sufficient to establish that a substance is a human carcinogen.

- EPA's commitment to list and regulate as hazardous air pollutants many more carcinogens than the Agency has to date.

- EPA's determination to develop a set of quick and inexpensive "generic" control measures for certain industrial categories likely to release multiple carcinogens, to be imposed swiftly as a first step after listing, while more protective standards are developed.

- EPA's commitment to examine whether there are substitute products or processes that allow a complete elimination of carcinogenic emissions.

- EPA's recognition that because new plants have greater pollution control opportunities than existing ones, and because expansion of reliance on carcinogens should not be encouraged, new plants should be subject to greater emission control requirements than existing ones.

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In critical areas, however, the proposed policy must be radically improved if it is to meet the mandate of the law and the need to protect public health.

Our comments are directed to six key areas:

I. The Role of Airborne Pollutants in the Induction of Cancer

II. The Need for a Legally Binding, "Action Forcing" Process for Screening, Listing, and Controlling a Meaningful Number of Hazardous Air Pollutants

III. The Need to Resolve and Foreclose Generic Scientific Issues

IV. Determining the Appropriate Control Level for Airborne Carcinogens

V. The Need to Eliminate Arbitrary Dependence on Unreliable Quantitative Risk Assessments

VI. The Need for Improved Generic Controls as an Interim Measure

At this time NRDC and EDF are submitting a summary of our position on these issues. Before the close of the period for supplementary comments, we shall submit thorough analysis and documentation in support of the positions conveyed in this summary.

I. THE ROLE OF AIRBORNE POLLUTANTS IN THE INDUCTION OF CANCER

The World Health Organization as well as respected members of the scientific community have estimated that 60 - 90 percent of human cancers are associated with environmental factors. Support for this conclusion derives in part from the great variation in the incidence of most cancers, both from place-to-place and time-to-time; from the experience of migrants, among whom the risk of cancer changes to that of the adopted country in the course of one or two generations; and from the increasingly frequent demonstration of excessive cancer among various industrial groups.

Whereas some have suggested that lifestyle factors (diet, alcohol and cigarette smoking) are the major sources of environmental cancer, a recent NCI, NIEHS and NIOSH Report[1/] concluded that those estimates were based on the erroneous assumption that each cancer should be assigned to a single specific cause, were limited to the small number of known examples and were largely unsupported by documentation or critical review of data. In contrast, this NCI, NIEHS and NIOSH Report, the conclusions of which were considered by American Industrial Health Council consultants to be reasonable, estimated that in coming decades up to 20 percent and perhaps as much as 40 percent of cancer in the U.S. might be associated with occupational factors.[2/] While the possibility of overestimation has been raised regarding this report, it should be noted that the report only dealt with six substances instead of at least 18 substances known to be confirmed human occupational carcinogens. In arriving at these estimates, the NCI, NIEHS and NIOSH

1/ 45 Fed. Reg. 5031, 5033 (January 22, 1980).

2/ Ibid.

Report[1] noted:

> The initiation and development of cancer is a multi-phased, multi-causal process in which both external and internal factors act, probably at each of several stages, before frank, clinical cancer appears. It is likely that many, if not most, cancers are influenced by two or more different external factors acting simultaneously or sequentially. Thus, alcohol by itself appears to be a minor cause of cancer -- but alcohol combined with cigarette smoking leads to risks 15 times higher than those experienced by non-smoking non-drinkers. If a drinker smoker develops cancer of the oral cavity, to which 'cause' should it be attributed? Drinking or smoking? If we could correctly identify the proportions of cancer incidence 'attributable to' each of the classes of environmental factors considered by Wynder and Gori, the sum of these percentages would be considerably higher than 100. One of the best-studied examples of interaction between exogenous agents is that between asbestos and cigarette smoke in inducing lung cancer. Most lung cancers 'attributable to' asbestos are probably simultaneously 'attributable to'smoking. If current theories of a multi-causal process are correct, it seems likely that a large fraction of cancers which at first appear to be 'attributable to' smoking should also be 'attributable to' asbestos, radiation, and/or other occupational factors.

Of the six substances considered in the NCI, NIEHS and NIOSH Report, several including asbestos, arsenic and vinyl chloride have been emitted into or are present in the ambient air in such a way that significant human exposure results. Numerous studies have reported an excess of cancer among individuals residing in close proximity to industrial sources emitting each of these same three substances.

With regard to asbestos, Wagner's[2] study in South Africa, Newhouse's[3] studies in the United Kingdom and Bohlig's[4] study in Hamburg

1/ NCI, NIEHS and NIOSH Institutes. Report. 1978, p. 3. OSHA Hearing Exhibit 224b.

2/ Wagner, J. C., Steggs, C. A. and Marchand, P. Diffuse pleural mesothelioma and asbestos exposure in the North-Western Cape Province. Br. J. Ind. Med. 17: 260-271, 1960.

3/ Newhouse, M. L., and Thomps n, H. Mesothelioma of pleura and perit neum following exp sure to asbestos in the London area. Br. J. Ind. Med. 22: 261-269, 1966.

4/ Bohlig, H. and Hain. E. Cancer in relation to (cont'd on p. I-3).

reported that the risk of mesothelioma has spread beyond the factory, mine or asbestos mill gate. In 1964 Newhouse and Thompson[1] reported numerous cases of mesothelioma among individuals whose only identified asbestos exposure was associated with living one-half mile from an asbestos factory. This form of cancer only rarely is found in the absence of exposure to asbestos.

With regard to arsenic, three studies have shown an excess of lung cancer among inhabitants of communities with smelters emitting arsenic. Blot and Fraumeni[2] demonstrated that the 36 counties in the U.S. with copper, lead and zinc smelting and refining industries had a significantly higher lung cancer mortality among males ($p<0.001$) and females ($p<0.05$) than did counties in the rest of the U.S. Those 35 counties with industries processing nonferrous ores other than copper, lead and zinc showed no such excess of lung cancer mortality. According to the authors, the most likely explanation for the elevated lung cancer mortality was neighborhood air pollution from industrial sources of inorganic arsenic. In like manner, Newman, et al.,[3] demonstrated that the rate of lung cancer mortality among females resident in Anaconda, Montana, the site of a copper smelter known to be the point source for arsenic air pollution was significantly elevated (2.9/10,000 vs. 1.4/10,000; $p<0.05$).

(continued from preceeding page)
environmental exposure, type of fibre, dose, occupation and duration of exposure, in Bogovski, P. Gilson, Jr., Timbrell, V. Wagner, J.C. (eds): Proceedings of the Conference on Biological Effects of Asbestos, Lyon.

1/ Newhouse and Thompson, op. cit.

2/ Blot, W. J. and Fraumeni, J. F. Arsenical air pollution and lung cancer. Lancet 2: 142-144, 1975.

3/ Newman, J. A., Archer, V. A., Saccamano, G., Kuschner, M., Auerbach, O., Grondauhl, R. D., and Wilson, J. C. Histologic types of bronchogenic carcinoma among members of copper mining and smelting communities. Ann. N.Y. Acad. Sci. 271: 260-268, 1976.

More recently, Matanoski[1] reported that the lung cancer mortality for males residing in the census tract in which an arsenical-producing insecticide plant is located was significantly higher than for males in control census tracts. Exclusion of lung cancer deaths of persons who had been employed in the plant did not alter the statistical significance of the excess risk. The female rate of lung cancer mortality in that same census tract was higher than most control tracts, but the numbers were too small to attach any statistical significance to it.

Regarding vinyl chloride, Infante[2] and Iturra[3] each have reported an excess of central nervous system (primarily brain) mortality among residents of communities having vinyl chloride monomer or polymerization plants. These studies, while based upon relatively small numbers, are consistent with results showing a statistically significant excess of brain cancer among individuals occupationally exposed to vinyl chloride.[4] More recently, Brady, et al.[5] reported the results of a study of 26 confirmed cases of liver angiosarcoma and a similar number of controls with an internal malignant tumor other than primary liver

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1/ Matanoski, G. M. Progress in a community arsenic study. Proceedings of Toxic Substances in the Air Environment Specialty Conference. Pittsburg, 1976, pp. 31-41.

2/ Infante, P. F. Oncogenic and mutagenic risks in communities with polyvinyl chloride production facilities. Ann. N. Y. Acad. Sci. 271: 49-57, 1976.

3/ Iturra, H. A community vinyl chloride mortality analysis study. Proceedings of Toxic Substances in The Air Environment Speciality Conference. Pittsburgh, 1976, pp. 96-113.

4/ Waxweiler, R. J. Stringer, W., Wagoner, J. K., Jones, J. Falk, H., and Carter, C. Neoplastic risk among workers exposed to vinyl chloride. Ann. N. Y. Acad. Sci. 271: 40-48, 1976.

5/ Brady, J., Liberatore, F., Harper, P., Greenwald, P., Burnett W., Davis, J., Bishop, M., Polan, A., and Vianna, N. Angiosarcoma of the liver: an epidemiologic survey. J. N.C.I. 59: 1383-1385, 1977.

cancer. These controls were matched with the cases on the basis of age of diagnosis, race, sex and general place of residence. The authors noted that of 10 female cases of liver angiosarcoma (no direct occupational or therapeutic exposure to arsenic, vinyl chloride or thorium dioxide) five lived for prolonged periods of time within one mile of a VC polymerization plant or a PVC fabrication plant whereas none of their matched controls did so. This observation, according to the authors, lent support to the hypothesis that indirect modes of exposure to VC-PVC might be important in the etiology of liver angiosarcoma.

While the existence of cancer hazards in the extraplant environment has been demonstrated, it must be recognized that these community-based studies involving asbestos, arsenic and vinyl chloride were succ ssfully completed only because of the relative rarity of the form of cancer under study, i.e., mesothelioma, liver angiosarcoma or brain cancer, all forms of cancer previously having been shown to be excessive in studies of occupationally exposed groups, or because of the emission of a single carcinogenic substance from predominantly isolated industrial facilities.

Therefore, given the high probability of multiple substance emissions associated with modern industrial processes and the limitations of sensitivity inherent in current epidemiological methods, it is unlikely that the true impact of cancer resulting from specific air pollutants can ever be fully documented. Nevertheless, epidemiological as well as experimental observations would indicate that the potential impact of air pollutants on cancer indication could be even more substantial. Studies of individuals occupationally exposed to asbestos or irradiation have indicated that in the presence of another

agent, cigarette smoking, the risk of lung cancer is more than additive, or would appear within a shorter tim period, i.e., reduced latent pe d. Experimental studies involving fast-neutron irradiation and carbon tetrachloride in like manner have demonstrated the interactive effects of several agents on carcinogenesis. These findings, both epidemiological and experimental, raise further concern for the interactive effects of multiple effluents from industrial sources.

It stands to reason therefore that a similar, while mitigated effect, of the various occupational and industry-related carcinogens present in the general air, especially of cities and industrialized regions, accounts for a substantial portion of cancers occurring in the general population.

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The foregoing is merely an overview of the data supporting th regulation of airborne carcinogens. EDF and NRDC will submit additional materials on this subject in both supplemental and rebuttal comments.

II. THE NEED FOR A LEGALLY BINDING, "ACTION FORCING" PROCESS FOR SCREENING, LISTING, AND CONTROLLING A MEANINGFUL NUMBER OF HAZARDOUS AIR POLLUTANTS

A. EPA's Ten-Year Failure To Protect The Public From Carcinogenic Air Pollutants

In 1970, Congress enacted special provisions of the Clean Air Act directing EPA to protect the American people from cancer and other especially serious illnesses related to air pollution. Section 112 of the Act requires swift, precautionary, and highly protective federal regulation of the air pollutants that pose such risks. The Administrator must maintain and continually update a list of "hazardous air pollutants," substances emitted from stationary sources that he judges "cause, or contribute to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness." Within 360 days of placing a substance on the Hazardous Air Pollution List, EPA must set standards to protect the public health with "an ample margin of safety." [Section 112(a)(1), (b)(1)(A), (b)(1)(B).]

In ten years EPA has failed to carry out this mandate or even to make a substantial beginning. The Agency has the legal responsibility to protect the public from cancer and similar illnesses related to air pollution. But EPA has failed to screen, list, and regulate any meaningful fraction of the hazardous air pollutants. Considering cancer alone, there are as many as

several hundred substances that are reported to cause cancer in human or animal studies and that may be emitted to the air from stationary sources. Yet to date EPA has never undertaken any organized screening of these substances, has listed only six hazardous air pollutants, and has set standards for only four. And in every instance EPA has missed the 360-day statutory deadline for setting standards.[1/]

B. The Elements Of An "Action Forcing" Process: A Candidate List, A Legally Binding Commitment To List And Control At Least Twenty Hazardous Air Pollutants Each Year, And A Testing List

The airborne carcinogens policy will not remedy EPA's ten-year failure to carry out its duties under Section 112 unless EPA simultaneously establishes a legally binding pr cess that will assure control of all hazardous air pollutants within a reasonable time, not just a token handful. The process must include two elements. First, at the same time that it promulgates the policy, EPA must adopt a "Candidate List of Potential Hazardous Air Pollutants." The Candidate List must consist of the substances which an initial screening of the scientific literature, reports, and other information sources reveal have been reported to to cause cancer in human or animal studies and which may be emitted from stationary sources. Initially

1/ Standards for emissions of benzene have not been set even though the chemical was added to the hazardous air pollutant list nearly three years ago. The 360-day period for radionuclides is still running.

the Candidate List probably will consist of several hundred substances, and it must be updated periodically to reflect the results of studies of additional substances. Second, also upon promulgation EPA must adopt a legally binding schedule for adding a minimum number of candidate substances to the Hazardous Air Pollutants List each year, and for setting standards for them,until the public is protected from all hazardous air pollutants.

The Candidate List would serve several important functions. First, it would notify the public, industry, Congress, and EPA itself of the true scope of the potential airborne carcinogens problem. This perspective is essential to EPA for rational internal planning and priority-setting. Undoubtedly it will also help the Agency make the case within the Administration and to Congress for additional resources to control hazardous air pollutants. Second, the Candidate List would stimulate industries and others to develop and come forward with data on a candidate substance's toxicity and on whether and to what extent it is emitted and the public exposed. Third, the list would encourage voluntary action by industries to curb emissions of suspect substances.

The binding schedule for listing and regulating a minimum number of hazardous air pollutants each year is necessary to guarantee that actual progress accompanies the airborne

carcinogens policy. Without this commitment, EPA could continue its current failure to act despite the promises of the policy, or could slip back into inaction in the future.

NRDC and EDF believe EPA must list as hazardous air pollutants and set standards for a minimum of 20 candidate substances each year. Anything less would fail to guarantee minimally adequate progress toward the goal of protecting the public from the panoply of hazardous air pollutants, and thus would fail to meet the mandate of Section 112 of the Act.

The commitment to a Candidate List and to listing and regulating a minimum number of hazardous air pollutants per year would provide a rational basis for EPA's proposed priority-setting process, which as contemplated now is largely a sham. EPA cannot rationally set priorities unless it has defined the number of potential hazardous air pollutants and established the rate at which it will control them. Without identifying the potential problems, EPA can have no assurance that the pollutants it selects for regulation are the most serious threats to the public health. And without a binding minimum number to control each year, priority setting can easily degenerate into rationalization for inaction -- an interminable scholastic discussion over which hazards are most important, never leading to control of more than a handful. With a binding schedule, this cannot happen.

Adoption of a Candidate List and a minimum number of hazardous air pollutants listed and controlled annually would ease our misgivings concerning EPA's proposed criteria for listing a hazardous air pollutant. Under Section III(A) of the proposed rules, EPA would list only pollutants judged to present a "significant" risk of cancer. This is defined as pollutants found to cause cancer in humans or animals for which there is evidence of "significant" public exposure. [44 Fed. Reg. at 58654] In the proposal notice EPA promises that the "significance" requirement is intended just to avoid listing substances for which there is no evidence of public exposure through air pollution, such as "laboratory curiousities." [44 Fed. Reg. at 58647] But unless EPA is bound to controlling a minimum number of hazardous air pollutants each year, there will be an unacceptable danger that EPA officials, now or in the future, will use the "significance" requirement to frustrate control of any meaningful number of pollutants. With such a commitment, continued inaction cannot occur.[1/]

One more element is essential to a rational airborne carcinogens policy and priority-setting process: an "Air Pollutants Testing List." The Testing List would include the pollutants for which EPA, in screening substances for the Candidate List, found insufficient health effects data. Like

1/ We have further comments on priority-setting in Section V of these comments.

the Candidate List, the Testing List must be established when the rules are promulgated and updated periodically. The Testing List would help guide EPA and other agencies in determining priorities for testing programs. Moreover, by publicizing the need for more health effects data on these pollutants, the List will stimulate industry and the scientific community to perform and report such research voluntarily.

C. Substances For The Candidate List

Before the close of the period for supplemental comments, NRDC and EDF will submit a list of substances we believe must be placed on the Candidate List. These ar substances:

(1) that are reported to increase the risk of cancer either in at least one human epidemiological study or in at least one mammalian bieassay, and

(2) that may be released as air pollutants from stationary sources.

Of course our list is only a start; EPA must undertake a more comprehensive screening of the literature and other information sources available to it.

D. Substances For Immediate Listing And Control As Hazardous Air Pollutants

NRDC and EDF also will submit a list of pollutants that we believe should be the first hazardous air pollutants listed and controlled after promulgation of airborne carcinogen rules. The evidence that these substances "cause, or

contribute to, air pollution" and that they "may reasonably be anticipated" to cause cancer in humans is so compelling and has been available to EPA for so long that the Agency would be arbitrary and capricious to delay listing them any longer. The only valid reason for not immediately listing one or more of these, in our view, would be that EPA judges another substance to be a higher priority and lists it instead.

The precautionary nature of the hazardous air pollutant section of the Clean Air Act deserves special emphasis. In 1977, Congress amended definition of a hazardous air pollutant to emphasize that EPA must take preventive action on the basis not only of well-established incontrovertible fact, but on suggestive, probative, though not completely certain, information as well. Congress replaced the earlier definition of hazrdous air pollutants -- substances which "cause, or contribute to, an increase in mortality or an increase in serious, irreversible, or incapacitating reversible, illness" -- with the current definition -- substances which "cause, or contribute to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness." [Section 112(a)(1)]

The legislative history of this change makes very clear that Congress intended EPA to take precautionary action

to prevent harm before it occurred. Congress perceived that the subtlety of cause-and-effect relationships usually precludes precise and certain delineation of pollution-induced injuries for years after they are first recognized. In the interim, however, since the public's lives and health are at stake, the Clean Air Act directs the Administrator to take preventive action based on suggestive, developing evidence, as well as on well established fact. The House Report specifically endorsed the opinion of the District of Columbia Circuit Court of Appeals in Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir. 1976) (en banc), cert. denied 426 U.S. 941 (1976), in which this precautionary approach to public health regulation was most fully expounded. The House Committee added that this approac to the evidence is mandatory, not just authorized:

> [A] substantial element of judgment, including making comparative assessment of risks, projections of future possibilities, establishing margins of safety and margins of error, extrapolating from limited data, etc., are both necessary and permissible under the Act in order to protect public health....

H.R. Rep. No. 294, 95th Cong., 1st Sess. 50-51 (1977) (emphasis added) (See, generally pages 43-51)

By emphasizing that EPA must protect the public against risks of harm as well as actually demonstrated harm, Congress redoubled the urgency of listing a meaningful number of airborne carcinogens as hazardous air pollutants and setting standards to protect people from them.

E. EPA's Obligation To Seek Additional Resources

EPA may not complain that it lacks the resources to undertake these commitments. The Agency now faces so large a backlog of hazardous air pollutants largely because it evaded its responsibilities under Section 112 in the 1970's. Moreover, EPA can hardly expect to receive additional resources until it makes Congress aware of the true scope of the hazardous air pollutants problem. We stand ready to support EPA's requests for additional resources.

F. Protecting Public Health From Serious Illnesses Other Than Cancer

EPA's responsibilities under Section 112 do not end with protecting the public from exposure to airborne carcinogens. The Agency also must take steps to protect the public health from hazardous air pollutants causing other killing and disabling diseases, e.g., non-neoplastic respiratory disease, reproductive disorders, mutations, central nervous system diseases, etc.

As an interim measure, in selecting the 20 carcinogens to list and control as hazardous air pollutants each year, EPA must consider whether certain candidate substances may reasonably be anticipated to cause death or illness from other diseases as well as cancer.

Of course, EPA may learn of a non-carcinogenic pollutant that threatens more harm than the candidate carcinogens. In that event, the Agency should list and regulate this pollutant in lieu of one of the 20 carcinogens.

After promulgating the airborne carcinogen rules, EPA will have a responsibility to develop similar rules for identifying non-carcinogenic hazardous air pollutants. NRDC and EDF are considering proposing criteria for additional Candidate Lists for such substances.

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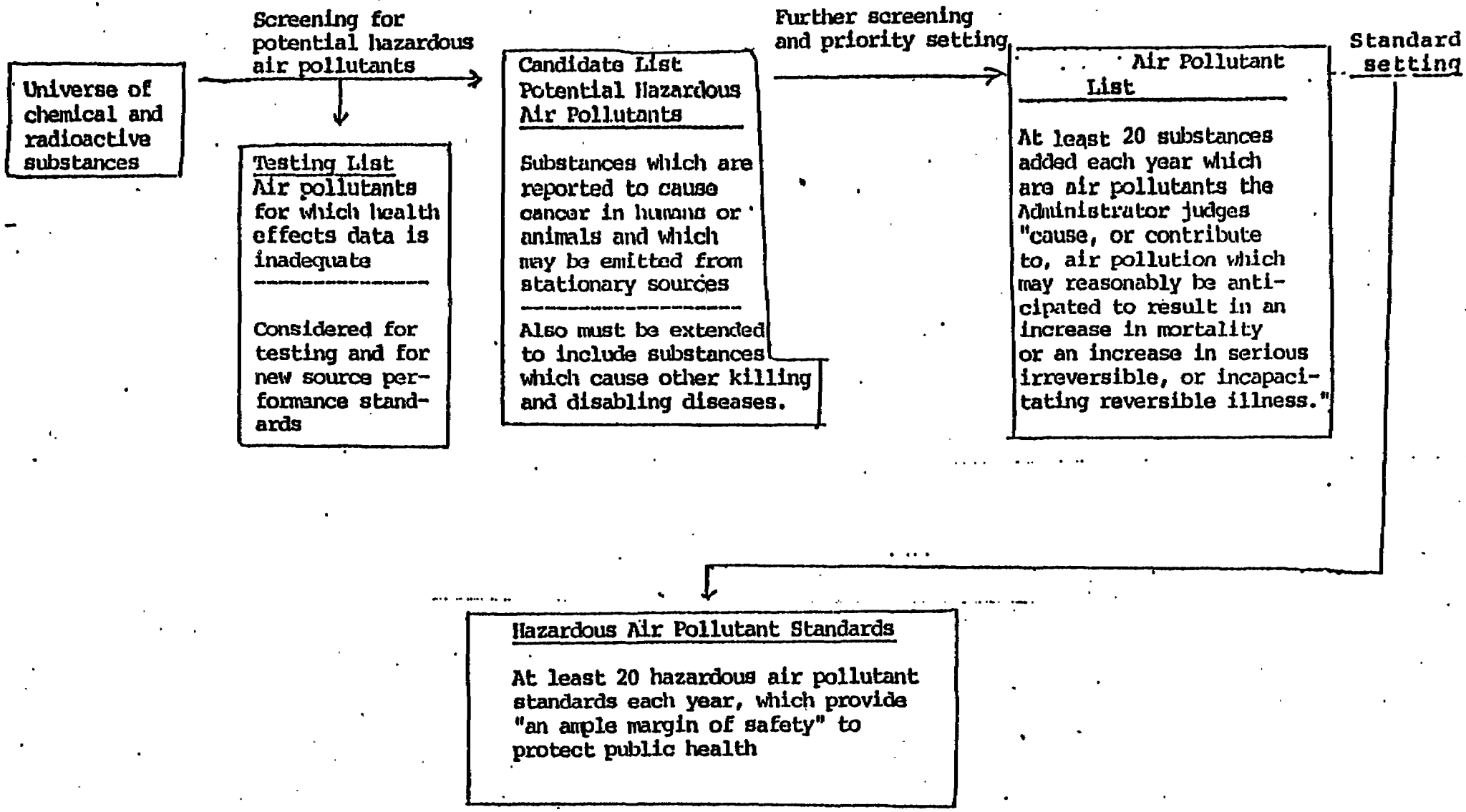
Figure II-1

An "Action Forcing" System For Screening, Listing, and Regulating Hazardous Air Pollutants



III. THE NEED TO RESOLVE AND FORECLOSE GENERIC SCIENTIFIC ISSUES

Experience regulating carcinogens in the 1970's has shown that there are many scientific issues common to every proceeding that transcend the particulars of each substance. They concern either common properties of all carcinogens, or questions that are equally "on the frontier of scientific knowledge" for all. Given the state of scientific understanding of carcinogenesis now and for the foreseeable future, and given the precautionary mandate of the Clean Air Act and other health and environmental protection laws, these generic issues necessarily must be resolved in the same way, on the same central body of evidence, in each proceeding.

In past proceedings, EPA and sister federal agencies have developed a consistent set of principles based both on the best scientific knowledge available today and on the precautionary public health protection policies embodied in their statutes. For example, that animal studies are a valid means of identifying human carcinogens, and that no safe dose of a carcinogen can be identified with current scientific knowledge. We expect that EPA will hold to these principles in future proceedings.

Yet in the current regulatory process, these issues are reconsidered from scratch in each regulatory proceeding,

despite the fact that generally no significant new information is presented that clarifies the issues on the frontiers of scientific knowledge or calls for a different resolution of them. This is enormously wasteful of the resources of the Agency, the scientific experts repeatedly called to testify or comment, and all parties to the regulatory proceedings. The only parties who gain are industries, who by relitigating these issues before EPA and the courts, delay the day when they must reduce the public's exposure to carcinogens.

To adopt and implement effective airborne carcinogen rules, EPA must foreclose the opportunity for this wasteful and dilatory rehashing of the generic scientific issues. In this generic proceeding EPA must adopt a set of principles, based on the best available scientific knowledge and the precautionary mandate of the Clean Air Act, that will not be proper subjects for relitigation in subsequent proceedings to set standards for individual carcinogens. To be sure, these issues may be reconsidered as science progresses, but only a proceeding to amend the generic airborne carcinogen rules.

The model for such action is the cancer policy recently adopted as a binding standard by the Occupational Safety and Health Administration. [45 Fed. Reg. 5001-5296 (Jan.22, 1980)] After the most exhaustive and thorough rule-making proceedings imaginable, OSHA adopted binding scientific

and policy conclusions that may be reconsidered only when significant evidence of a scientific breakthrough is presented, and only as an amendment to the generic cancer policy.

The central generic principles the policy must adopt and foreclose from reconsideration in substance-specific standard-setting proceedings are:

Epidemiology can never be positive in proving cause & effect

- That positive results either in at least one human epidemiological study or in at least one laboratory study in any mammalian species are sufficient for regulatory purposes to establish that a substance is a human carcinogen.

- That no safe level of exposure to a carcinogen can be identified.

- That positive studies must override studies that purport to show no effect, since the probability of failing to detect real effects in epidemiological and animal studies is very high.

- That in interpreting the results of animal tests:

  - positive results are valid even if the tumors are found only at doses higher than those to which people are exposed through air pollution. Such doses are necessary to detect carcinogens in small groups of animals.

  - tumors found in either sex and at any organ site are sufficient to establish that substance as a human carcinogen.

  - malignant and purportedly "benign" tumors must be given equal weight.

  - an increase in the rate of spontaneous tumors, or appearance of such tumors earlier than in unexposed animals, is sufficient for a positive finding.

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- positive findings in tests by inhalation and by other routes of exposure are entitled to equal weight.

- so-called "initiators" and "promoters" should not be distinguished and regulated differently.

- scientific understanding of metabolic and pharmokinetic processes is not yet adequate to rebut the human carcinogenicity of a substance shown to cause cancer in animals.

- results at the traditional level of "statistical significance" (95 percent confidence) are sufficient, but not necessary, for a positive finding of carcinogenicity. For example, the appearanc of rare tumors can warrant a positive finding even if the incidence is not "statistically significant.

- That regarding short-term or in vitro tests for mutagenesis:

  - positive results in a battery of such tests indicate a substantial risk of human carcinogenicity.

  - positive results support positive findings in human or animal studies.

  - positive results can support the conclusion that a substance is carcinogenic when the animal or human evidence alone would not.

  - positive results should give substances a high priority for animal or human studies, if these have not been performed.

  - negative results should be given no weight unless the substance is tested in a battery of short-term tests known to produce positive results for similar substances.

  - when a complex mixture of chemicals yields positive results in a battery of such tests, and when it is reasonably anticipated that multiple constituents of the mixture are independent mutagens, such results are sufficient alone to establish that the mixture is a human carcinogen.

- That regarding structural relationships among chemical substances:
  - structural similarity to known carcinogens, supported by positive results in short-term mutagenicity tests, or by human or animal evidence not alone sufficient, can establish that a substance is a human carcinogen.
  - chemicals structurally similar to known carcinogens should have a high priority for further testing.

NRDC and EDF will document the support for these principles in further submissions before the close of the period for supplemental comment.

IV. DETERMINATION OF APPROPRIATE CONTROL LEVELS FOR AIRBORNE CARCINOGENS

1. The Failure of the EPA Proposal to Address the Statutory Criteria Contained in §112.

Once a pollutant is listed under §112, the most important determination remaining is the appropriate degree of control to satisfy the statutory requirement. Section 112 of the Clean Air Act requires EPA to establish a standard which will provide an "ample margin of safety" to protect the public health. This requirement of an ample margin of safety stands in sharp contrast to the requirements contained in §108 and §109 which require only an "adequate margin of safety" for non life-threatening pollutants. Regrettably, the approach suggested by the Agency for determining emission standards which will protect public health with an ample margin of safety is at serious variance with the statutory requirements.

The Agency's proposal for meeting the statutory requirement relies on a two-step process. First, the Agency determines "best available technology" for both new and existing sources after considering the economic, energy and environmental impacts of various contr l technology options. For new sources, the Agency states that "for practical purposes this level of control . . . will, as a minimum, be quivalent to that which would be selected as the basis for a new source performance standard (NSPS) under §111. The requirement of 'best available technology' for new sources would consider 'economic feasibility' and would not preclude new construction."[1/]

1. 44 Fed. Reg. 68651 (Oct. 10, 1979).

For existing sources, the Agency states:

> The selection of BAT for existing sources may require consideration of the technological problems associated with retrofit and related differences in the economic, energy, and environmental impacts. In practice BAT for existing sources would consider economic feasibilty and would not exceed the most advanced level of technology that at least most members of an industry could afford without plant closures. 1/

Needless to say, neither of these specifications for the initial determination of appropriate control levels tracks the statutory language. Rather these are determinations which rely heavily on the consideration of economic and other factors unrelated to the basic health issues. As the Agency candidly noted, these procedures in fact become more akin to determinations under §110 and §111 than §112. By themselves these determinations are obviously inadequate to satisfy the statutory criteria.

It is only in the second phase of the control determination process that EPA even attempts to address the statutory health criteria. In this second phase, the Agency proposes to use the quantitative risk assessment developed for each chemical to determine whether the risk remaining after the application of best available technology to the source category is unreasonable. While this approach might be justified under other statutes which require EPA to regulate only if it can establish an unreasonable risk, this approach simply does not track §112 of the Clean Air Act.

Section 112 requires the Agency to establish standards which provide an ample margin of safety against the risk identified -- in this case of suffering incapacitating or irreversible health effects

1. Id.

from specific pollutants. By definition, any margin of safety is intended to make certain that no one suffers the threatened consequences. On the other hand, the EPA approach not only provides no margin of safety, but rather explicitly accepts a certain amount of residual risk to certain individuals. Needless to say, for these people there is no margin of safety, ample or otherwise.

Even more disturbing, EPA admits that it cannot define the term "unreasonable risk" in advance. The Agency is able only to state that among the factors to be considered are "(1) the range f total expected cancer incidence and other health effects in existing and future exposed populations to the anticipated operating life of existing sources; (2) the range of health risks to the most exposed individuals; (3) readily identifiable benefits of the substance or activity; (4) the economic impact of requiring additional control measures; (5) the distribution of the benefits of the activity versus the risk it causes; and (6) other possible health and environmental effects resulting from increased use of substitutes."[1] Needless to say, the factors listed above are not mentioned in §112, nor are they mentioned in the legislative history. Indeed, the whole concept of unreasonable residual risk is alien to §112. In effect, EPA has attempted to rewrite the statute to suit its own conception of an adequate regulatory scheme. Nowhere has the Agency squarely addressed the issue of what constitutes an ample margin of safety for airborne carcinogens. To address this issue, it is necessary to return to the statutory language itself as well as the pertinent legislative history.

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1. Id.

2. Legislative History of §112 of the Clean Air Act.

Because EPA has strayed so far from the original congressional intent, it may be useful to review the basic legislative history f §112, particularly the legislative history on the ample margin of safety requirement. Section 112 of the Clean Air Act originated with §115 of the Senate Bill, S.4358. This bill required the Secretary of the Department of Health, Education and Welfare (later the Administrator of EPA) to publish a "list of those air pollution agents or combination of such agents which available material evidence indicated were hazardous to the health of persons and which should be subject to a prohibition or emission standard established under this section." Like §112 in the present law, §115(b) of the Senate Bill defined a hazardous air pollutant as one whose "presence chronically or intermittently, in trace concentrations in the ambient air, either alone or in combination with other agents, causes or will cause, or contributes to, an increase in mortality or an increase in serious irreversible or incapacitating reversible damage to health."[1/]

To emphasize its concern over the hazards presented by these pollutants, the Senate Bill created a presumption that emissions of hazardous air pollutants should be prohibited altogether unless "the Secretary finds under paragraph 2(B) of this subsection that a departure from such prohibition for any stationary source will not be hazardous to the health of the persons. . . ."[2/] In short, the Senate Bill created a clear presumption that a prohibition on emissions would be issued -- that is, a zero emission standard. A departure from this flat prohibition, that is the promulgation

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1. S.4358, §115, 91st Cong., 2d Sess. (1970), reprinted in "A Legislativ History of the Clean Air Act Amendments of 1970," Vol. 1, Senate Committee on Public Works, 93rd Cong., 2d Sess. (1974), at 565-66.

2 Id.

f an emission standard which allowed some emissions, was authorized only if "the S cretary finds, bas d on a preponderance of the evidence on the record compiled at such hearing, . . . that the agent is hazardous to health but a departure from the proposed prohibition will not be hazardous to health, and he shall publish an emission standard for such agent."[1/]

EDF and NRDC submit that the only situation where the "agent itself is hazardous to health but a departure from the proposed prohibition will not be hazardous to health" is one where the agent is hazardous to h alth only at certain levels and does not present a hazard to health at levels below that concentration. Clearly, airborne carcinogens do not fit into this category. The Agency itself has stated on numerous occasions that there is no threshold level for carcinogens below which no health hazard exists.

Indeed, there is evidence that the Senate was especially concerned with pollutants which produced adverse health effects at even very low levels. For example, Senator Muskie stated:

> The bill provides the Secretary with the authority to prohibit the emission of hazardous substances. The Committee was presented with strong evidence that any level of emission of certain pollutants may produce adverse health effects that cannot be tolerated. 2/

In short, it is apparent that the Senate Committee clearly understood the difference between hazardous air pollutants which have definite health effects thresholds and those for which "any level of emission . . . may produce adverse health effects. . . ." In the latter case, the Senate clearly expected EPA to prohibit emissions altogether

1. S. Rep. No. 91-1196 at 58; Legislative History, supra, Vol. 1 at 458.

2. 115 Cong. Rec. 32902 (Sept. 21, 1970).

unless industry could make a convincing case that a threshold did in fact exist.

The House Bill contained similar language. The House, however, focused primarily on hazardous emissions from new sources. Section 112(B) of the House Bill set up two categories of new emission s urces -- those that emit extremely hazardous pollutants and those which emit other pollutants which imposed a less serious threat to health. Under the House Bill, EPA was required to set emission standards which would provide that:

> (1) If such emissions are extremely hazardous to health no new source of such emissions shall be constructed or operated, except where (and subject to such conditions as he deems necessary and appropriate) the Secretary makes a specific exemption with respect to construction and operation.
> (2) In the case of other emissions, any new source of such emissions shall be designed and equipped to prevent and control such emissions to the fullest extent compatible with the available technology and economic feasibility, as determined by the Secretary. 1/

In short, the House approach was similar to that of the Senate. The House created an explicit presumption that new sources of extremely hazardous emissions were to be prohibited altogether, unless the Secretary made a specific finding that their emissions would not endanger health. Ironically, the approach suggested by EPA in the proposed policy to regulate emissions of hazardous pollutants is much closer to that suggested by the House for the regulation of "other emissions," emissions which the House recognized were clearly much less hazardous and did not threaten irreparable injury. Significantly, it was only in the case of these other emissions

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1. H.R.17255, 91st Cong., 2d Sess. §5 (1970); Legislative History Vol. 2, at 920-22.

that the House was willing to have EPA consider the economic feasibility of availabl control techn logy.

The section of the Conference Bill which ultimately became §112 tracked both the House and Senate thinking. The Conference substitute specifically adopted the Senate provision for emission standards and recognized that such standards must provide "an ample margin of safety" to assure public health protection. If there was any remaining confusion as to whether an emission standard under the Conference Bill could require zero emissions, Senator Muskie dispelled that confusion. In an analysis of the Conference Committee Report prepared by Senator Muskie entitled "Discussion of Key Provisi ns," the Senator stated:

> The standards must be set to provide an ample margin of safety to protect the public health. This could mean effectively that a plant would be required to close because of the absence of control techniques. It could include emission standards which allowed for no measurable emissions. 1/

In short, §112 as finally adopted by the Congress created a presumption of a zero emission standard for those hazardous pollutants which had no identifiable health threshold. The presumption could be overcome in the course of rulemaking, but the burden of pro f was placed on those who would alter that presumption. In any event, the final emission standard was required to protect public health with an ample margin of safety.

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1. "Discussion of Key Provisions," reprinted in Legislative History, supra, Vol. 1 at 133.

3. Application of the "Ample Margin of Safety" Requirement to Airborne Carcinogens

Having reviewed the legislative history on the ample margin of safety requirement, the next step is to apply this requirement to EPA's proposed policy on airborne carcinogens. As noted in the introduction to this section, EPA has yet to come to grips squarely with the issue of what constitutes an ample margin of safety for an airborne carcinogen. Rather than face this issue directly, the Agency has chosen to adopt a totally different standard -- that of unreasonable residual risk -- to determine whether controls beyond the equivalent of NSPS or RACT in the case of existing sources are called for by the statute. The use of the unreasonable residual risk criterion explicitly accepts the fact that some people will contract cancer, even after BAT controls have been applied to new and existing sources of airborne carcinogens. This willingness to accept a certain number of cancer deaths stands in sharp contrast to the statutory command that a standard protect affected individuals with an ample margin of safety.

Ironically, the approach proposed by EPA to regulate airborne carcinogens may actually afford the population relatively less health protection than the approach taken to regulate pollutants covered by §109 standards. Under §109, EPA is required to adopt ambient air quality standards which provide an "adequate margin of safety." Although the safety factors which have been incorporated into the existing ambient air quality standards are quite modest, it can be argued that at least these standards do provide some margin of safety, that is, the standard is set sufficiently below the threshold at which health effects have been identified that even susceptible members f the population are protected from the

observed effects. 1/

In contrast t the foregoing approach, EPA is explicitly proposing to reject its responsibility to protect all members of the population with some margin of safety from the threat posed by airborne carcinogens. Because the Agency has been unable to identify a threshold for carcinogens, it has simply decided that it will accept a certain number of deaths and ignore the ample margin of safety requirement. In short, the Agency feels it has no responsibility to protect each exposed member of the population. Rather, it assumes that it has fulfilled its statutory responsibility if it protects most members of the population, even if the remaining residual members contract cancer. For these residual members of the population, there is obviously no margin of safety, ample or therwise.

The foregoing analysis is also supported by applicable case law on the ample margin of safety requirement. Although there has been no explicit holding on section 112, there is case law interpreting the "ample margin of safety requirement" in §307 of the Federal Water Pollution Control Act, which is directly applicable. In Environmental Defense Fund v. Environmental Protection Agency, 598 F.2d 62 (D.C. Cir. Nov. 3, 1978), the D.C. Circuit ruled directly on the ample margin of safety requirement contained in §307. Even more important, the court referred directly to the use of that term in the Clean Air Act. To quote the court's opinion:

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1. EPA's recent revision to the ozone standard makes it arguable whether the present standard provides any margin of safety for susceptible populations. Nevertheless, the Agency has at least accepted its responsibility to set a standard with an adequate margin of safety in theory.

The "ample margin of safety" standard was taken originally from technical jargon for use in section 112 of the Clean Air Act Amendments of 1970, the hazardous pollutants provision. See note 28 supra. One academic commentator has traced the history of the use of this term:

> The term [margin of safety] seems to have been borrowed in the first instance from the field of engineering. It is a common engineering practice to incorporate a factor of safety into the design of a structure to "ensure that under full working loads the stress will nowhere exceed a safe working limit." The safety factor is meant to compensate for uncertainties and variabilities in design, materials, workmanship, and so forth; the greater the variability, the larger the factor of safety.
>
> That the use of the term "margin of safety" in section 307(a) was similarly meant by Congress to take into account and compensate for uncertainties and lack of precise predictions in the area of forecasting the effects of toxic pollutants is confirmed by reference to the Clean Air Act. FWPCA section 307(a) is very similar to section 112 of th Clean Air Act. Among the similarities is the requirement in both that any standard set should provide "an ample margin of safety." 1/

In short, the court makes it clear that its interpretation of the ample margin of safety requirement in §307 of the Federal Water Pollution Control Act is taken from its understanding of the comparable phrase in §112 of the Clean Air Act. To place the ample margin of safety requirement in context, the court also refers to the adequate margin of safety requirement in §109 discussed above:

> Congress . . . provided in section 307(a) of the FWPCA, as in section 112 of the Clean Air Act, that the "margin of safety" be "ample." This is in contrast to the requirement of section 109 of the Clean Air Act that primary air standards assure an "adequate margin of safety"; the requirement of the Safe Drinking Water Act that contaminant levels for public water supplies be set

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1. EDF v. EPA, 598 F.2d at 80-81.

> at a level to assure "an adequate margin of safety"; or the requirement of section 303(d)(1)(C) of the [1972 Act] that waste load allocations be established at simply "a margin of safety."
>
> "Ample" is defined as "abundant; plentiful; more than adequate." Clearly Congress intended that in dealing with toxic pollutants that pose a threat to human health, margins of safety should be generous to ensure protection of human health and aquatic ecosystems to the greatest extent possible.

Hall, The Control of Toxic Pollutants Under the Federal Water Pollution Control Act Amendments of 1972, 63 Iowa L. Rev. 609, 629, 630 (1978) (footnotes omitted) (emphasis in original). 1/

Of particular importance in the case of airborne carcinogens is the court's statement that "[t]he foregoing analysis demonstrates that the term 'margin of safety' was intended to provide protection 'against hazards which research has not yet identified.'"2/ It is precisely because of the difficulties in quantifying the risks posed by airborne carcinogens that the court concluded that a margin of safety was necessary in the setting of standards to control these substances.

The extent of government authority to protect public health from carcinogens is demonstrated by the court's discussion of a series of cases regarding OSHA's attempts to regulate carcinogens in the workplace. In commenting on these cases, the court noted:

> These cases demonstrate the inevitable tension attending regulation of carcinogens. Frequently, such regulations have severe economic impact. Indeed, sometimes, as alleged by industry petitioners in this case, such regulations may jeopardize plants or whole industries, and the jobs depending on them. In such circumstances, the temptation to demand that the agency furnish conclusive proof of carcinogenicity as support for the regulations is great. However, the decision to delegate authority to an agency to control suspected

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1. Id. at 81.

2. Id.

> carcinogens is a legislative judgment that is not open to question in this court. Congress's direction to EPA to protect against incompletely understood dangers could not be carried out if we were to adopt the proof requirements advocated by industry petitioners.
>
> . . . If regulation were withheld until the danger was demonstrated conclusively, untold injury to public health could result. Accordingly, we find that Congress has allowed EPA to support a prohibition on the basis of strongly contested and merely suggestive proof.1/

Perhaps most significant, the D.C. Circuit has explicitly rejected the consideration of economic and technical feasibility in setting standards for carcinogens. As noted above, EPA proposes to rely very heavily on technical and economic feasibility judgments in defining best available technology and in determining what additional controls it might consider if it determines that an unreasonable r sidual risk remains after application of BAT. In Hercules, Inc. v. Environmental Protection Agency, 568 F.2d 91 (D.C. Cir. 1978), decid the same day as EDF v. EPA, the court explicitly held that the ample margin of safety requirement of §307 of the FWPCA does not authorize EPA to consider economic and technical feasibility factors in setting standards. In reaching this conclusion, the court went through a lengthy analysis comparing the technology-based provisions of the FWPCA with those provisions designed to control toxic substances. Because a similar distinction exists in the Clean Air Act, it may be useful to review the court's reasoning. Indeed, the court in its analysis, once again, relies on the distinction in the Clean Air Act between §§111 and 112.

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1. EDF v. EPA, supra, at 88-89.

> The legislative background explains why Congress focused on public and environmental protection, rather than discharge control technology, in the setting of toxic standards. The regulatory scheme is similar to that of the Clean Air Act Amendments of 1970, Pub.L.No. 91-604, 84 Stat. 1676, which distinguished between pollutants subject to technology-based regulation under section 111, and hazardous substances, subject to health-based regulation under section 112. Recognizing that "certain pollutants" required special treatment because of risk to health, Congress enacted section 112, dealing with hazardous pollutants, without provision for considerations of feasibility. 1 Senate Comm. on Public Works, 93d Cong., 2d Sess., A Legislative History of the Clean Air Act Amendments of 1970 (hereafter, Clean Air Legislative History), at 133 (Comm. Print 1974) (remarks of Sen. Muskie) (The Senate subcommittee on Air and Water Pollution "was presented with strong evidence that any level of emissions of certain pollutants may produce adverse health effects that cannot be tolerated." Id. at 227.). 1/

After reviewing similar language in the legislative history of the 1972 Federal Water Pollution Control Act Amendments, the court concluded:

> In light of this clear statutory wording and legislative history, it is not surprising that numerous commentators agree that considerations of technological and economic feasibility do not play a part in standard-setting for toxic substances. 2/

In reaching this conclusion, the court explicitly recognized that the technology may not presently exist which will reduce levels of carcinogens to levels low enough to provide an ample margin of safety. The court noted that the Supreme Court in Train v. NRDC, 421 U.S. 60, 91 (1975), determined that:

> . . . certain sections of the Clean Air Act imposed requirements of a "technology-forcing character." In Union Electric Co. v. EPA, 427 U.S. 246, 257, 96 S.Ct. 2518, 49 L. Ed.2d 474 (1976), the Court elaborated that such statutes "are expressly designed to force regulated sources to develop pollution control devices that might at the time appear to be economically or technologically infeasible." 3/

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1. Hercules, Inc. v. EPA, supra, at 112.

2. Id. See also discussion at 111, "...nor is there present any term commonly used to den te a feasibility consideration..."

3. Id., n.41.

In response to Velsicol's argument that, if feasibility is not considered in setting standards for carcinogens, the resulting regulations will be promulgated at irrationally strict levels, the court noted that:

> However, the congressional selection of factors is a legislative determination that the need of the public and the environment for protection from toxic chemicals is more important than the problems of stringent regulation. This congressional determination is a rational response to the dangers presented by toxic substances. The meaning of the statute being clear, it is not this court's prerogative to impose considerations of feasibility. See Tennessee Valley Authority v. Hill, 437 U.S. 153, 98 S.Ct. 2279, 57 L.Ed.2d 117 (1978); Union Electric Co. v. EPA, 427 U.S. 246, 96 S.Ct. 2518, 49 L.Ed.2d 474 (1976). 1/

In short, it is now well settled that EPA may not consider questions of technical and economic feasibility in setting emission standards under §112 of the Clean Air Act. The Federal Water Pollution Control Act cases are directly applicable since the court's analysis in those cases proceeds from its understanding of Congress' intent regarding similar provisions in §112 of the Clean Air Act.

Finally, EPA is in no position to argue that the ample margin of safety requirement in §112 has implicitly been overruled by the passage of the Toxic Substances Control Act and the adoption f unreasonable risk criteria for regulation in that Act. The D.C. Circuit in EDF v. EPA dealt explicitly with this issue. In that case industry had argued that the adoption of the Toxic Substances Control Act effectively "preempted" EPA's authority under §307 of the 1972 Federal Water Pollution Control Act Amendments. They

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1. Hercules, Inc. v. EPA, supra, at 112.

asserted that EPA's ban on the discharge of polychlorinated biphenyls (PCBs) into waterways made manufacturing and processing f PCBs impossible and that TSCA's phaseout timetable and exemption authority showed that Congress did not intend PCBs to be completely and immediately phased out.

The court rejected the industry argument and agreed with EPA. To quote the court:

> Strictly speaking, the claim made by industry petitioners is one of "repeal by implication," the overriding of one statute by a later enactment sub silentio, rather than a claim of "preemption." "It is, of course, a cardinal principle of statutory construction that repeals by implication are not favored." United States v. United Continental Tuna Corp., 425 U.S. 164, 168-69, 96 S.Ct. 1319, 1323, 47 L.Ed.2d 653 (1976) (collecting cases). "Implied repeals occur if two Acts are in irreconcilable conflict." Runyon v. McCrary, 427 U.S. 160, 172-73 n.10, 96 S.Ct. 2586, 2595, 49 L.Ed.2d 415 (1976) (emphasis added). When confronted with statutes that are "capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." Regional Rail Reorganization Act Cases, 419 U.S. 102, 133-34, 95 S.Ct. 335, 353, 42 L.Ed.2d 320 (1974) (quoting Morton v. Mancari, 417 U.S. 535, 551, 94 S.Ct. 2474, 41 L.Ed.2d 290 (1974)).
>
> Not only is there no "clearly expressed congressional intention" that TSCA repeal EPA's prior regulatory authority, and no "irreconcilable conflict" between TSCA and the 1972 Act, but, in fact, Congress carefully and explicitly harmonized TSCA with prior enactments. Section 9(b) of TSCA, 15 U.S.C. §2608(b) (1976) (emphasis added), provides, in part:
>
> > If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in . . . other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this chapter. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

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> Section 9(b) leaves EPA the choice of regulating toxic substanc s under TSCA, other statut s (such as the 1972 Act), or both. Throughout debate over passage of TSCA, representatives of the chemical industry urged that it would be unnecessarily duplicative of existing authority, and that EPA should not be given a choice among multiple regulatory authorities. Congress rejected those arguments which petitioners, in effect, now seek to resurrect. Congress determined that a choice among regulatory authorities was necessary so that EPA could use the most effective means available to combat unknown and potentially extreme risks from toxic substances, and that judicial review of EPA's choice was inappropriate. Our interpretation of section 9(b) is reinforced by section 6(e)(5), 15 U.S.C. §2605(e)(5) (1976), which states: "[t]his subsection [6(e) (governing PCBs)] does not limit the authority of the Administrator, under any other provision of this chapter or any other Federal law, to take action respecting any polychlorinated biphenyl." 1/

In the case of §112, the argument is even more compelling. Congress amended the Clean Air Act in 1977 following the passage of the 1976 Toxic Substances Control Act and decided to retain the ample margin of safety language contained in §112.2/ Congress did amend §112 but increased EPA's ability to regulate carcinogens by authorizing work practice standards where emission standards were not feasible. In no way did the amendment to §112 reduce EPA's responsibility to set standards to protect health with an ample margin of safety. Thus, there is no statutory basis in TSCA or any other subsequent legislation to argue that the ample margin of safety requirement in §112 has been repealed by implication. Unless EPA can find some firm statutory or other support for its unreasonable residual risk standard, the approach must fall.

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1. EDF v. EPA, supra, at 76-77.

2. In addition to explicitly retaining the "ample margin of safety requirement," Congress expanded EPA's authority by directing it to regulate not only substances which "cause" irreversible health effects, but also those which may "reasonably be anticipated" to do so. This further emphasizes the precautionary appr ach embodied in §112.

4. Proposed Approach for Determining Appropriate Control Levels for Carcinogens Regulated under §112

Having reviewed the deficiencies of the EPA proposal for determining control requirements in light of the legislative history of §112 and applicable case law, the next step is to present a modified approach which will more closely meet the requirements of the law. EDF and NRDC believe that a number of approaches are feasible, but will describe them only briefly in this section of the comments. A more detailed discussion will be presented in the public hearings and in subsequent rebuttal comments. To clarify the analysis, we will divide our comments into requirements applicable to existing sources and those applicable to new sources. Furthermore, in this section, we will deal primarily with proposals designed to reduce emissions from discreet process sources and defer discussion of EPA's proposed housekeeping requirements to reduce fugitive emissions until the next section. Finally, much of the discussion which follows will focus on control requirements applicable to the synthetic organic chemical industry, since this industry is the source of many of the potential candidates for regulation under §112. However, EDF and NRDC wish to emphasize that control of inorganic carcinogens under §112 should receive equal priority. Because control requirements for these latter sources are somewhat different, however, they will not be stressed in these comments and will be reviewed in more detail lat r at the public hearing.

A. Control Requirements Applicable to Process Emissions From Existing Sources of Airborne Carcinogens

From the foregoing review of the legislative history and applicable case law, it would be relatively easy to conclude that

Congress intended EPA to establish a zero emission standard for any airborne carcinogen for which evidence of a threshold was lacking. Needless to say, this would cover virtually all of the known carcinogens, since thresholds have not yet been established for any of them. This, of course, does not mean that thresholds could not exist. It may be that as additional research is completed that thresholds will be identified for at least some carcinogens.

In the meantime, EDF and NRDC suggest that the Agency adopt the approach recommended in the legislative history -- that is, that a presumption be created for a standard of no measured emissions unless the affected industry can establish that such a standard is not immediately achievable through either product substitution or process change. To make certain that a decision on appropriate controls is made in a timely fashion, EDF and NRDC suggest that the proposed policy provide that a no measured emission standard will go into effect within one year of the listing of a chemical, unless an alternate standard has been agreed upon by the affected industry and the Agency. This will give industry a strong incentive to quickly review the opportunities for product substitution as well as process change. If the companies can demonstrate to EPA that neither approach is available to reduce emissions to essentially the zero level, the industry would have the burden of demonstrating that no control technology was available which could achieve the no measured emission level.

If control technology capable of achieving no measured emissions is not currently available, the Agency should establish a schedule of phased reductions leading to the zero emission goal. This schedule would require immediate installation of the best available

technology and would mandat specific additional reductions along a phased schedule. This approach is consistent with the requirements of §112 and is further authorized by the Supreme Court's holding in Union Electric Co. v. EPA, 427 U.S. 246, 257 (1976) where the Court specifically found that certain sections of the Clean Air Act are expressly designed "to force regulated sources to develop pollution control devices that might at the time appear to be economically or technologically infeasible."

This approach will also reduce the resource burden on EPA considerably and allow the Agency to regulate many more carcinogens under §112 than would otherwise be possible. If EPA adopts the approach outlined in the proposed policy, it is quite likely that a tremendous expenditure of time and resources would be required to establish even the baseline BAT standards. EPA has proposed to go through essentially the NSPS process for each pollutant subject to regulation under §112. EDF and NRDC feel that this approach is b th unwise and ultimately unworkable. Effectively, it will mean that development of even proposed standards may take from one to two years after a decision has been made to regulate a particular chemical. Furthermore, EPA itself is assuming a completely unnecessary burden of proof which is self-imposed. The legislative history makes clear that a prohibition on emissions is to be the presumption in cases of airborne carcinogens. If industry wishes to challenge that presumption, it should carry the burden of proof. EPA's only responsibility is to determine whether a listed substance meets the health criteria outlined in §112. If it does, and if no threshold has been identified, then the burden of proof as to appropriate control requirements shifts to industry. If industry chooses to not

not assume this burden, then a "no measured emissions" standard would automatically go into eff ct 360 days after listing.

B. Control Requirements Applicable to New Process[1] Emission Sources

The approach for determining appropriate emission limits for new sources of airborne carcinogens is similar to that used for existing sources, except that the additional problem of expansion at existing sites must be addressed. For new "greenfield" sites, the presumption of a no measured emission standard applies, unless industry can conclusively demonstrate that substitutes for the product are not available or that a combination of process change and control technology cannot achieve a no measured emission level.

For expansions at existing sites, a different set of rul s must be adopted. EDF and NRDC suggest that the Agency extend its existing emission offset policy to these modifications at existing sources. Under this approach, a facility could expand only if it could demonstrate that the additional emissions generated by the expansion would be offset by an additional reduction in emissions of the same hazardous pollutant from the existing facility. This offset approach will preclude any increase in ambient concentrations of hazardous pollutants at existing sites. Needless to say, a simple best available control technology standard for expansions at existing sites would not ensure this goal. EDF and NRDC submit that the only alternative to such an offsets approach is a flat prohibition on expansions of sources at existing sites. Adoption of an offset

1. "Process," as used herein, refers to emissions from discreet vents or "stacks" intended to convey emissions to the outside air.

policy, however, should make this unecessary if existing sources continue to move toward a zero or no measured emission goal.

The proposals outlined above depart significantly from those contained in the EPA airborne carcinogen policy. EDF and NRDC do not believe that the provisions applicable to new sources set out in the policy meet the requirements of §112. Although the EPA policy would establish presumptive emission standards based solely on health effects considerations, the Agency has provided for an elaborate exemptions process which will effectively ensure that most sources are regulated under one of the exceptions, rather than under the presumptive emission standard. Moreover, the risk avoidance criteria, by providing for a waiver from the presumptive emission standard, will actually encourage the proliferation of facilities emitting carcinogens in presently lightly populated areas. Needless to say, this is not an emissions control approach; it is an emission dispersion approach. Unfortunately, EPA has no authority to control the use of land around new sites. It cannot impose subsequent growth controls and prevent people from moving into areas around new sources of carcinogens. If there is any doubt about this proposition, one only has to consider the experience of airport operators who have located facilities in previously "remote" areas. Dulles Airport in Washington, D.C. is an immediate example that comes to mind.

In short, EPA simply cannot prevent people from "coming to the nuisance." The only solution is either a prohibition on new sources or an extremely tight set of standards.

V. THE NEED TO ELIMINATE ARBITRARY DEPENDENCE ON UNRELIABLE QUANTITATIVE RISK ASSESSMENTS

Under the proposed rules EPA would continue to mak unwarranted use of unreliable quantitative methods for assessing human cancer risk. This is neither required by the Clean Air Act nor a rational exercise of EPA's discretion.

However desirable quantitative accuracy may be in principle, the scientific knowledge necessary for reasonably reliable and precise estimates simply is not yet available. Current knowledge about chemical and radioactive carcinogenesis is primarily qualitative, not quantitative. Through epidemiological and animal studies, submammalian tests, and studies of structural relationships, it is possible to identify reliably substances that pose a cancer risk for humans. It is not currently possible, however, to predict the size of that risk with anywhere near the precision and reliability needed for the estimate to be useful in making regulatory decisions. We summarize here the reasons why quantitative risk assessments may not rationally be used as EPA has proposed, and we will file supplementary comments with further information on these points.

A. The Unreliability of Quantitative Risk Assessments Derived from Animal Studies

Most human cancer hazards are identified through tests on laboratory mice, rats, or other rodents. Though qualitatively reliable, these tests cannot provide usefully precise and reliable

quantitative estimates of human risk. The sources of uncertainty are:

- High-to-Low Dose Extrapolations. For practical reasons, laboratory studies must be conducted with small groups of animals, usually not more than several hundred, usually at doses much higher than those to which the general public is exposed. The first obstacle for quantitative risk assessments is to extrapolate the results of the high-dose tests to the incidence likely in animals at lower doses. Reflecting scientific uncertainties over the mechanisms of cancer induction, there are numerous mathematical models for extrapolating to low dose risks. Although the models all "fit" the high-dose data reasonably well, they yield widely divergent estimates of the risks associated with low doses. For example, the major models differ by a factor of 100,000 on the dose projected to cause one extra cancer in a million animals.1/

- Scaling Factors. Additional uncertainty is added by the need to extrapolate across species lines from animals to humans. Rodents are smaller than humans. They live approximately 1/35th as long. Their rates of metabolism and cell division are much faster. These and other differences complicate quantitative comparisions. There is uncertainty whether the proper way to scale doses is on the basis of relative body weights, relative cell surface areas, relative lifespans, or on some other basis.2/

Recent attempts to quantify the risk from saccharin graphically illustrate the magnitude of the uncertainties attributable just to differences among models and scaling assumptions. Using the results of recent animal sutdies, the various plausible models, and different assumptions about how to cross species lines, the National Academy of Sciences attempted to quantify the effects of

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1/ Cornfield, "Carcinogenic Risk Assessment," 198 Science 593, 694 (1977).

2/ Rall, "Problems of Low Doses of Carcinogens," 64 Wash. Acad. of Sci. 63 (1974).

consuming one can of diet soda per day. The NAS concluded that in each 50 million people there could be as few as 0.0007 cancers per year or as many as 3,640. This is a range of error more than 5 million-fold.1/ See Table V-1, on the following page. A more recent study calculates an even higher risk for exposure to saccharin, extending the range to 10-million-fold.2/ Estimates for the human risk associated with exposure to one part per million of vinyl chloride extend over a one million-fold range as well. See Table V-2.

- Differences in Species' Sensitivity to Carcinogens. There is ample evidence that different species -- even different strains within species -- have markedly different sensitivities to carcinogens. Animal species can exhibit differences of as much as two or more orders of magnitude. The interspecies differences are neither regular nor predictable. One test species can be more sensitive than another to one carcinogen, and less sensitive to a second carcinogen. Few comparisions are possible between test animals and humans, since there is no direct human evidence for most carcinogens. In some instances, however, the human species has been shown to be far more sensitive than the animal species that reacted most strongly in laboratory experiments. These differences are not accounted for in the above estimates of uncertainties attributable to the mathematical models and scaling assumptions. They widen the potential error even more.

- Individual Variation in Human Sensitivity. Even beyond interspecies differences, there is greater individual variation in sensitivity among humans than among test animals. This is a result of the fact that humans are genetically heterogeneous, while test animals are bred for maximum genetic homogeneity. Because purposeful experimentation on humans is ethically unacceptable, and because

1/ National Academy of Sciences, Saccharin: Technical Assessment of Risks and Benefits, p. 3-72, table 3-8 (1978).

2/ Miller and Howe, "Saccharin -- The Risks and Benefits," 273 Nature 8 (1978).

TABLE V-I

Estimated Human Risks From Saccharin Ingestion of 0.12 g/Day (From NAS 1978, p. 3-72)

	Lifetime cases/million exposed	Cases per 50 million/yr
Rat dose adjusted to human dose by surface area rule:		
Method of high- to low-dose extrapolation:		
Single-hit model (Hoel, 1977)	1,200	840
Multi-stage model (with quadratic term) (Hoel, 1977)	5	3.5
Multi-hit model (Scientific Committee of the Food Safety Council, 1978)	.001	0.0007
Mantel-Bryan probit model (Brown, 1978)	.450	315
Rat dose adjusted to human dose by mg/kg/day equivalence:		
Method of high- to low-dose extrapolation:		
Single-hit model (Saccharin and its Salts, 1977)	210	147
Multi-hit model (Scientific Committee of the Food Safety Council, 1978)	.001	0.0007
Mantel-Bryan probit model (Brown, 1978)	21	14.7
Rat dose adjusted to human dose by mg/kg/lifetime equivalence:		
Method of high- to low-dose extrapolation:		
Single-hit model (Brown, 1977)	5,200	3,640
Multi-hit model (Scientific Committee of the Food Safety Council, 1978)	.001	0.0007
Mantel-Bryan probit model (Brown, 1978)	4,200	2,940

Source: National Academy of Sciences, Saccharin: Technical Assessment of Risks and Benefits at p. 3-72 (1978).

TABLE V-2

Estimates of Lifetime Risk From Exposure to 1 ppm Vinyl Chloride

Source	Estimate of lifetime risk	Method of extrapolation	Source of data
Wilson (S. 53)	2.5x10[illegible]	Linear	Epidemiological unexposed source.
Wilson (Exh. 231 B)	5x10[illegible]	Linear	Epidemiological and Maltoni extrapolation.
Crump and Guess (1977), exhibit to [illegible] statement	2x10[illegible]	Multi-stage, upper confidence limit.	Maltoni (1975).
Guess et al. (1977), exhibit to [illegible] statement	2x10[illegible]	Multi-stage, upper confidence limit.	Maltoni (1975).
	1x10[illegible]	Mantel-Bryan, upper confidence limit.	Maltoni (1975).
Case (S. 38)	0	Assumption of threshold at 10[illegible] molecules per cell, estimated to occur at exposure level of 4.9 ppm.	
[illegible] (post-hearing comment, p. 8)	4x10[illegible] to 1x10[illegible]	Linear	Maltoni (1977), Table 12.
Gehring et al. (1978), p. 590	10[illegible]	Log-probit, extrapolation of observed dose-response curve.	Gehring et al. (1978), dose-response curve based on metabolized VC.
[illegible] and [illegible] (1977)	Greater than 10[illegible] (rats)	Linear	Maltoni (1977), liver angiosarcomas.
	Greater than 10[illegible] (rats)	Linear	Maltoni (1977), mammary tumors.
	10[illegible] to 10[illegible] (humans)	Linear, extrapolated to humans.	Maltoni (1977).
Food Safety Council (1978)	10[illegible]	Multi-hit	Maltoni (1975).
Do.	2x10[illegible]	Multi-hit, upper confidence limit.	Maltoni (1975).
Do.	5x10[illegible]	Multi-stage	Maltoni (1975).
Do.	6x10[illegible]	Multi-stage, upper confidence limit.	Maltoni (1975).
NAS (1977), exhibit to [illegible] and Rall statement, p. 734.	2x10[illegible]*	Multi-stage, upper confidence limit.	Maltoni (1975).

* Assumed breathing rate of 15 m³/day to convert from oral intake to inhalation exposure.

Source: OSHA, "Identification, Classification, and Regulation f Potential Occupational Carcinogens," 45 Fed. Reg. 5001, 5200 (January 22, 1980).

no method of measuring human sensitivity to carcinogens is available, the range of human sensitivities is an important source of imprecision of uncertain dimensions in quantitative risk estimates.

- Differences in Metabolism, Pharmokinetics, and Repair Capabilities. Very little information is available on the role of metabolic, pharmokinetic, and repair mechanisms in carcinogenesis, or on differences in such mechanisms within and between species. Nonetheless, while there is enough basic similarity that animal sutdies are reliable means of identifying human carcinogens, there are differences that are likely to affect the magnitude of carcinogenic response in different species. These differences add further unpredictable uncertainty to quantitative risk assessments.

- Interactions and Synergisms. Animals are usually exposed to only one suspect substance in carefully controlled settings. Humans, however, are exposed to a wide variety of other chemicals and radiation, and other carcinogenic co-factors in almost infinite combinations. Because of interactions among these co-factors, exposure to a carcinogen can result in a much greater incidence in humans than in animals.

  In addition, some risk factors interact synergistically. The risk from exposure to both is far greater than the sum of the risks from exposure to each alone. There is good reason to expect that two-or-more-factor synergism is common. Yet, most synergisms have not been identified, let alone quantified, because little human epidemiological data is available and animals are exposed only to single substances.

- Differences Due to Sporadic, Uneven Exposure vs. Constant Exposure. Test animals typically are exposed to a constant dose for a predetermined prolonged period, usually a full lifetime. People, however, tend to receive uneven exposures from day to day. Some may receive only a single or sporadic high doses. Some are exposed only in middle age, while others are exposed as children. The relation of constant exposure to sporadic, uneven exposures equalling the same total does is unknown. T sts in animals have shown that a single, massive dose of a carcinogen in a young animal can cause cancer later in life, but the

quantitative relationship between such doses and constant exposure is highly uncertain.

These uncertainties preclude deriving usefully precise quantitative risk estimates from animal experiments. Some of the sources of uncertainty are "wild cards", on which it is impossible even to place reasonable outer boundaries. Estimates can be wrong by thousand-fold or million-fold factors.

B. The Unreliability of Quantitative Risk Estimates Derived from Human Studies

Similar limitations prevent derivation of reliable quantitative estimates from epidemiological studies. The most serious limitation is that there is epidemiological evidence for only a few substances identified as carcinogenic in animal experiments. Beyond this, epidemiological studies are relatively insensitive; in such studies there are inherently high probabilities of failing to detect a true effect at all, and of misrepresenting the magnitude of an effect even if it is identified. The reasons for the insensitivity and quantitative inaccuracy of epidemiological studies are:

- Confounding Factors. Epidemiological studies are performed in an uncontrolled setting, introducing many unknown factors that can obscure true relationships between cause and disease. Most epidemiological studies are conducted among occupational groups, who are exposed to chemicals at higher doses and more regularly than the general population. Nonetheless, many well-designed studies would fail to detect cancer caused by a chemical or radioactive substance unless it is occurring at a rate five times higher than normal. Even the best large epidemiological studies

usually cannot reliably detect effects occurring at less than 50 percent above the normal rate. Their insensitivity for identifying carcinogens at all extends to the quantification of risk.

- The Effects of Latency. Latency periods -- the time between the first exposure and diagnosis of diseases -- of 20 years or more are common for carcinogens. Studies which do not follow exposed subjects for their full lifetimes can fail to detect a carcinogenic effect entirely, or can miss the bulk of late-occurring cases.

- Failure to Follow All Members of the Exposed Group. A common failure of occupational studies is the failure to follow employees who change jobs. Since ill employees are the most likely to leave employ, ignoring this factor can be significant. Their state of health, or even if they are still alive, is not determined. This tends to understate the true risk. Follow-up problems are even greater for many non-occupational studies.

- Ignorance of True Exposure Levels and Durations. Dose information is often highly speculative, especially for periods two or more decades ago. This problem is especially severe for epidemiological studies concerning environmental pollutants. Even monitoring and modelling done today is subject to serious errors. Without accurate dose information, no quantitative conclusions can be made.

- Failure to Relate Common Cancers to Their Causes and Failure to Detect Rare Cancers. Some kinds of cancer, such as lung cancer, are relatively common and have many causes. Frequently, such cancers are assigned *in toto* to smoking (or to unknown causes), when another substance is also a causal factor. In the opposite extreme, a substance may cause a relatively rare cancer at a rate that is below the sensitivity of epidemiological studies. Both factors lead to underestimating human risk by an uncertain amount.

- Errors in Reporting. Few states have accurate, reliable systems for recording cause of death. Even where organized records are kept, mistakes in diagnosis can distort an epidemiological study.

- Errors in Describing the Study and Control or Failures to Adjust for Age, Socioeconomic Status, and Other Variables. Errors in describing the group exposed and the comparison control can introduce serious errors into quantitative estimates. The same result can occur from failures to adjust for age, income and race, and other variables.

The result of these sources of uncertainty is that epidemiological studies, even when available, can misstate the true carcinogenic risk by several orders of magnitude or more.

C. The Unreliability of Exposure Monitoring and and Modelling Data

A necessary element of quantitative risk assessments is accurate data on the magnitude of human exposure to airborne carcinogens. Such data is needed to determine exposure levels from current emissions and to predict the levels to be expected from new emissions. But for hazardous air pollutants EPA does n t generally have either the historical monitoring data base or modelling methods of sufficient accuracy for reliable quantitative risk assessments. Modelling methods for even the conventional pollutants, such as TSP and SO_2 are not capable of making predictions consistently within even a factor of two of actually monitored levels. Many carcinogenic air pollutants are reactive, and modelling for reactive substances (such as photochemical oxidants) is even less advanced.

The lack of precise monitoring data and modelling methods further undermines the reliability of quantitative risk assessments. When all the sources of uncertainties are considered together, huge errors in risk estimates are nearly unaviodable on a frequent basis.

D. EPA Itself Recognizes the Uncertainties that Make Quantitative Risk Assessments Unreliable and Imprecise

NRDC and EDF find EPA's proposed extensive reliance on quantitative risk assessments all the more difficult to understand because EPA itself appears to recognize, or at least pay lip service to, the irreducible uncertainties inherent in quantitative risk assessments. The proposal states:

> The assumptions and procedures . . . for extrapolation and for exposure estimates are subject to considerable uncertainty. Where only animal data are available to assess the magnitude of cancer risk to human populations, the differences in susceptibility between animal species and humans, and the need to extrapolate dose-response data in very low ambient concentrations, result in risk estimates that must be regarded only as rough indications of effect.
>
> Uncertainty in exposure estimates arises from the use of limiting monitoring, pollutant transport models, mobility of the exposed population and other factors. In combining these exposure estimates with dose extrapolations to provide estimates of cancer incidence, the total uncertainties are increased.

(44 Fed. Reg. 58649.)

Our belief that this represents only lip service is reinforced by the absence of any detailed discussion of the

uncertainties in the Statement of Basis, by the absence of any reference to weaknesses of quantitative risk assessments in Part D of the proposed rule (44 Fed. Reg. 58654), and by EPA's blithe commitment to use these techniques anyway.

E. Nothing in the Clean Air Act Imposes Quantitative Requirements

EPA's current fascination with quantitative risk assessment methods finds no support in the Clean Air Act. Nothing in Section 112 imposes the prerequisite of a quantitative risk assessment before EPA may protect the public from a carcinogenic air pollutant. Congress recongized that under the current state of scientific knowledge cancer hazards can be identified even though their precise magnitude cannot be quantified. But Congress did not require EPA to delay regulation until this precise quantification is possible or force EPA to undertake sham quantitative analyses. Rather, because the public's lives and health are at stake, Congress directed EPA to take highly precautionary, protective action to prevent cancer based on qualitative evidence identifying carcinogens, because that is the only reliable evidence available.

The Clean Air Act requires EPA to list as hazardous air pollutants each substance that "may reasonably be anticipated to result in an increase in mortality or an increase in serious, irreverisble, or incapacitating reversible, illness." [Section 112(a)(1), (b)(1)(A)] The Agency must swiftly propose and

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promulgate standards providing the public health with "an ample margin of safety," unless it is proved that the substance "clearly" does not have those effects. [Section 112(b)(1)(B)] Nothing in these phrases or elsewhere in the law or legislative history even suggests that EPA must be able to demonstrate the magnitude of the cancer hazard before regulating, or in determining how much to reduce emissions.

F. Even if Balancing Risks and Benefits were Legal Under Section 112, Use of Quantitative Risk Assessments to Determine "Unreasonable Residual Risk" Would be Arbitrary

EPA proposes to use quantitative risk assessment as the centerpiece of determining whether the "residual risk" remaining from emissions allowed by a BAT standard are "unreasonable." EPA states that "despite their lack of precision" and "considerable uncertainties," the Agency has the "belief" that the quantitative risk assessment methods "can . . . provide useful estimates" for use in making such unreasonable risk determinations. [44 Fed. Reg. 58649] We have already shown that such a balancing of risks and benefits is not authorized under Section 112 of the Clean Air Act. Even if EPA's risk-benefit analysis proposal were legal, the use of the grossly unreliable and imprecise quantitative risk assessments would be an abuse of discretion.

Although NRDC and EDF strongly support EPA's commitment to considering whether emissions of a carcinogenic air pollutant can be eliminated completely by substitutions and process changes -- indeed we believe such measures are required -- we do not believe that the unreliable and imprecise methods for

quantitative risk assessments can play a rational part in a decision whether certain emissions of carcinogenic substances are reasonable. The likelihood of huge errors in the risk estimates means that EPA has adopted only an illusion of precision. While quantitative accuracy is desirable, false precision is arbitrary.

EPA's summary recitation of the limitations of these methods has not in the past restrained decision-makers and others from treating these numbers as though they were reliable indications of the true risk, and will not in the future. Since EPA cannot prevent these estimates from being abused, by itself as well as by others, we believe quantitative risk assessment should play no role in determining the level of standards for hazardous air pollutants.

Even if it were legal and rational to use quantitative risk assessments in determining whether residual risk is unreasonable, the proposed rules fail to adequately insulate the determination of the minimum BAT standard from this risk-benefit balancing process. The proposal merely promises that quantitative risk assessments will not be used in determining BAT. But since the estimates will have been generated at an earlier stage, NRDC and EDF have no confidence that EPA will ignore the estimates in determining BAT. We fear that the careful division that EPA has proposed will in fact disappear, and that even the definition of the minimum best technology will be compromised by the use of unreliable quantitative estimates.

G. Quantitative Risk Assessments Methods Possibly may be Used Rationally for a Very Rough Form of Priority Setting, But not as EPA has Proposed

Considering the unreliability of the quantitative risk assessment methods, their use for making any sort of close distinctions among chemicals is not rational. Nonetheless, EPA proposes to use quantitative risk assessment as the major element in setting priorities in a manner that makes closer distinctions than the techniques can reliably allow.

It has sometimes been suggested that even though quantitative risk assessments are not accurate enough to be used in any way for determining the level of standards, they could be used to help in priority setting. The fundamental assumption here is that even if the exact magnitude of the risk associated with the chemical cannot be known, the relative seriousness of two hazards can be compared. That is, using a single mathematical model and a constant set of assumptions about interpreting the data one could rank chemical hazards in order of their seriousness.

There are important reasons why this is nowhere near as easy as it sounds. First, many of the elements that 1 ad to uncertainties in the risk assessment operate as "wild cards," that is, they do not necessarily tend in the same direction as with the same force with different chemicals. All other things being equal, such rankings might be made. But if one chemical

participates in synergistic reactions and another does not, all bets are off. Similarly, two chemicals may appear to be comparable in risk, but if they are metabolized differently, the true risks may well be vastly different. So even the rationality of using quantitative risk assessments as a means of ranking chemicals in order of seriousness is substantially doubtful.

It might not be arbitrary, however, to use these methods for priority setting as long as only the very grossest distinctions are made, between the most serious hazards and ones which are less pressing (though by no means should be ignored). This might be a justifiable approach as long as the distinctions that are made are at least several orders of magnitude in the apparent risk. Closer distinctions are not reliable because of the "wild card" elements described above.

Ultimately we do not believe that a priority setting system based on even these sorts of gross distinctions will be much more useful to the Agency than one based solely on such factors as the number of pounds of a substance emitted per year, or the number of persons living in the surrounding area and potentially exposed.

A very serious problem with the use of quantitative risk assessments even for priority setting purposes is that the unreliable numbers generated are then used, inadvertently or not, in an arbitrary manner in the subsequent proceedings to

determine the level of a standard. Thus, NRDC and EDF believe that the use of quantitative risk assessment for even gross priority setting will be valid only if the Agency makes much more clear the range of error that precludes the use of these estimates for standard setting, and commits itself not to use these results of the priority setting exercises in such subsequent standard setting. It is very important that the estimates created for priority setting purposes be given in the form of the broad ranges within which the risks may lie. To put forward a single point estimate, or even a single point estimate and an upper bound, is unacceptable (particularly if the term "best estimate" is used), because of its misleadingly precise character.

VI. THE NEED FOR IMPROVED GENERIC INTERIM CONTROLS FOR ORGANIC CARCINOGENIC CHEMICALS

1. Introduction

In a separate rulemaking notice entitled "National Emission Standards for Hazardous Air Pollutants: Advance Notice of Proposed Generic Standards," EPA has proposed a series of "housekeeping requirements" as a first step in controlling carcinogenic emissions from rganic chemical facilities. As pointed out in the preamble, these generic standards are focused primarily on fugitive emissions (as opposed to process emissions) and would require little or no capital investment on the part of the affected industries. While EDF and NRDC strongly endorse the concept of requirements which can be applied quickly after the listing of a §112 pollutant, we feel that the proposed standards are deficient in several respects.

These deficiencies fall into two areas: first, procedural deficiencies in the way the Agency intends to implement the proposed standards, and second, substantive deficiencies which involve the requirements themselves. Each of these will be addressed separately.

2. Procedural Improvements

According to the preamble to the proposed generic standards, EPA intends to separately propose the standards each time a new chemical is added to the list under §112. This approach is likely to prove both time consuming and possibly ineffective. First, EPA should substantially reduce its workload by proposing in one proceeding the generic standards for all those organic chemicals which can be regulated

by the proposed standards and which are likely to ultimately be listed under §112. Under this approach, the Agency would rephrase the regulation to apply to any organic chemical which met certain criteria, one of which would be listing under §112. This type of "fill in the blank" regulation would thus allow EPA to resolve all the pertinent legal and factual issues in one rulemaking and make r proposal of the standard for each pollutant unnecessary.

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A second alternative which would accomplish the same end, and one which EDF and NRDC intend to pursue at a later point in this rulemaking, is to request the Agency to propose the generic standards for a specific set of pollutants which we believe should now be listed under §112. EDF and NRDC intend to submit such a list of candidates for listing either during the public hearing or shortly thereafter. At that time, we will also submit a subset of these chemicals which we believe are suitable for quick regulation under the proposed generic standards.

EDF and NRDC feel that this is the minimum which EPA should agree to since many of the generic controls proposed are very modest and will provide considerably less control than even RACT for existing sources of hydrocarbons which are regulated because the hydrocarbons are precursors in the formation of photochemical oxidant smog. EDF and NRDC also suspect, based on discussions with various industry representatives, that many of these measures have already been implemented and that any objections can be adequately dealt with in a single generic rulemaking proceeding. Such a single rulemaking proceeding will also reduce the possibility of conflicting court decisions should different companies plan to contes

the requirements for specific chemicals.

3. Improvements in the Substantive Requirements

There are a number of avenues for improving the proposed generic standards, some of which involve a fundamental change in the nature of the Agency's thinking and others of which involve relatively modest but significant improvements. In this section we will briefly outline both types of improvements.

First, EDF and NRDC question EPA's decision to limit the generic standards to measures which require no significant capital investment. We believe that once a substance has satisfied the qualitative criteria for listing as a §112 pollutant that the Agency should move as expeditiously as possible to require compliance with whatever generic standards can be developed, whether those standards apply to process or fugitive emissions. Regrettably, the standards proposed by EPA are limited to housekeeping measures and do not require even minimum control of emissions from process sources and storage sources using widely accepted technology.

For example, the EPA synthetic organic chemical manufacturing industry (SOCMI) study has already concluded that controls for fugitive and storage emissions are available which can be applied to most sources of carcinogenic air pollution. Given the fact that these requirements are unlikely to change as a result of further investigation and the fact that they generally make economic sense as well, we see no reason for deferring these requirements until the proposal and promulgation of process source oriented regulations. For example, EPA could include a requirement for floating roofs in storage tanks rather than simply requiring that existing tanks be painted

white. Floating roofs are already being widely adopted by industry to reduce emissions, both for air pollution and economic reasons. Other examples of widely accepted generic control devices are double mechanical seals for pumps, and the venting of certain leak sources t control systems. Once again, most of these and other measures will be included in the control technology guideline for the organic chemical industry when it is finally released. It makes little sense to delay controls for carcinogenic hydrocarbons until a second rule-making when the Agency is preparing to require these same types of controls for hydrocarbons which are precursors to ozone.

Prompt implementation of at least these "baseline" generic process and fugitive emission controls is especially important since it may be many years before EPA promulgates ultimate control requirements for even a small number of the chemicals which are likely to be listed under §112. As a result, these first line controls become even more important in providing at least a minimal d gree of health protection to Americans who continue to be exposed to highly dangerous air pollutants.

In general, EDF and NRDC submit that EPA should include in these generic controls all those measures which are, or will be, required for existing sources of hydrocarbons under the ozone component of state implementation plans, unless there is some reason t believe that the technology which would be used to control these emissions once a substance is listed under §112 will be substantially more effective than the technology the Agency is planning to use for ozone attainment. In other words, any control measure, such as the use of floating roofs, which is both generic to the chemical industry and cannot be significantly improved upon as a result of further rulemaking,

should be required as soon as possible.

In short, the procedure would be as follows. First, EPA would identify all generic process and fugitive emission controls which it is currently considering for regulating organic chemicals. These controls would then be broken into two groups: (1) those controls which are likely to be required in any event and which raise few marginal cost issues as control requirements are increased; and (2) those measures where the degree of control or performance expected of a particular device will be an issue. Thus, the issue of whether to require one or two activated carbon beds in a particular control device as well as the decision as to the replacement frequency of the carbon itself would be placed in this second category. Similarly, if EPA felt that it was possible that a pressurized tank as opposed to the use of a floating roof might be required for certain chemicals, a decision would be deferred until the second round of rulemaking. The object is to avoid requiring investment in control devices which later would have to be replaced with even more sophisticated devices as a result of the second rulemaking.

We submit that this criterion of "no duplicative investment" is a far superior one to the "no capital investment" criterion proposed by the Agency. Furthermore, the "hurdle" for listing of a chemical under §112 is sufficiently high that industry is not in a position to argue that immediate imposition of these generic control requirements is unjustified until further rulemaking takes place. Even the generic controls cannot be applied until the first rulemaking is conducted and an opportunity for public hearing provided.

With regard to the proposed housekeeping or fugitive emission

controls themselves, EDF and NRDC have a number of suggestions for improving the proposed system. First, we are concerned that EPA is placing undue reliance on industry reporting requirements to ensure compliance with the proposed controls. In its preamble EPA has acknowledged the potential importance of independent enforcement either through EPA field inspectors or through other mechanisms but has failed to develop an adequate alternative enforcement proposal. EDF and NRDC appreciate the fact that the Agency's enforcement resources for this program are limited and believe that any proposal must make optimal use of those resources.

To accomplish this objective, two possible approaches suggest themselves. First, EPA could require affected industries to retain an "environmental auditor" who would not be employed by the company, but would be responsible for reviewing the company's compliance with the generic standards and reporting the results of his audit to EPA. The concept is similar to the use of an outside accountant to perform an annual financial audit on corporations for purposes of SEC requirements. The outside environmental auditor would be responsible for not only reviewing the records required to be kept by the company but would also be responsible for performing periodic field spotchecks himself to determine adequate compliance with the reporting requirements. Since an environmental auditing profession does not presently exist, it is possible that engineering consulting firms could be retained to perform this task initially. Some of the large "big eight" accounting firms have management consulting staffs which could also be retained to do the job. This approach would significantly reduce the burden on EPA's own enforce

ment resourc s, while providing a relatively high quality check on company compliance with the generic requirements.

A second possible approach would be to use EPA enforcement personnel, but use them selectively to ensure that certain performance standards were satisfied by industry. In the preamble, EPA has pointed out that CMA has argued for a more flexible system which would reduce reporting requirements on industry and rely more heavily on performance standards to reduce fugitive emissions. EDF and NRDC believe that EPA should give consideration to a modified version of the CMA proposal. Under this modified approach, industry w uld be given somewhat more flexibility in developing control plans but would be held to a higher standard of performance. For example, a series of performance standards relating to the frequency and magnitude of leaks which would be allowed could be developed. During a random inspection of a selected number of potential sources, the facility would be limited to a specified number of permissible leaks within certain concentration ranges. For example, leaks in excess of 15,000 parts per million (ppm) might be limited to one percent of the fugitive sources tested. Those between 10,000 ppm and 15,000 ppm might be limited to three percent of the sources tested, and those less than 10,000 ppm might be limited to five percent of the sources tested. A minimum sample might be 100 leak sources, a sample which could be completed within a reasonable period of time.

After sufficient experience had been gained with the program, the number of permissible leaks could gradually be reduced in each category in order to improve the line of overall performance. To encourage companies to meet the performance standards, heavy fin s

should be levied on any leaks which are found in excess of the permitted numbers. In addition, the company could be required to resume weekly or even more frequent reporting of leaks from all possible sources at the facility. In short, by providing strong incentives to fulfill its own management plans, the Agency could not only reduce the resource burden on itself, but also reduce reporting requirements for industry. Naturally, the feasibility of this program would depend on EPA having available at least enough enforcement personnel to perform these random sample inspections. If such personnel are not available, it may be necessary to resort to the extensive routine reporting required in the proposed regulations.

The key point, in any event, is that both industry and government resources should be focused on reducing emissions from fugitive sources as quickly as possible. Simply reporting and requiring the repair of leaks will not necessarily ensure improved performance over time. Only increasingly restrictive performance standards can achieve this goal. We submit that industry should be given the flexibility it desires if it can demonstrate that it can consistently meet stringent performance standards. If it fails to meet those performance standards, the Agency will then have full justification for resorting to a more burdensome set of reporting and monitoring requirements. To establish the initial performance standards, we submit that EPA should immediately require the targeted industries to submit data pursuant to §114 of the Clean Air Act to allow the Agency to establish leakage frequency rates for different sources

within the industry. Since the development of this baseline data will take considerable time, we suggest that the Agency proceed immediately to require industries to begin developing this data. Once the data is developed, it will allow the Agency to focus on those sources which appear to be most significant in terms of total emissions. Such data will also give Agency inspectors knowledge of which sources should be spotchecked during inspections.

In short, this second alternative might actually encourage industry to perform more frequent checks of potentially leaking valves and other sources than would actually be required by a formal set of reporting requirements. Since industry would not know when an EPA inspector might arrive, it would be required to keep in a constant state of readiness. Regular reporting requirements might actually produce the opposite incentive. Industry would know that it was only required to have the system in good operating condition at the time of its regular reporting. A system with less certainty as to when checks would be made may actually produce improved compliance. In any event, we submit that EPA ought to consider a hybrid which might involve some routine reporting, with the addition of spotchecks geared to specific performance standards as outlined above. We believe that all of these ideas need further discussion and would welcome a careful review of this area prior to promulgation of final generic standards.

VII. CONCLUSIONS

As noted in the preceding sections, during the remaining period for supplementary comment NRDC and EDF will submit additional material in support of and in further explanation of the analysis and recommendations contained in these comments. We have summarized here the major elements we believe are necessary to generic rules to implement the hazardous air pollutants provisions of the Clean Air Act with respect to airborne carcinogens.

First, EPA must establish a candidate list of carcinogens which may be emitted from stationary sources as air pollutants. At a minimum, this list must contain several hundred substances which are now known to cause cancer in humans or in animals and which are used in industrial facilities and may be emitted as air pollutants.

Second, from the candidate list EPA must select a minimum of 20 substances per year to list as hazardous air pollutants and regulate as Section 112 requires. Considering that EPA has regulated only four substances to date, and that there are several hundred potential hazardous air pollutants, the Agency has grossly failed to carry out its mandate under the Clean Air Act. Nothing less than a commitment to regulating 20 substances per year will satisfy that mandate, because nothing less will guarantee that within a reasonable time the public will be protected from cancer caused by airborne chemical and radioactive substances released from stationary sources.

Third, the Agency must resolve in this generic proceeding certain essential scientific issues which arise in the same manner and must be resolved on the same evidence in each proceeding involving an individual carcinogen. These scientific issues would be foreclosed from further consideration in proceedings to regulate individual substances. Only when significant new information is presented which calls for a different resolution of the generic scientific issues, will such issues be reconsidered, and only in the context of a general proceeding to amend the general rules. This resolving and foreclosing of the generic scientific issues is essential if a rational and efficient consistent airborne carcinogens policy is to be implemented, and a significant number of substances brought under control.

Fourth, the Agency must establish in this general proceeding that when a carcinogen is listed as a hazardous air pollutant, within 360 days a standard of no measurable emissions will automatically go into effect, unless industry shows that it cannot be achieved through process changes and product substitution and unless EPA has established by that time an alternative standard which deviates from no measurable emissions to the minimum extent required. The substitute standard must provide for a phased reduction to zero emissions at a reasonable point in the future. The presumption necessarily is harder to overcome for new plants than old, since new sources of carcinogenic emissions

have considerably greater emissions control flexibility and, of course, need not be built at all. Dispersal of sources of carcinogenic air pollutants is not an acceptable alternative to controlling their emissions.

Fifth, EPA must abandon its arbitrary and unlawful reliance on quantitative risk assessment methods. Quantitative risk estimates can be wrong by a factor of 5 million times or more and thus are too unreliable and imprecise to play a rational role in determining the level of controls applied to a hazardous pollutant. Such estimates may have a role in the grossest form of priority setting, but that will be valid only if the Agency much more explicitly recognizes the uncertainties of the estimates and commits itself to not using them in any way in subsequent standard setting.

Sixth, EPA should expand the scope of the proposed "first step" generic controls that will be applied quickly to include those controls on process emission points which are not expensive, or likely to be inconsistent or duplicative of more effective technological controls to be considered thereafter. Moreover, EPA should consider restructuring these interim rules in ways that may enhance voluntary compliance and permit more effective enforcement.