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REPORT BY THE

Comptroller General

OF THE UNITED STATES

Delays In EPA's Regulation Of Hazardous Air Pollutants

The Clean Air Act of 1970 requires the Environmental Protection Agency (EPA) to develop a listing of hazardous air pollutants. Once a polluting substance is listed, EPA has to propose standards to regulate the emission of the substance. The Congress, environmental groups, and others have been concerned about EPA's progress in listing and regulating air pollutants.

Since passage of the act, EPA has listed only seven substances as hazardous air pollutants and established emission standards for four of them. Between 1977 and 1982, EPA identified 37 additional substances as candidates for the hazardous substances listing. However, none of these substances have been approved for inclusion on the listing and emission standards have not been proposed.

GAO found that various policy shifts at EPA and uncertainty over the type and amount of scientific data needed to support a regulatory action are major contributing factors to delays in developing the hazardous substance listing. Delays also occurred in proposing emission standards after pollutants were listed because of the time required to develop technical and cost information and analyze public comments.

GAO/RCED-83-199
AUGUST 26, 1983

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D.C. 20548

B-211085

The Honorable John D. Dingell
Chairman, Subcommittee on
Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

As requested in your November 16, 1982, letter and our subsequent discussions with your office, this report discusses the Environmental Protection Agency's (EPA's) hazardous air pollutant program. EPA is required to develop a listing of hazardous air pollutants and standards for regulating the emission of those pollutants into the air. We examined the major factors contributing to delays in developing the hazardous substance list and in proposing and finalizing emission standards.

As arranged with your office, unless you publicly release its contents earlier, we will make this report available to other interested parties 30 days after the issue date. At that time copies of the report will be sent to appropriate congressional committees; the Administrator, EPA; and the Director, Office of Management and Budget.

Sincerely yours,

Charles A. Bowsher

Comptroller General
of the United States

D I G E S T

Section 112 of the Clean Air Act of 1970 requires that the Environmental Protection Agency (EPA) develop standards to control the emissions of hazardous air pollutants. This section is designed to protect the public from air pollutants which are not regulated under other sections of the Clean Air Act and which EPA believes may reasonably be anticipated to result in increased human mortality or serious illness. The act also requires EPA to establish air quality criteria and national ambient air quality standards for other air pollutants.

EPA has identified 37 substances or pollutants which are candidates for review and regulation under section 112. EPA plans to analyze the extent to which the public is exposed to each substance and to draft health assessment documents which discuss the substances' health effects. EPA will submit each health assessment document to its Science Advisory Board (SAB), a group of outside experts who review and attest to the scientific validity and adequacy of assessments. After SAB approval, EPA will decide whether to include each substance on its list of hazardous air pollutants for regulatory action. This is known as "listing."

The Clean Air Act requires that EPA (1) propose emission standards for sources of a hazardous pollutant within 180 days after listing and (2) publish final standards within 180 days of proposal. The act requires such standards to be set at a level that provides "an ample margin of safety" to protect the public health.

The Congress, environmental groups, and others have expressed concern over EPA's progress in reviewing and regulating hazardous air pollutants. Since 1970 EPA has "listed" only seven substances and promulgated regulations for four of them.

The Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked GAO to provide information on several issues (see pp. 5 and 6) concerning EPA's hazardous air pollutant program, and the following issues are discussed in this report:

--How the list of 37 hazardous air pollutant candidates was developed.

--The procedures and practices followed by EPA in preparing health assessment documents.

--SAB's involvement in the hazardous air pollutant program.

--EPA's progress in establishing standards, including its interpretation of the act's requirement that standards be set at a level that provides an "ample margin of safety" to protect the public.

DEVELOPMENT OF LIST OF 37

EPA developed a list of 43 potentially hazardous air pollutants in 1977 based on a 1976 contractor study that compiled information on 632 industrial organic compounds. Between 1977 and 1982 EPA refined the list to 37 by adding substances such as nickel and manganese and removing several substances that were found to break down in the atmosphere or were produced in low volume. (See pp. 9, 10, and 11.)

In 1981 EPA began developing a new procedure to allow it to more accurately screen and rank potentially hazardous air pollutants. In 1982 EPA tested the new procedure by ranking 184 substances, including 34 of those on the list of 37. Only 18 of the original 37 substances ranked among the top 37 in the new ranking and screening process. However, EPA considers the list of 37 important because of the emphasis given it by the Congress during its 1982 deliberations on the Clean Air Act; as a result, EPA plans to conduct health assessments of all 37 substances. EPA is also examining four other potentially harmful substances and, based on the ranking of 184 substances, is considering analyzing others not on the original list of 37. (See pp. 11 and 12.)

DELAYS IN FINALIZING HEALTH ASSESSMENT DOCUMENTS

Since EPA listed and regulated several substances in the early 1970's, industry resistance to regulation has grown so intense that EPA believes it must develop the best health case it can to avoid future legal action. As a result, EPA utilizes contractors and in-house experts to review and assess available health effects literature on each substance and draft health assessment documents.

EPA has initiated health assessments on 19 of the substances on the list of 37. EPA estimates that it should take 1 to 2 years to draft a health assessment document and 3 to 6 months to obtain SAB review and approval. EPA, however, has been working on several documents and has yet to receive SAB approval. For example, EPA initiated a health assessment of perchloroethylene, a solvent used in dry cleaning, almost 5 years ago, and although SAB reviewed draft documents in 1980 and 1982, EPA has not yet received SAB approval of the assessment. (See pp. 15 and 16.)

Several factors have contributed to EPA's difficulty in obtaining SAB approval on documents such as the perchloroethylene assessment. SAB has disagreed with EPA over the sufficiency of data needed to show cancer-causing effects and over the best method to characterize a substance's potential adverse health effects. EPA has grappled with the nature and adequacy of scientific information necessary to support a listing decision. For example, air monitoring data is limited, and because of the time and expense involved in developing data on emission rates, EPA must rely on engineering estimates which sometimes prove to be inaccurate.

Additional delays have been caused by several policy shifts since 1978 concerning the type of information to be included in the health assessment documents. For example, in late 1980 EPA began shifting its emphasis from examining only the cancer-related health effects to an analysis of all health effects. This shift caused EPA to spend significant time updating the content of health assessments. Extensive reviews within EPA have also contributed to delays in finalizing health

assessment documents. EPA officials believe that, although the various reviews have contributed to delays, they have also improved the quality of health assessments. (See pp. 18 through 23.)

The resulting delays have contributed to an increase in the cost of health assessments. For example, EPA estimates that in 1978-80 it spent $155,000 drafting an air health assessment document for perchloroethylene. After shifting its policy in 1981 from an air-only approach to one that examines other routes of exposure as well as air, EPA spent an additional $75,000 developing another document for perchloroethylene.

EPA's difficulties in obtaining SAB approval of health assessments have delayed regulatory action on several substances. Two years ago EPA developed draft standards for coke oven emissions (particulate matter emitted during production of coke in the iron and steel industry), but it has yet to provide SAB with an acceptable health assessment document. (See pp. 26 and 27.)

In January 1982 EPA developed plans to accelerate the preparation of health assessment documents and received an increase in its budget for fiscal year 1984 to intensify efforts to prepare health assessments. (See p. 27.)

SAB REVIEW OF HEALTH ASSESSMENT DOCUMENTS

In order to ensure that EPA is basing its decisions on accurate and current information, EPA will not make a regulatory decision on a pollutant until SAB has reviewed and approved the health assessment document. Although other SAB subcommittees conducted the reviews in the past, SAB's Environmental Health Committee is now responsible for reviewing health assessment documents. The Committee is comprised of eight health experts and utilizes consultants to provide expertise when reviewing certain documents. (See pp. 28 through 32.)

Whenever SAB critiques a health assessment document, EPA takes the time to make the necessary changes to obtain SAB approval.

This often results in going back to SAB two or three times before approval is obtained, delaying the finalization of the document. Other delays in finalizing health assessment documents are also attributable to the SAB reviews. For example, SAB ran out of travel funds in 1980 and could not hold a scheduled meeting to review the health assessment document on arsenic. In addition, action on assessments of five chemicals that SAB approved orally in December 1982 and April 1983 has been delayed because EPA will not take a regulatory action until it obtains written approval from SAB. SAB has decided not to send EPA a written letter of approval until SAB has received a finalized health assessment document with the SAB changes incorporated. (See pp. 34 and 35.)

DELAYS IN ISSUING STANDARDS

EPA has obtained SAB approval of the health assessments for two substances on the list of 37. Although SAB approved one assessment in September 1978 and the other in August 1982, EPA had not made a listing decision on either of them as of June 1983. EPA deferred the decision on one substance until the health assessment document incorporating SAB comments was finalized. EPA is now incorporating the results of another study which may alter the document's conclusions. EPA is moving cautiously on the other substance because it says that it will be the first time that EPA has proposed a notice stating that it will not regulate a substance. (See pp. 37 and 38.)

EPA was not able to meet the congressionally mandated deadlines to propose standards within 180 days of listing for two hazardous air pollutants. EPA has also missed the 180-day deadlines for finalizing standards after proposal for another hazardous air pollutant. EPA listed this pollutant in 1977; proposed standards for various sources in April 1980, December 1980, and January 1981; but had not published final regulations as of June 1983. (See pp. 38 through 40.)

According to EPA, the 180-day deadlines are impossible to meet because the process of proposing standards takes about 2 years to identify sources, obtain the technical and cost information from industry, and have the

package reviewed in EPA. According to EPA, finalizing standards takes at least 1 year because of the time required to obtain and analyze public comments and obtain additional technical and cost data.

The Sierra Club and the State of New York won lawsuits against EPA for not meeting the 180-day requirement for one hazardous air pollutant by June 1980 and a second pollutant by December 1980. The court determined that EPA should propose standards within 180 days of the decisions--or by April 1983 for one pollutant and July 1983 for the other. To meet the court-imposed deadlines, EPA has had to shift resources away from other projects and, as a result, activities under section 112 and other sections of the act have been deferred. (See pp. 42 and 43.)

When establishing standards for hazardous air pollutants, EPA does not interpret section 112's "ample margin of safety" clause to mean that standards require zero emissions. EPA has taken the position that, while it must focus primarily on health risks, it may also consider economic and technological factors in adopting a regulatory control strategy. EPA's consideration of cost and technological factors in setting standards also contributes to delays and the difficulty EPA has had meeting the 180-day deadlines.

While only the courts can resolve definitively the scope of EPA's authority under section 112, GAO believes that, based on GAO's review of section 112, its legislative history, and applicable case law, the Congress intended that EPA establish standards at a level that eliminates significant public health risks. Congress did not intend economic considerations and technological feasibility to be relevant considerations in setting standards. This could require EPA to prohibit any emission of hazardous air pollutants if EPA cannot identify a threshold below which emissions would not be expected to cause adverse health effects. (See pp. 43 and 44.)

EPA has a policy to review established hazardous air pollutant standards every 4 years. Of the four hazardous air pollutants for which EPA has established standards, it has not completed standard reviews for three

of them. Although standards for the three pollutants were established almost 10 years ago, EPA has not completed the reviews to determine if new health effects information indicates a need to change the standards. EPA has reviewed and is in the process of revising a standard for one pollutant which was established in October 1976. (See pp. 44 and 45.)

AGENCY COMMENTS

GAO did not obtain EPA or SAB comments on this report.

Contents

ABBREVIATIONS

EPA	Environmental Protection Agency
GAO	General Accounting Office
OAQPS	Office of Air Quality Planning and Standards
OHEA	Office of Health and Environmental Assessment
SAB	Science Advisory Board

GLOSSARY

Carcinogenic	Cancer producing.
Exposure assessment	The determination of the extent of human exposure before or after application of regulatory controls.
Genotoxic	Compounds which are carcinogenic, mutagenic, or teratogenic.
Isomer	One of two or more chemical substances having the same elementary percentage composition and molecular weight but differing in structure, and therefore in properties.
Linear non-threshold model	A mathematical model used for extrapolation of risk from high to low doses which is frequently applied to carcinogenicity data, either using experimental animal or human studies. The model assumes that incidence at low levels is directly proportional to dose.
Mutagen	Any substance that causes changes in the genetic structure in subsequent generations.
Teratogenic	A substance that is suspected of causing malformation or serious deviations (which cannot be inherited) from the normal type in or on animal embryos or fetuses.
Volatile	Any substance that evaporates at a low temperature.

CHAPTER 1

INTRODUCTION

The basic goal of the Clean Air Act is to protect and enhance the quality of the Nation's air so as to promote the public health and welfare. Sections 108 and 109 of the act require that the Environmental Protection Agency (EPA) establish air quality criteria and national ambient air quality standards for several pollutants so as to provide an adequate margin of safety to ensure protection of public health.

Because of the act's explicit requirements for these "criteria" pollutants, all other air pollutants have come to be known collectively as noncriteria air pollutants and are regulated under sections 111 and 112. Section 111 requires EPA to establish new-source performance standards to limit emissions of air pollutants from new and modified sources. It also requires that States establish performance standards for existing sources of pollutants that "may reasonably be anticipated to endanger public health or welfare" but are not hazardous as defined under section 112.

Section 112, entitled National Emission Standards for Hazardous Air Pollutants, defines "hazardous pollutant" as an

> "air pollutant to which no ambient air quality standard is applicable and which in the judgement of the Administrator causes, or contributes 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."

EPA has identified about 40 substances which have a potential for adversely affecting human health but has regulated only 4 under section 112. Section 112 requires EPA to publish a list of each hazardous air pollutant for which it plans to establish an emission standard. This is known as "listing" a substance. As shown in the following table, EPA has listed only seven substances and has promulgated standards for only four.

Pollutants Listed/Regulated Under §112

Pollutant	Date listed	Regulation proposed	Regulation promulgated	Major sources
Mercury	3/71	12/71	4/73	Mercury ore processing Chlor-alkali cells producing chlorine gas
		10/74	10/75	Sewage sludge incinerators
Beryllium	3/71	12/71	4/73	Extraction plants Foundries Ceramic plants Rocket motor firings
Asbestos	3/71	12/71	4/73	Asbestos mills Roadway surfacing Manufacturing processes
		10/74	10/75	Demolition and renovation
Vinyl chloride	12/75	12/75	10/76	Plants producing ethylene dichloride and vinyl chloride
Benzene	6/77	4/80		Maleic anhydride manufacturing
		12/80		Ethylbenzene and styrene manufacturing
		1/81		Equipment leaks within refineries and plants
		12/80		Benzene storage
Radionuclides	12/79	4/83		Department of Energy (DOE) facilities Nuclear Regulatory Commission licensed facilities and non-DOE Federal facilities Underground uranium mines Elemental phosphorous plants
Inorganic arsenic	6/80	7/83		Nonferrous smelters

Section 112 also requires EPA to propose regulations establishing emission standards applicable to both new and existing sources within 180 days after a pollutant is listed. It requires EPA to promulgate final regulations within 180 days of publishing proposed regulations. According to the act, standards must be set at a level that "provides an ample margin of safety" to protect the public health.

PROCESS ESTABLISHED BY EPA

EPA has established a multistep process to review a hazardous air pollutant candidate before listing and regulating it. EPA conducts an extensive chemical-by-chemical and source-by-source analysis in which it identifies a pollutant, conducts health and exposure analyses, has the health analysis reviewed by the Science Advisory Board (SAB),[1] and then determines whether or not to list the pollutant and regulate its various emission sources.

Identification of pollutant

EPA's Office of Air Quality Planning and Standards (OAQPS) is responsible for identifying candidate substances that may be potentially hazardous air pollutants which need to be assessed. EPA has developed a list of 37 such candidate pollutants to which it has given priority attention.

Health assessment document

After OAQPS has identified a candidate pollutant, it requests EPA's Office of Health and Environmental Assessment (OHEA) in the Office of Research and Development to review and assess available health effects literature on the substance in question. OHEA analyzes the various references and drafts a health assessment document examining the health effects of that candidate pollutant.

Exposure assessment

Simultaneously with OHEA's work on health assessments, OAQPS prepares an exposure assessment on the hazardous air pollutant candidate to determine if it is emitted or is present in the air to a degree that significant human exposure results. It also determines the approximate number of people exposed to differing levels of the candidate pollutant.

SAB review

Before taking any regulatory action, EPA requests that SAB conduct a review of the health assessment document. EPA revises

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[1]An advisory group of independent scientists who review the quality and sufficiency of scientific data underlying regulatory development for some EPA actions. SAB is divided into four standing committees and sometimes utilizes subcommittees to examine specific issues.

the document and incorporates the SAB comments until SAB is satisfied. SAB then drafts a letter of formal closure--or approval--stating that the health assessment document is scientifically accurate and up to date.

While other SAB subcommittees have handled this review in the past, the Environmental Health Committee is now responsible for reviewing health assessment documents. Although health assessment documents for hazardous air pollutants are among its primary responsibilities, the Committee is responsible for reviewing other health information related to other EPA programs. As of June 1983 the Committee's membership was composed of eight health experts, and the Committee uses consultants on an as-needed basis. Announcements of the meetings are made public in the Federal Register and are open to the public.

Administrator's decision

Based on the SAB-reviewed health assessment document and the exposure assessment OAQPS makes its recommendation to the Administrator as to whether the substance should be listed as hazardous. The Administrator then makes the final decision.

Standard setting

If the Administrator lists the pollutant, the Standards and Engineering Division of OAQPS conducts a more detailed assessment of the sources and resulting exposure and develops emission standards for proposal and promulgation. EPA is also supposed to conduct periodic reviews of previously established standards.

AIRBORNE CARCINOGEN POLICY

The Congress, environmental groups, and others have expressed concern about delays in EPA's review and regulation of hazardous air pollutants. EPA agrees that progress has been slow. In an attempt to establish an effective regulatory process for hazardous air pollutants, EPA published a proposed policy for regulating airborne carcinogens in October 1979. The proposed airborne carcinogen policy grew out of an Environmental Defense Fund lawsuit against EPA alleging that EPA had failed to protect the public with an ample margin of safety in establishing standards for vinyl chloride. After signing a settlement agreement with EPA, the Environmental Defense Fund filed a petition for rulemaking calling on EPA to promulgate a generic procedure for the regulation of airborne carcinogens under section 112.

The proposed policy attempted to streamline the listing decision by basing it on whether there is (1) a high probability that a substance is a human carcinogen and (2) evidence of significant public exposure via the ambient air from emissions from one or more categories of stationary sources. Because it concentrated on carcinogens and was proposed at a time when there was a change in administrations and the Clean Air Act was being reauthorized, the

airborne carcinogen policy was never finalized. According to the Assistant Director of the Strategies and Air Standards Division of OAQPS, the policy has been superseded by the proposed toxic air strategy.

PROPOSED TOXIC AIR STRATEGY

In June 1982 the EPA Administrator established the Hazardous Airborne Pollutant Policy Group to identify ways to address hazardous air pollutants under the Clean Air Act and solve problems that EPA has had in regulating such pollutants in the past. The Policy Group is chaired by the Assistant Administrator for Air, Noise and Radiation and is composed of heads of various EPA offices and divisions.

Under the sponsorship of the Policy Group, OAQPS has drafted a proposed toxic air strategy which describes a process that EPA hopes will allow it to discharge more effectively its responsibilities to evaluate and control toxic air pollutants. Among the changes in the evaluation and control processes outlined in the strategy are provisions that (1) clarify the use of other sections of the Clean Air Act and other Federal and non-Federal control alternatives and (2) involve SAB and the public to a greater degree. According to the proposed strategy, the estimated time to complete the review and control process steps will be 4 to 7 years. OAQPS officials have discussed the proposed policy with industry and environmental groups and plan to publish it in the Federal Register although, as of June 1983, they did not have a publication date.

OBJECTIVES, SCOPE, AND METHODOLOGY

In a November 16, 1982, request letter and our subsequent discussions with his office, the Chairman, Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked us to examine and provide a historical perspective of the following issues:

--How EPA determines what substances should be considered as candidates for listing, including how the list of 37 was developed and the procedures and problems in developing such candidates.

--The procedures and practices followed by EPA in preparing health assessment documents.

--The debate over the adequacy and extent of scientific data required in the listing of substances.

--SAB's involvement in the Hazardous Air Pollutant Program, including (1) how it decides to call meetings and (2) the expenditure of money and level of pay for Board members for their involvement in the program.

--EPA's progress in setting standards, including its interpretation of the "ample margin of safety" clause of Section 112 of the Clean Air Act and our analysis of its interpretation.

--The extent to which EPA utilizes contractors in the Hazardous Air Pollutant Program.

Our work was completed between January and June 1983 at EPA headquarters in Washington, D.C.; OAQPS in Durham, North Carolina; and OHEA's Environmental Criteria and Assessment Office in Research Triangle Park, North Carolina.

To determine how EPA developed its list of 37, we talked with officials in OAQPS, including the environmental engineer who developed EPA's original list of candidate hazardous air pollutants, and reviewed EPA's methodology for establishing the list of 37 pollutants. We also reviewed EPA documents and its contractors' studies used to help develop its list of candidate hazardous air pollutants. A major study that EPA used in developing its list of 37 was conducted by the Mitre Corporation in 1976. We discussed this study with Mitre officials.

To determine the procedures and practices EPA followed in preparing health assessment documents, we talked with EPA officials responsible for drafting the documents. We reviewed several health assessment documents, memorandums, and EPA reports outlining procedures and problems in developing health assessments. We also discussed the health assessment documents with officials from the primary contractor involved in their preparation--Syracuse Research Corporation. Because EPA could not provide actual cost information, we obtained cost estimates from EPA for developing health assessment documents. Much of this information was based on the EPA staff's recollection and could not readily be verified. We also discussed the adequacy and extent of scientific data required to support a listing decision with EPA officials as well as several special interest groups and corporations, including the Environmental Defense Fund, the Natural Resources Defense Council, Inc., the Chemical Manufacturers Association, the American Petroleum Institute, Merck Pharmaceuticals and Company, the Dow Chemical Corporation, and Diamond Shamrock Corporation.

To examine SAB's involvement in the hazardous air pollutant program, we talked with the current director and former directors of SAB, the former chairpersons of earlier subcommittees that reviewed hazardous air pollutant documents, and current and former members and consultants of the Environmental Health Committee. We attended two meetings of the Environmental Health Committee and reviewed SAB closure letters and transcripts of meetings of the Subcommittee on Airborne Carcinogens and the Environmental Health Committee. We examined SAB committee charters and documentation concerning member compensation and the 1981 decision to reduce the size of SAB. We also examined compensation data for members and consultants to the Environmental Health Committee.

To determine EPA's interpretation of the "ample margin of safety" clause and examine other standard-setting issues, we talked with the lawyer responsible for section 112 of the Clean Air Act in EPA's Office of General Counsel and reviewed EPA's 1979 proposed policy for the regulation of airborne carcinogens and the 1983 proposed toxic air strategy. We also discussed listing and standard-setting procedures with officials in OAQPS and the Office of Radiation. We reviewed decision memorandums for arsenic and cadmium and other documentation relating to emission standard setting. We also obtained information from EPA on the extent to which contractors have been involved in the standard-setting process for fiscal years 1982 and 1983.

As requested by the chairman's office, we did not obtain official agency comments on the report. We did, however, discuss the matters contained in the report with EPA officials responsible for the hazardous air pollutant program. Their comments have been incorporated in the report where appropriate. Our review was performed in accordance with generally accepted government auditing standards, except as noted above.

CHAPTER 2

EPA's LIST OF 37 MAY NOT INCLUDE THE MOST HAZARDOUS POLLUTANT CANDIDATES

The identification of hazardous air pollutant candidates is a critical first step in the regulation of substances under Section 112 of the Clean Air Act. EPA has identified and reported to the Congress a list of 37 substances to which it has given priority attention to determine if any are potentially hazardous air pollutants. The list of 37 was refined from a 1976 contractor study of over 600 substances. Many of the chemicals on the list of 37 did not rank among the highest candidates when EPA analyzed 184 substances in 1982 using its newly developed prioritization system. Finally, EPA is examining several hazardous air pollutant candidates that do not appear on the list of 37.

DEVELOPMENT OF EPA's LIST OF CANDIDATES FOR ASSESSMENT

The list of 37 substances evolved from an earlier list of 43 substances developed in 1 week after a limited contractor study in 1976. The contractor study was completed in a short time frame and was not a complete assessment of hazardous air pollutants.

The EPA environmental engineer who developed the original list of 43 stated that he put the list together over a period of about a week, using as its basis a 1976 study conducted by the Mitre Corporation. Mitre compiled a list of 632 industrial organic chemicals and made an initial attempt to rank them based on their production, volatility, and toxicity.

The study cost $26,297 and was completed in 4 weeks and submitted to EPA in June 1976. Because of the limited time allowed for the initial task, Mitre Corporation encountered difficulties procuring the required information and did not detect duplications and printing errors. It revised the original report and resubmitted it to EPA in October 1976.

The EPA environmental engineer who refined the list said that the Mitre study was not a complete assessment of potentially hazardous air pollutants because the study did not include inorganic air pollutants, information was lacking on about 400 of the identified chemicals, and some data provided was incorrect. For example, the study incorrectly listed some chemicals as genotoxic (compounds which are carcinogenic, mutagenic, or teratogenic). A December 1980 SRI International study on health research, unregulated pollutants, and standard-setting also pointed out several potential weaknesses in the Mitre study. For example, since Mitre studied only high-volume synthetic organic chemicals released from manufacturing plants, other types of potentially harmful pollutants, such as fine particulates, may have been ignored by EPA.

Based on the Mitre information, the EPA environmental engineer identified and further screened 147 genotoxins and three nongenotoxins which scored highly in the Mitre ranking. The screening of the 150 chemicals revealed that

--2 compounds were already listed under Section 112 of the Clean Air Act (vinyl chloride, benzene);

--43 priority compounds should be assessed, or were already being assessed (this list became the basis for EPA's list of 37);

--16 compounds required additional information to supplement Mitre data before determining whether a full assessment was warranted;

--26 compounds had no production information, suggesting low production; and

--63 compounds were considered low priority because they showed no indication of genotoxicity (e.g. food additives), were unlikely to be in the ambient air, or were pesticides regulated under the Federal Insecticide, Fungicide, and Rodenticide Act.

Of the 482 remaining nongenotoxins developed by Mitre, 70 were pesticides which would not receive further screening because they were regulated under the Federal Insecticide, Fungicide, and Rodenticide Act, and the other 412 were to be screened for structural similarities to known genotoxins, for other significant acute or chronic health impacts, and for air pollution potential. According to a December 1977 memorandum to the Chief of the OAQPS Pollutant Strategies Branch, this screening should result in a requirement for assessing several additional pollutants. However, officials in OAQPS did not remember any attempts to reexamine the 70 pesticides or 412 other nongenotoxins.

According to the environmental engineer who developed the original "list of 43," the list was a good initial effort but by no means a comprehensive or all-inclusive assessment of suspected hazardous air pollutants.

Refinement of list to 37 substances

Between 1977 and 1982 EPA refined the list of 43 priority hazardous air pollutants to be assessed to the current list of 37. In early 1981 the National Commission on Air Quality published EPA's "list of 43" chemicals then under assessment, but it was not the original list of 43 drafted in 1977. EPA had removed three chemicals, counted six as two, added eight, and consolidated one into another category. For example, three cresols and three xylenes were counted separately on the earlier list; EPA later counted them as two entries--o-,m-,p-xylene and o-,m-,p-cresol--because they have the same chemical formula and are generally made

together. Acetylene tetrachloride was dropped from the original list because EPA later determined that it is produced in low volume. The eight chemicals added included two metals, a nitrosamine, dioxin, and a chemical used to make the pesticides aldrien and dieldrin.

According to the Chief of the Pollutant Assessment Branch in OAQPS, EPA did not utilize any precise formal methodology to reduce the original list of 43 to a list of 37. Instead EPA added or deleted candidates informally as new information became available.

In 1981 EPA began utilizing the results of exposure assessments developed under contract with Systems Applications, Inc., and SRI International to reduce the number of available candidates. The majority of the assessments were conducted under a September 1978 contract to Systems Applications, Inc., which subcontracted much of its work to Hydroscience Incorporated (now IT Enviroscience) and Minimax Research Corporation.

According to the Chief of the Pollutant Assessment Branch in OAQPS, the Systems Applications, Inc., study was never finalized because EPA ran out of money on the contract. Under a work assignment to an existing contract, EPA contracted with Wapora, Inc., to recalculate some of the exposure assessments and incorporate public comments received on the draft report based on the Systems Application, Inc., work.

On the basis of the information developed in the exposure assessments by the three contractors, EPA reduced its priority list to 34. For example, OAQPS removed several chemicals, including dioxane, methyliodide, and three nitrosamines (N-nitrosodiethylamine, nitrosethylurea, and nitrosomethylurea) because they are not produced in any great volume in the United States. Other chemicals, including Bis(chloromethyl) ether and chloromethylmethyl ether, were found to break down in the atmosphere and removed from the list.

EPA later added cadmium, coke oven emissions, and beryllium to bring the current list to 37. Cadmium and coke oven emissions (a major source of polycyclic organic matter) were added because these are two of the four substances on which the Congress, in the 1977 amendments to the Clean Air Act, directed EPA to make a regulatory determination. Beryllium was added because of new evidence that it may be carcinogenic. The following chart identifies EPA's current list of 37 chemicals under assessment.

List of 37

Acetaldehyde
Acrolein
Acrylonitrile
Allyl chloride
Benzyl chloride
Beryllium
Cadmium
Carbon tetrachloride
Chlorobenzene
Chloroform
Chloroprene
Coke oven emissions
o-,m-,p-Cresol
p-Dichlorobenzene
Dimethyl nitrosamine
Dioxin
Epichlorohydrin
Ethylene dichloride
Ethylene oxide
Formaldehyde
Hexachlorocyclopentadiene
Maleic anhydride
Manganese
Methyl chloroform (1,1,1 trichloroethane)
Methylene Chloride (dichloramethane)
Nickel
Nitrobenzene
Nitrosomorpholine
Perchloroethylene
Phenol
Phosgene
Polychlorinated biphenyls
Proplyene oxide
Toluene
Trichloroethylene
Vinylidene chloride
o-,m-,p-Xylene

SOME SUBSTANCES ON THE LIST OF 37 RANK LOW IN EPA's NEW PRIORITIZATION PROCESS

In 1981 EPA contracted out to develop a new process for screening and ranking hazardous air pollutant candidates. Using the methodology established in the new process, EPA ranked 184 substances, including 34 of the pollutants on the list of 37. Many of those 34 did not rank highly in the process, raising questions about the quality of the list of 37.

According to a December 1982 internal OAQPS memorandum prepared by the Chief of the Pollutant Assessment Branch, a long-time deficiency in EPA's hazardous air program has been the lack of an objective method for screening and ranking new chemicals of potential concern. EPA has tried to address this problem by contracting with Argonne National Laboratories to develop a process for ranking hazardous air pollutant candidates. Argonne sifted through approximately 40 ranking methodologies, took the best aspects of each, and developed one process for hazardous air pollutants.

According to officials in the OAQPS Strategies and Air Standards Division, the Argonne method is useful for preliminary screening but its results should not be construed as final. They noted that the Argonne method helps them to develop a rational "first cut" and that it has always been intended only for initial internal priority setting.

In late 1982 EPA used the Argonne method to rank 184 substances. Of the 184 chemicals, 34 of the substances on the list of 37 were included; beryllium, cadmium, and coke oven emissions were excluded because of their advanced stage of assessment. The

sources of the 184 chemicals selected for ranking in the Argonne process are as follows:

Sources	Number
List of 37	34
Chemicals included to test the methodology[a]	3
From earlier "list of 43"	8
Identified from a May 1982 Mitre study[b]	93
Contributed by EPA's Office of Toxic Integration	40
Isomers from xylene and cresol	4
Added by Argonne[c]	2
	184

[a]Two already regulated chemicals, benzene and vinyl chloride, and one small volume chemical, cumenchydroperoxide.

[b]Part of a list of 216 chemicals developed by Mitre Corporation under a task order to an existing Office of Research and Development contract.

[c]Dimethylnitrosamine and morphaline.

Only 5 of the 34 chemicals selected from EPA's list of 37 were included in the top 10 pollutants ranked in the Argonne procedures. Only 18 of the 34 appear in the first 37 of the Argonne method. Several candidates from the list of 37 ranked very low in priority, including:

Chemical	Argonne National Laboratories' ranking out of 184 candidates
Benzyl chloride	89
Hexachlorocyclopentadiene	96
Nitrobenzene	118
Chlorobenzene	124
Nitrosomorpholine	139

According to officials in OAQPS, EPA considers the "list of 37" important because of the emphasis the Congress has given it during its 1982 deliberations on the Clean Air Act. EPA plans to conduct health assessments on all 37 chemicals and will evaluate them to the maximum extent to support defensible regulatory actions. However, in a memorandum to the Director of the OAQPS Strategies and Air Standards Division, the Chief of the Pollutant Assessment Branch noted that, if EPA were to reanalyze a list of priorities, some substances on the list of 37 might be dropped and a number of others added. According to the Deputy Director of the OAQPS Strategies and Air Standards Division, OAQPS will discuss with OHEA the options for replacing some of the substances scheduled for health assessment in fiscal year 1984 with other substances that ranked highly on the Argonne procedure.

EPA IS ASSESSING CHEMICALS NOT INCLUDED ON LIST OF 37

EPA's list of 37 does not include all of the priority pollutants that are being examined for possible regulatory action under Section 112 of the Clean Air Act. OAQPS is examining four suspected hazardous air pollutants not included on the "list of 37"--chromium, mineral fibers, butadiene, and CFC-113. OAQPS has requested a health assessment document on chromium because of recent health studies indicating that certain chromium compounds might be carcinogenic. Mineral fibers are under assessment because OAQPS is concerned that adverse health effects could be the result of the shape or size (if not the chemical composition) of the mineral fiber. OAQPS has recently received some information from EPA's Office of Pesticides and Toxic Substances indicating that butadiene may be a carcinogen. If further screening substantiates this preliminary data, EPA will initiate the development of a health assessment document on butadiene in fiscal year 1984.

OAQPS has requested that, when developing health assessment documents, OHEA give higher priority to some of these chemicals than to several of the substances on the list of 37.

CHAPTER 3

DELAYS IN DEVELOPING HEALTH ASSESSMENT DOCUMENTS

The development of a health assessment document has become a critical step in EPA's process for regulating hazardous air pollutants. EPA estimates that it takes from 1 to 2 years to draft a health assessment document and another 3 to 6 months to obtain SAB review. Several documents, however, have taken much longer. EPA's delays in completing health assessment documents have been a major obstacle in listing and regulating these pollutants. Although OAQPS has had a priority list of hazardous air pollutant candidates since 1977, health assessment documents on only two of these chemicals have been completed to date.

Several factors have contributed to EPA's delays, including shifts in its policies, extensive internal review, and debate over the adequacy of scientific data needed to list a substance under section 112. The resulting delays have contributed to escalating costs per document, constant research data update requirements, and delays in regulatory action. In January 1983 EPA developed new plans to combat these problems by formalizing the content of the health assessment documents and accelerating their production.

FEW HEALTH ASSESSMENTS COMPLETED TO DATE

EPA has developed a detailed and lengthy process for evaluating and regulating potentially toxic air pollutants which is based on an assessment of the effects on human health and the environment of the candidate pollutant. EPA requests that SAB review and give closure to these health assessment documents before they are finalized and used as a basis for regulatory action. The health assessment document has become a critical step in the process of regulating hazardous air pollutants.

Health assessment documents are developed by various offices in OHEA, including the Reproductive Effects Assessment Group, the Cancer Assessment Group, the Exposure Assessment Group, and the Environmental Criteria and Assessment Office. The Environmental Criteria and Assessment Office has field offices in Research Triangle Park, North Carolina, and Cincinnati, Ohio; the former handles the majority of the workload for hazardous air pollutants.

In preparing a health assessment document, OHEA utilizes extramural contractors and/or in-house experts who review and assess available health effects literature concerning the pollutant. OHEA and its contractors do not perform the basic research, however. Instead they consolidate data from the best studies and use it as a basis for drafting the health assessment document.

According to the Director of OHEA, EPA's in-house staff drafts most of the assessments for chemicals that are suspected carcinogens.

OHEA has a contract with Syracuse Research Corporation to work on health assessments for six chemicals, including acrylonitrile, chloroform, chromium, dichlorethane, toluene, and vinylidene chloride. As of March 1983, EPA had spent $427,773 on the contract. Syracuse Research Corporation also drafted health assessment documents on polycyclic organic matter and coke oven emissions under a December 1977 contract with EPA for $167,225. According to officials at Syracuse Research Corporation, they have never subcontracted work on health assessments under these contracts.

EPA has also hired consultants besides the Syracuse Research Corporation to write portions of 12 health assessment documents. These consultants are paid a fee of up to $240 per day. For example, EPA paid $9,660 to three consultants to help draft the methylene chloride health assessment document.

In 1979 OHEA instituted a policy whereby all draft health assessment documents would be reviewed by peer review workshops comprised of experts from within and outside EPA. According to the Director of the Environmental Criteria and Assessment Office in Research Triangle Park, the results of the reviews are incorporated into the documents before they are further reviewed within EPA or sent to SAB. For example, OHEA paid $9,810 to five university professors and two consultants to review the methylene chloride health assessment document. He noted that the reviews are beneficial although they contribute to a more expensive and time-consuming review process.

Progress to date

Although EPA has had a list of priority hazardous air pollutant candidates since 1977, it has completed health assessment documents on only two substances. As of June 1983, EPA had initiated health assessment documents on 19 of the 37 chemicals on its priority list. SAB written closure has been obtained on only two of these documents. EPA has also initiated health assessments on 4 chemicals not on the list of 37, none of which had received written closure from SAB as of June 1983.

In its March 23, 1983, draft Toxic Air Strategy, EPA estimated that it takes 1 to 2 years to draft a health assessment document and another 3 to 6 months for SAB review. As can be seen in the table on the following page, however, EPA has been working on certain health assessment documents for several years without obtaining SAB closure. For example, EPA initiated the health assessment for perchloroethylene almost 5 years ago. Although reviewed twice by SAB, the document had not been finalized as of June 1983. EPA initiated the vinylidene chloride document in December 1979 but had not yet presented it to SAB for review as of June 1983.

Suspected Hazardous Air Pollutants Under Assessment

LIST OF 37	Health assessment document started	1st SAB review	2nd SAB review	3rd SAB review	4th SAB review	SAB closure	Document finalized	Decision to list/ not list
Acetaldehyde[a]	(b)							
Acrolein[a]	(b)							
Acrylonitrile[a]	12/79	9/80	8/82	12/82	6/83[d]	12/82[c]		
Allyl chloride (for Carcinogenicity)								
Benzyl chloride[a]								
Beryllium (for carcinogenicity)	12/82							
Cadmium	12/77	8/78				9/78	10/81	
Carbon tetrachloride[a]	6/81	12/82	4/83			4/83[c]		
Chlorobenzenes	(b)							
Chloroform[a]	2/82							
Chloroprene[a]	(b)							
Coke oven emissions	7/77	5/78	8/82	12/82	6/83[d]	12/82[c]		
O-,M-,P-Cresol[a]								
P-Dichlorobenzene[a]								
Dimethyl nitrosamine								
Dioxin	3/83							
Epichlorohydrin[a]	1/82							
Ethylene dichloride[a]	2/82							
Ethylene oxide[a]	2/82							
Formaldehyde[a]								
Hexachlorocyclopentadiene	2/83							
Maleic anhydride[a]								
Manganese	12/82							
Menthyl chloroform[a]	6/79	9/80	9/82	12/82	6/83[d]	12/82[c]		
Methylene chloride[a]	4/79	9/80	9/82					
Nickel	12/78							
Nitrobenzene[a]								
Nitrosomorpholine[a]								
Perchloroethylene[a]	8/78	9/80	9/82					
Phenol[a]	(e)							
Phosgene[a]								
PCB[a]								
Proplyene oxide[a]	(b)							
Toluene[a]	8/80	9/80	8/82			9/82	5/83	
Trichloroethylene[a]	6/79	9/80						
Vinylidine chloride[a]	12/79							
O-,M-,P-,Xylene[a]								
OTHER CHEMICALS								
CFC-113	4/79	12/82	6/83[d]			12/82[c]		
Chromium	2/82							
Mineral fibers	11/82							
POM	11/77	8/78						

[a]Identified by EPA in 1977 on its original list of 43 potentially hazardous air pollutants.

[b]In August 1982 OHEA initiated work on these chemicals through a task order to a level-of-effort contract with Mitre Corporation. The work cost $76,121 and is a preliminary literature search and accumulation of references. OHEA will begin work on the health assessment documents in 1984.

[c]Oral conditional closure only; OAQPS will not take regulatory action until SAB written closure is obtained.

[d]Final revisions reviewed during June 1983 meeting.

[e]Some health assessment work was conducted on Phenol in 1980 for the Love Canal project.

Source: EPA.

DEBATE OVER THE ADEQUACY OF SCIENTIFIC DATA NEEDED CONTRIBUTED TO DELAYS

EPA's uncertainty as to the nature and adequacy of scientific data needed to list a substance under section 112 has contributed to the delays in finalizing health assessment documents. In response to increased industry awareness and potential legal ramifications, EPA has greatly expanded the amount of health information required to support a listing decision under section 112. A number of issues, including the best way to utilize quantitative risk assessment, have complicated EPA's implementation of section 112.

Increased detail of health assessment documents

EPA's policy concerning the sufficiency of scientific data needed to list a substance as a hazardous air pollutant under section 112 has changed since asbestos, beryllium, and mercury were listed in 1971. To support those listing decisions, EPA did not develop detailed health assessments but instead based the decisions on qualitative--not quantitative--data. Since that time, however, industry resistance has grown so intense that EPA believes it must develop the best health case possible to avoid future legal action. As a result EPA has initiated the lengthy process of drafting detailed health assessment documents utilizing quantitative risk assessment and obtaining SAB closure on those documents.

Because new health studies on various substances are constantly being undertaken and completed, EPA has had difficulty maintaining up-to-date documents. New studies with important information often require EPA to update its health assessment documents. This, in turn, causes EPA to update the document and obtain further internal review of the added information. EPA's failure to update a document could result in the establishment of standards based on data that may not reflect the most current findings.

Quantitative risk assessment and other issues

According to EPA's March 23, 1983, draft toxic air strategy, a number of issues have complicated the implementation of Section 112 of the Clean Air Act. Among those issues "not clearly resolved to date" are:

--Can toxicity to humans be established based on animal data?

--What is the best method to extrapolate from high-dose animal tests to low-dose human exposure at actual ambient concentrations?

--What is the appropriate level of emission controls for pollutants for which health effects thresholds have not yet been demonstrated adequately?

Further delays in finalizing health assessment documents have been caused by disagreements on how best to use quantitative risk assessments. Quantitative risk assessment is a method of characterizing the potential adverse health effects of human exposures to environmental hazards based on numerical data.

The data used for a quantitative estimate can come from either epidemiological or high-dose animal studies. Epidemiology is the strongest form of evidence and is derived largely from high-dose occupational exposures to suspected hazardous air pollutants requiring extrapolations to ambient concentration levels of risk. High-dose animal tests are based on dose extrapolation to humans. EPA assumes that, if a carcinogenic response occurs at the dose levels used in the animal study, it will also occur at all lower doses with an incidence determined by one of several extrapolation models. Several methods can be used to extrapolate the data to a real life human exposure via the ambient air.

Several factors, including disagreements over extrapolating methods, uncertainty about emission rates and dispersion patterns, and limited monitoring data, have made it difficult for EPA to develop the absolute magnitude of the risk to human health based on the available data. For example, because of the time and expense involved in developing data on emission rates, EPA must rely on engineering estimates which sometimes prove to be inaccurate.

SAB has been critical of the method EPA has used to extrapolate health data from animal studies. Among the criticisms of the SAB Subcommittee on Airborne Carcinogens during its September 1980 meeting was that it questioned EPA's use of a single model--the linear non-threshold model--for extrapolating from high to low doses. The chairman of the SAB Subcommittee told us that EPA went too far in trying to quantify the risk assessment. He believes that it is better not to use any method rather than to rely on a number developed under one extrapolation method. This disagreement resulted in SAB's refusal to give closure to several health assessment documents. During a December 1982 SAB meeting, EPA agreed with the Environmental Health Committee's recommendation to use other models in addition to the linear non-threshold one to extrapolate health data.

SHIFT IN AGENCY POLICIES CONTRIBUTED TO DELAYS

Another reason for the various delays in completing health assessment documents has been the numerous shifts in EPA policy as to what should be included in the documents. Since 1978 EPA has shifted its emphasis from full health assessments to those

that examine cancer only and back to full assessments. Furthermore, EPA changed its approach from developing health assessments for air only to a complete multimedia analysis. Finally, for a period of several months, EPA shifted its resources away from health assessment documents to develop several health documents in response to the Love Canal hazardous waste situation.

Evolution of full health assessment

EPA has been working on health assessment documents for hazardous air pollutants since 1977. Since then EPA has come full circle--full health to cancer-only and back to full health--in its policy outlining what should be included in those documents.

During 1977-78 EPA's hazardous air pollutant health assessment documents evaluated all health effects including both carcinogenic and noncarcinogenic. The earliest work on these documents was completed under work assignments to an OAQPS contract with PEDCO Environmental, Inc. EPA requested that PEDCO develop health assessments on coke oven emissions, arsenic, and benzene; PEDCO subcontracted the first two to the American Health Foundation and the third to a professor at New York University. In 1978 EPA created the Environmental Criteria and Assessment Office in Research Triangle Park to prepare air criteria documents and health assessments for hazardous air pollutants. The next year the Assistant Administrator for Research and Development consolidated several groups into OHEA to centralize these functions.

In 1979 EPA proposed its airborne carcinogen policy which placed heaviest emphasis on the evaluation of potential carcinogenicity and significant exposure as the primary basis for listing a substance as a hazardous air pollutant. As specified in the public notice announcing the policy, EPA began following the proposed policy in the interim before final approval. As a result, OHEA shifted its emphasis to produce cancer assessments and to prepare brief health effects summaries excerpted from the detailed health assessment documents. These two documents, along with an exposure assessment drafted by OAQPS, were presented to SAB for review. OHEA also completed drafts of full-scale health assessments, but they were "put on hold" and not reviewed by SAB.

In late 1980/early 1981 EPA shifted its emphasis away from cancer assessments back to full-scale health assessments. On January 7, 1981, the Director of OAQPS sent a memorandum to the Director of OHEA stating,

> "The strategy of employing a 'low hurdle approach' for initiating regulatory action to control potential hazardous air pollutants was a principal feature of the Airborne Carcinogen Policy. I am now of the opinion that, in the future, a comprehensive health assessment [emphasis added], reviewed by the SAB, is necessary before listing a substance as a hazardous air pollutant

under section 112 of the Clean Air Act or designating a substance as a pollutant under section 111(d). This is a recent change in our thinking with respect to commencing the regulatory process * * *. While the assessment of carcinogenic risk is important, I believe that it should not be overemphasized or divorced from consideration of other health effects."

According to the Director of OHEA, the health assessment documents for hazardous air pollutants were completely reworked as a result of this policy shift. In late 1980/early 1981 OHEA merged the previously separate assessment efforts into a single, comprehensive document for each candidate hazardous air pollutant then under assessment. OHEA reactivated the earlier health assessment documents and included chapters on carcinogenicity; the detailed cancer assessments were attached as appendixes. OHEA later merged the cancer assessments into the body of the health assessment documents.

Multimedia documents

In late 1980/early 1981 OHEA also began to shift its emphasis from air-only to multimedia documents. A multimedia document examines the health effects from other routes of exposure (e.g., ingestion) as well as air. In January 1981 the Director of OAQPS wrote the Director of OHEA stating that he wanted health assessments that provide multimedia assessments consisting of the collection, summarization, analysis, and interpretation of scientific data regarding all health consequences.

According to the Chief of the Pollutant Assessment Branch, Strategies and Air Standards Division, OAQPS, the development of multimedia documents (versus air-only assessments) is more time consuming but is less costly to EPA in the long run because it helps prevent duplication of effort by other program offices. He also stated that the multimedia documents focus more on air than any other medium.

Love Canal documents

EPA's decision to divert resources into the development of "Love Canal" documents also delayed the development of health assessment documents for hazardous air pollutants. Love Canal documents were multimedia health risk assessments for several chemicals suspected of being present at Love Canal based on initial monitoring data. In the early fall of 1980, the Assistant Administrator for Research and Development directed OHEA to assist in EPA's Love Canal evaluation activities. The EPA Deputy Administrator had originally requested the work as part of her commitment to provide an environmental assessment study to residents of Love Canal by December 1980. The Deputy Administrator notified OHEA that its work on the Love Canal exposure and risk assessments would result in delays to its work schedule, including a 3-month delay in the preparation of 12 health assessment documents. According to a December 1980 internal OHEA memorandum from the

Director of the Environmental Criteria and Assessment Office in Research Triangle Park, the scope of the Love Canal document project would have normally required many more months or in excess of a year to complete. It required OHEA to redirect a considerable portion of its extramural contract funds allocated for the preparation of hazardous air pollutant and water quality/hazardous waste documents.

In response to the Love Canal directive, OHEA developed draft health assessment documents for 35 chemicals. According to a physical scientist in the Environmental Criteria and Assessment Office, these documents were completed under existing contracts with five contractors, including Syracuse Research Corporation; Biospherics, Inc.; EnviroControl; Battelle Memorial Institute; and the Mitre Corporation.

OHEA held peer review workshops in Research Triangle Park and Cincinnati for the draft health assessment documents in December 1980 and January 1981. OHEA was in the process of incorporating those comments into the drafts when the project was terminated in March 1981 because EPA's Acting Administrator decided that EPA should defer to the Centers for Disease Control in the Department of Health and Human Services for any health interpretations of the Love Canal data. According to Office of Research and Development officials, the documents are still in peer-reviewed draft form and were never forwarded to the Centers for Disease Control or used to support a decision on Love Canal. The Director of the Environmental Criteria and Assessment Office at Research Triangle Park said that although the documents were never used for their intended purpose, the effort was not completely wasted because his office was later able to utilize some of the information developed in the Love Canal documents. The project, however, lasted about 5 months, required a large shift in resources, and resulted in further delays in drafting hazardous air pollutant health assessment documents.

EXTENSIVE INTERNAL REVIEW DELAYED HEALTH ASSESSMENT DOCUMENTS

Extensive internal reviews within the Office of Research and Development and other program offices have contributed to delays in getting hazardous air pollutant health assessment documents to SAB for review. However, officials in OAQPS and OHEA stated that, although the reviews have been time consuming, they have resulted in improvements to the various health assessment documents.

Office of Research and Development internal reviews

Health assessment documents for hazardous air pollutants have always been subjected to a detailed internal review by the various groups within OHEA. In 1981, however, the Administrator slowed the health assessment document development process by adding further layers of review. Because of a belief that EPA's Office

of Research and Development did not subject its work to sufficient review, the Administrator directed OHEA to send the documents to the Assistant Administrator for Research and Development for a policy review by various components of the Office of Research and Development.

According to officials in OHEA, the entire internal review process was lengthened with the addition of the Office of Research and Development policy review. This review added between 6 months and 1 year to the time needed to develop external drafts of the nine health assessments that were finally sent to SAB in April 1982. The Director of the Environmental Criteria and Assessment Office in Research Triangle Park noted that the various layers of review contributed to the fact that no documents were available to be transmitted to SAB in 1981. Health assessment documents for hazardous air pollutants have since been exempted from the Office of Research and Development policy review.

These layers of review have resulted in delays to other documents, as well. For example, the Environmental Criteria and Assessment Office initiated a health assessment document for vinylidine chloride in December 1979 and, as of June 1983, had still not released a draft for SAB and public review. The Office submitted its first draft for OHEA review in May 1980 and had it further reviewed by a peer review workshop in September 1980. A revised second draft was prepared in March 1981 and sent out for comments within OHEA and the Office of Research and Development during the spring of 1981. The Environmental Criteria and Assessment Office prepared a third draft and in December 1981 requested another OHEA review. Final and usable comments were not received from all parties until October 1982. After obtaining that input, the Office consolidated the comments into the report and, after sending it back to the contractor for information updating, provided the report to OHEA's Cancer Assessment Group and the Office of Research and Development laboratories one last time for a final review. As of June 1983 EPA planned to release the vinylidene chloride external review draft for SAB review about November 1983.

OAQPS has expressed concern about delays caused by the Office of Research and Development reviews. In an October 1981 memorandum to the Acting Assistant Administrator for Research and Development, the Director of OAQPS stated that he was concerned about the status of health assessment documents on seven high-priority substances and strongly recommended that the requisite internal reviews be completed as soon as possible so that they could be released to SAB and the general public for review and comment. In November 1981 EPA's Assistant Administrator for Air, Noise and Radiation wrote a memorandum outlining her concerns that various health assessment documents, including those for high-priority substances, were to be "reviewed under newly developed Office of Research and Development peer review procedures prior to release to the SAB." She noted the importance of the SAB review and stated her interest in having the documents submitted to SAB for review as soon as possible.

Other EPA reviews

Other EPA offices besides the Office of Research and Development have been involved in the review of health assessment documents. OAQPS, as the customer program office, reviews each document. In 1981-82 several documents were submitted to the Toxic Substances Priority Committee and the Assistant Administrator for Pesticides and Toxic Substances. The latter review was sequential to those by the Office of Research and Development and contributed to the delay in making the documents available for public and SAB review.

In March 1981 OHEA was assigned the responsibility of preparing drafts of six health assessment documents to be reviewed by the Toxic Substances Priority Committee. The Committee, comprised of officials from various EPA program offices, was formed to coordinate issues of common concern throughout EPA. Because OHEA had already initiated work on six solvents that were of interest throughout EPA, the Director of OHEA agreed to expand the health assessments into more comprehensive documents; the Toxic Substances Priority Committee reviewed them in July 1981 and OHEA incorporated its comments. The Committee was disbanded in 1981 by the Assistant Administrator for Pesticides and Toxic Substances because he believed it was becoming involved in making policy decisions.

In January 1982 the Director of OHEA requested that the Assistant Administrator for Pesticides and Toxic Substances review and comment on the health assessment documents for six substances before they were sent to SAB. The documents (on methyl chloroform, methylene chloride, CFC-113, perchloroethylene, carbon tetrachloride, and trichloroethylene) had already been subjected to extensive reviews, including peer review workshops, the Toxic Substances Priority Committee, and internally within EPA. On February 26, 1982, the Assistant Administrator responded, commenting on each of the documents and giving his approval to forward them to SAB. OHEA incorporated his comments into the drafts which were among the nine released in the Federal Register in April 1982.

DELAYS RESULTED IN HIGHER DOCUMENT COSTS AND POSTPONED REGULATORY ACTION

The problems in finalizing health assessment documents caused by policy changes, extensive reviews, and uncertainty over the adequacy of scientific data needed have resulted in higher document costs, constant data updates, and delayed regulatory actions.

Health assessment costs

EPA estimates that the total costs to date of the health assessment documents for 23 hazardous air pollutants are about $4.1 million, with the various documents ranging from $68,000 to

$320,000. The individual document costs depend in part on the complexity and extent of scientific data evaluated, the amount of controversy associated with a substance, and the difficulties in obtaining SAB closure. The following table provides a summary of EPA's estimated costs for producing various health assessment documents.

EPA Estimated Costs for Developing Health Assessment Documents[a]

Hazardous air pollutant candidate	In-house costs	Outside contractor costs	Total costs
	----------(000 omitted)----------		
Acrylonitrile	$ 162	$ 85	$ 247
Arsenic	142	64	206
Cadmium	100	42	142
Carbon tetrachloride	210	25	235
Chlorobenzenes	73	127	200
Chlorofluorocarbon-113	49	19	68
Chloroform	53	44	97
Chromium	36	50	86
Coke oven emissions	198	57	255
Dioxin	50	120	170
Epichlorohydrin	100	41	141
Ethylene dichloride	113	34	147
Ethylene oxide	110	34	144
Hexachlorocyclopentadiene	30	60	90
Manganese	45	130	175
Methyl chloroform	184	20	204
Methylene chloride	181	41	222
Nickel	68	37	105
Perchloroethylene	283	37	320
Polycyclic organic matter	95	188	283
Toluene	67	95	162
Trichloroethylene	223	40	263
Vinylidine chloride	69	86	155
Total	$2,641	$1,476	$4,117

[a]These are estimates developed by OHEA through March 1983; they do not include in-house administrative overhead or the expenses for SAB reviews.

According to the Director of the Environmental Criteria and Assessment Office in Research Triangle Park, these documents would not have been as costly if it were not for all the various "starts and stops" brought on by various policy changes. The following table indicates how EPA's various shifts in policies have contributed to the costs of these documents. For example, EPA estimates that the original air health assessment document for perchloroethylene (evaluating all health effects) cost $155,000. When EPA shifted its policy to emphasize cancer only, it developed a cancer assessment document for an estimated $60,000. EPA estimates that it spent another $10,000 developing a perchloroethylene document in response to the Love Canal request. Finally, EPA estimates it has spent another $75,000 developing a health assessment document that reflects its shift from cancer back to full health and from an air-only to a multimedia format.

EPA Estimated Costs for Perchloroethylene Health Assessment

Timespan of assessment		In-house	Outside contractor	Total
		------(000 omitted)------		
1977-78	Preliminary cancer assessment	$ 20	$ 0	$ 20
1978-80	Air health assessment document	138	17	155
1979-80	Cancer assessment document	60	0	60
1980-81	Love Canal document	5	5	10
1981-83	Multimedia health assessment document	60	15	75
Total		$283	$37	$320

Dated research information

The delays brought on by various policy shifts and lengthy reviews have resulted in dated information which, in turn, has caused EPA to spend more time and money updating the documents.

A consultant to SAB's Environmental Health Committee told us that, because of the lengthy administrative review process within EPA, the literature used as a basis for the health assessment documents is sometimes dated.

After the various internal reviews given the vinylidene chloride document, the EPA project manager wrote the contractor in January 1983 stating that the draft of November 1981 was obviously out of date and should be updated to include new literature. The contractor updated the information at a cost of $7,992. After obtaining comments from the Office of Research and Development laboratory directors and OAQPS, OHEA sent the draft back to the contractor in May 1983 to incorporate these comments at a cost of about $3,500.

According to an official at Syracuse Research Corporation, similar research information updates are common and have been completed on virtually every document with which they have been involved. He said that for some documents Syracuse Research Corporation has updated the research information more than once. He noted that the updates are completed under purchase orders under the existing contract. Our review of these purchase orders showed that most updates by Syracuse Research Corporation take about 1 month to conduct and cost about $8,000-$9,000 per update.

Delayed regulatory action

Because it is EPA's policy not to take a regulatory action on a hazardous air pollutant until SAB has reviewed and given closure to the health assessment document, delays in finalizing the documents ultimately affect the regulatory process. Over the past 3 years OAQPS has repeatedly expressed concern to OHEA about delays in preparing health assessment documents for SAB review and the effect of those delays on regulatory schedules.

For example, EPA action on coke oven emissions has been significantly delayed because of problems with the health assessment. In an August 22, 1980, memorandum to the Director of OHEA, the Director of OAQPS wrote:

> "OAQPS has a very significant effort underway to develop national emission standard regulations for certain coke oven sources. This effort is nearing completion and any delay in getting SAB review of the coke oven risk and exposure documents will cause us to delay proposal of these major regulations."

In April 1981 the Acting Assistant Administrator for Air, Noise and Radiation forwarded a draft Federal Register package and supporting documentation for the coke oven regulations to EPA Steering Committee members. In his cover letter he stated that EPA's schedule for listing coke oven emissions has been delayed due to delays in OHEA's assessment of carcinogenicity. He also noted that he expected an SAB review of that document in July 1981 and a listing publication in September 1981.

In November 1981 the Assistant Administrator for Air, Noise and Radiation wrote the Acting Assistant Administrator for Research and Development stating her concern about the status of the coke oven emissions document, as well as those for five organic solvents and acrylonitrile. She said that regulatory decisions are awaiting favorable SAB review of all of these documents. Because of the various review processes discussed earlier, EPA did not send these documents to SAB until April 1982. The coke oven document had not received written closure as of June 1983. According to the Chief of the Pollutant Assessment Branch in OAQPS, the coke oven emissions standards are drafted and ready to be released as soon as SAB gives closure to the health assessment document. The health case for coke oven emissions remains

unchanged; SAB, however, continues to have problems with the manner in which EPA has presented the data in the health assessment document. He said that the health assessment document will have no impact on the wording of the proposed regulations.

NEW OHEA PLANS FOR DEVELOPING HEALTH ASSESSMENT DOCUMENTS

OHEA has developed plans to combat some of the problems that have plagued the health assessment document process in the past. An OHEA report, dated January 10, 1983, provides guidance for future health assessment documents and specifically discusses document content, degree and type of assessment, and document preparation and review. Following are some specific policies established by the plan:

--The immediate purpose of the documents is to meet the needs of OAQPS under the Clean Air Act; however, attempts will be made to identify other user offices in EPA and some documents will be multimedia in nature.

--The largest proportion of each document should be devoted to health effects information.

--Health assessment documents should be completed in three stages--preliminary literature review, intermediate stage assessment, and comprehensive health assessment--with a determination whether the next stage will be conducted to be made after each assessment.

--The health assessment documents will be reviewed by OAQPS, the Office of Research and Development, and an independent peer-review panel at various points in the three-stage process.

The January 1983 report also outlined two options for accelerating the review of hazardous air pollutants. One option provides that EPA will evaluate 40 chemicals in 4 years (i.e., by mid-1987), and the second option provides for the evaluation of those 40 chemicals within 2 years. Both alternatives would require more resources; in its fiscal year 1984 budget request, EPA asked for an increase in resources to help meet the goals of the first option. For fiscal year 1984, EPA requested and obtained an increase of $121,200 for its in-house budget and $1,100,000 for its outside contract budget to intensify efforts to prepare health assessments for use by OAQPS in hazardous air pollutant listing decisions.

CHAPTER 4

SAB's ROLE IN REVIEWING HEALTH ASSESSMENT DOCUMENTS

SAB plays a critical role in the review of hazardous air pollutant health assessment documents. Before taking any regulatory action on a suspected hazardous air pollutant, EPA requires that SAB review the health assessment document developed on the chemical to assure that the document is scientifically accurate and adequately represents the latest knowledge on health effects. Between 1978 and 1981 SAB utilized several different mechanisms to review these documents, including ad hoc subcommittees and a Subcommittee on Airborne Carcinogens.

In 1981 SAB transferred all responsibility for reviewing hazardous air pollutant health assessment documents to one of its standing committees--the Environmental Health Committee. The Environmental Health Committee is composed of nationally known health experts who are supplemented by consultants to help review specific documents. The Committee met four times in 1982 and twice in 1983 as of June. In 1981 EPA reduced the size of the Environmental Health Committee and did not reappoint 10 of the 11 members whose terms expired.

Some delays in finalizing health assessment documents are attributable to SAB. Delayed or postponed SAB meetings have had some impact on health assessment documents. Delays in obtaining written letters of closure from SAB have also slowed the regulatory process.

SAB no longer reviews exposure assessments developed by OAQPS as it did prior to 1981.

NATURE OF SAB REVIEW HAS EVOLVED

An integral part of EPA's process for regulating hazardous air pollutants is the SAB review of the health assessment documents that form the scientific basis for decisionmaking. According to section 117(c) of the Clean Air Act, prior to publishing any list or standard under section 112(b)(1), the EPA Administrator shall, "to the maximum extent practicable within the time provided, consult with appropriate advisory committees, independent experts, and Federal departments and agencies." As a result EPA consults with SAB before making a listing decision. Although section 117(c) directs the Administrator to consult with appropriate advisory committees, it is EPA's policy that it not take a regulatory action until it obtains SAB closure on the health assessment document. The SAB review is conducted to assure that EPA's documents are scientifically accurate and adequately represent the latest knowledge on health effects. According to EPA officials, the SAB review has resulted in significant changes and improvements in the various health assessment documents.

SAB has been reviewing health assessment documents for hazardous air pollutants since 1978. Several different SAB committees and subcommittees have been involved in the reviews over the years, including several ad hoc subcommittees, the Subcommittee on Airborne Carcinogens, and the Environmental Health Committee.

In 1978-79 SAB established various special ad hoc subcommittees to review the health assessment documents. These subcommittees were comprised of SAB committee members and consultants and met on the following dates.

Subcommittee	Meeting dates
Arsenic	May 22-23, 1978, and January 10, 1979
Cadmium	August 9-10, 1978
Coke Oven Emissions	May 30-31, 1978
Polycyclic Organic Matter	August 3-4, 1978

The SAB standing Committee on Environmental Health also reviewed the health assessment document for benzene during two meetings--January 18 and February 3, 1978. According to the Executive Secretary of the Environmental Health Committee, the workload of the standing committees was heavy enough to warrant establishing the special subcommittees listed above. He also noted that the special ad hoc subcommittees provided more specialized expertise in reviewing the documents.

In 1980 SAB established a Subcommittee on Airborne Carcinogens to review several health assessment documents drafted under EPA's proposed airborne carcinogen policy. According to the former Director of SAB, the Subcommittee was established so that SAB would have a single group that could give a consistent review of potential carcinogenicity. The Subcommittee met on September 4, 1980, and reviewed six cancer risk assessment documents EPA had prepared under airborne carcinogen policy guidelines. The Subcommittee criticized the EPA documentation as being incomplete and uneven in quality and stated that EPA's findings of carcinogenicity were based on insufficient evidence. According to the chairman of the Subcommittee, the documents were poorly written and suffered from insufficient data.

At the completion of the September 1980 meeting, the Subcommittee tentatively planned to meet again and EPA began to completely revise those documents to satisfy the Subcommittee's criticisms. However, the Subcommittee did not reconvene because the Administrator reorganized SAB, and the SAB Director transferred the review responsibility to the Environmental Health Committee.

ENVIRONMENTAL HEALTH COMMITTEE MEMBERSHIP AND COMPENSATION

In 1981, EPA made several changes to SAB that affected all committees, including the Environmental Health Committee. The EPA Deputy Administrator decided not to renew most of the Committee members' terms and EPA also reduced the size of the Committee.

Consistent with prior practice, SAB continues to use consultants and pay them a fee of up to $240 per day. The major factors in scheduling meetings for the Environmental Health Committee are the time it takes EPA to develop the health assessment documents and the availability of Committee members.

Most members' terms not renewed

In 1981, EPA's Deputy Administrator did not extend most existing SAB members whose terms were expiring. Of the 11 members of the Environmental Health Committee whose term expired on September 30, 1981, 10, including the chairman, were not renewed as members. Many of those not renewed had been members for several years. For example, the chairman had been a member of SAB since 1974 and his term had been extended continually since then.

Size of Committee reduced

In 1981 the Deputy Administrator of EPA reduced SAB from 90 to 50 members in order to achieve cost savings for travel, per diem, and compensation. These changes resulted in SAB's committees being reduced from approximately 15 to between 7 and 10 members. The Environmental Health Committee was reduced from 13 members in January 1981 to 8 members by March 1983. According to the Executive Secretary of the Environmental Health Committee, these reductions could result in increased workload. He said that since the Committee size was reduced, the absence of one or two members can have a more serious impact on the scheduling of meetings because, while all members are not needed, it is desirable to have full attendance.

Both of the former directors of SAB stated that the recent size reduction may have some adverse effects on the Committee's ability to function. The former Chairman of the Environmental Health Committee told us that, as long as consultants can be added to enhance the Committee's expertise, the reduction in membership would not be a problem. He cautioned, however, that the Committee needs a core of members to provide continuity and that it would be handicapped if only 5 or 6 members attended a meeting.

Environmental Health Committee compensation

SAB members are paid $100/day plus travel and subsistence expenses for their services. The subsistence expense is based on the Federal Government allowance which has a current ceiling of

$75/day. The $100/day compensation has not been increased since 1975. The Director of SAB, the former directors, and several of the current and former SAB members told us that the level of compensation for SAB members is very low relative to what the members can command in private industry.

According to the Director of SAB, the Environmental Health Committee--like other SAB committees--meets between three and five times per year. The meetings last 1 or 2 days. Members are paid for their preparation time as well as the time they actually spend attending the meetings. SAB does not require the members to complete timesheets; instead, the members informally report their time to the executive secretary of their respective committees.

The Environmental Health Committee held four meetings in calendar year 1982: July 7, August 2-3, September 28-29, and December 8-9. As of June 1983, the Committee had met twice in 1983--April 25 and June 10--and plans to hold two more meetings during the year.

We reviewed the timecards that the Executive Secretary maintains on the Committee members and found that members charged up to 16 hours preparation time in addition to the time spent in meetings. For 10 different Committee members who attended some or all of those meetings, 776 hours were charged, resulting in a total compensation of $9,700 for calendar year 1982. The following table shows the Environmental Health Committee expenditures for members in 1982-83.

Year	Travel	Compensation	Total
1982	$14,482	$ 9,700	$24,182
1983[a]	1,959	1,400	3,359
	$16,441	$11,100	$27,541

[a]As of May 15, 1983.

On April 28, 1983, the General Services Administration proposed new regulations to eliminate compensation paid to Federal advisory committee members (including SAB) in most cases. On April 29, 1983, EPA's Acting Assistant Administrator for Administration sent a letter to the Administrator of the General Services Administration expressing concern about the proposal and stating that EPA feels very strongly that each agency head should determine whether to compensate committee members. The letter stated that the Government subsistence allowance of $75 per day is usually insufficient to cover expenses and that EPA's $100 per day honorarium is partly used to defray expenses. The General Services Administration's proposed regulations were open for public comment until July 27, 1983.

Use of consultants

The Environmental Health Committee--like other SAB committees --utilizes various consultants in reviewing EPA scientific documentation. Consultants to SAB are paid up to $240 per day. SAB maintains a "pool" of consultants hired for 1-year renewable terms and uses them on an as-needed basis. According to the Executive Secretary, the Environmental Health Committee uses consultants to add specific expertise when reviewing documents on certain pollutants. He noted that consultants are often better able than members to delve into the technical detail of the studies discussed in health assessment documents.

The Executive Secretary also stated that, because of its reduced membership, the Environmental Health Committee uses more consultants than in the past. Because consultants earn about twice as much as members, this trend could help offset the savings of reducing Committee size.

In 1982, the Environmental Health Committee used seven consultants to review hazardous air pollutant health assessment documents. Four of them reviewed the coke oven emissions document. Another consultant helped review six different documents. The other two consultants were Committee members whose terms expired on September 30, 1982, after which they were utilized as consultants. Both were present at the December 1982 meeting and were paid consultant fees of $170.24 and $221.12, respectively, per day, or about twice as much as they would have earned as Committee members for doing the same amount of work. In 1982 EPA compensated Environmental Health Committee consultants $6,714 for working 296 hours, or an average of $181.46 per day.

The following table shows Environmental Health Committee expenditures for consultants in 1982-83.

Year	Travel	Compensation	Total
1982	$3,552	$6,714	10,266
1983[a]	1,062	1,439	2,501
	$4,614	$8,153	$12,767

[a]As of May 15, 1983.

How meetings are scheduled

The two major factors involved in scheduling an Environmental Health Committee meeting are the length of time it takes EPA to prepare the health assessment documents and the availability of Committee members. The Director of SAB decides when to call a meeting of the Committee after consulting with officials in OHEA

and OAQPS to see when the health assessment documents in question will be ready for review. The Executive Secretary of the Committee contacts the members to give them alternative dates and then selects a time when the most members can be present. According to the Executive Secretary, meetings are scheduled on an as-needed basis. He said that several factors are involved--having sufficient business for the Committee, availability of members, and providing adequate time for public input. Because SAB allows public groups to comment on the documents, the Committee wants to ensure that the public can obtain a document in sufficient time to present comments. The number of health assessments available also determines whether the meeting will be 1 or 2 days in length. He also said that it is often difficult to find dates when all or most of the Committee members can be present. He will not hold a meeting on a date for which one or two key members or consultants cannot be present.

SOME DELAYS IN FINALIZING HEALTH ASSESSMENT DOCUMENTS ATTRIBUTABLE TO SAB

Whenever SAB suggests changes to a health assessment document, EPA takes the time to make the necessary changes to obtain SAB closure. This often results in going back to SAB two or three times before final closure is obtained, delaying the finalization of the document. SAB has been responsible for other delays in finalizing health assessment documents for hazardous air pollutants. Canceled or delayed meetings because of scheduling problems have affected at least two documents. Also, delays in obtaining written closure after the Environmental Health Committee has given oral closure to health assessment documents have slowed the regulatory process.

Delays from scheduling meetings

According to officials in OAQPS, most of the delays in obtaining SAB review have not been the result of SAB scheduling problems. Most problems have been caused by EPA's failure to quickly make changes to incorporate SAB suggestions. However, in at least two instances, delays or postponements of SAB meetings have contributed to delays in completing health assessment documents. In 1980 a scheduled SAB meeting to review the inorganic arsenic document was never held because SAB ran out of travel funds. A February 1982 meeting to review the carbon tetrachloride document was delayed because the chairman had a scheduling conflict with another SAB committee.

Although inorganic arsenic was listed in June 1980 as a hazardous air pollutant under Section 112 of the Clean Air Act, the decision was not based on SAB closure of the inorganic arsenic health assessment document. In 1977 EPA began work on an arsenic health assessment document under a contract to the American Health Foundation. The document was reviewed and rejected by the SAB

Subcommittee on Arsenic in May 1978 and January 1979. In April 1979 the Subcommittee released a report which outlined its problems with the document and stated that the majority of its recommendations had not been incorporated into the January 1979 version. In January 1979 EPA's Assistant Administrator for Research and Development shifted the overall responsibility for revising the document from the Office of Research and Development in Washington to the Environmental Criteria and Assessment Office in Research Triangle Park. The Office completed its draft of the arsenic document in April 1980, and EPA scheduled an SAB review for May 1980. That review never took place, however, because SAB ran short of travel funds.

EPA listed arsenic as a hazardous air pollutant under the proposed airborne carcinogen policy in June 1980. The decision was partially based on a January 1980 letter from the Chairman of the SAB Subcommittee on Arsenic which acknowledged that "a decision to 'list' arsenic as a hazardous air pollutant under the * * * airborne carcinogen policy is consistent with and supported by past documentation reviewed by the Subcommittee." The chairman had reviewed the April 1980 version of the health assessment document and generally approved it, but that version was never formally reviewed and given closure by the entire SAB Subcommittee.

Because EPA never obtained written SAB closure of the arsenic document, it has had to shift resources and delay the development of other health assessment documents in 1983. In a January 1983 decision, The State of New York v. EPA 81 Civ. 6678, the U.S. district court ruled that because EPA had failed to meet the Clean Air Act's 180-day deadline for proposing hazardous air pollutant standards, EPA would have to publish such standards by July 1983. As a result of the decision on arsenic, EPA has resurrected its earlier document and updated it which, in turn, has caused it to rearrange its priorities and delay work on other health assessment documents.

The carbon tetrachloride document was also delayed about 2 months because of SAB scheduling problems. In February 1983 the Environmental Health Committee had scheduled a meeting to review, among other things, the carbon tetrachloride health assessment document. Because the chairman of the Committee is also a member of another SAB review group that met on the scheduled date, the Environmental Health Committee meeting was delayed until April 25, 1983.

Delays in obtaining written closure affect regulatory process

Although the Environmental Health Committee gave oral conditional closure to four health assessment documents in December 1982 and one in April 1983, it had not finalized the written closure letters as of June 1983. The closure letters are drafted by the Committee's Executive Secretary with input from the Director of SAB. Once completed, the letters are forwarded to the

members for final review and then signed by the chairman. The Executive Secretary and the Chairman of the Environmental Health Committee will not draft a closure letter on a substance until the Committee receives a final health assessment document from EPA which demonstrates that the Committee's comments have been incorporated.

This delay can result in a slowdown of the regulatory process. According to the Chief of the Pollutant Assessment Branch, although OAQPS will begin drafting the decision memorandum to the Administrator based on the oral closure, it will not forward the memorandum to the Administrator until it has received written closure from SAB. He stated that OAQPS has drafted decision memorandums on acrylonitrile and coke oven emissions which will be forwarded to the Administrator for review as soon as a written closure letter is obtained. He also stated that, because OAQPS is treating all the solvents as a package, it will not forward the decision memorandums on those documents until SAB's written closure has been received for all of them.

SAB NO LONGER REVIEWS EXPOSURE ASSESSMENTS

SAB's Environmental Health Committee does not review the exposure assessments that, combined with the SAB-reviewed health assessment document, form the basis of the total risk analysis for a hazardous air pollutant. Before 1981 SAB reviewed both the health assessment document and the exposure assessment. Instead, EPA now includes a very general overview in the health assessment document which summarizes the exposure assessment results.

Both the ad hoc SAB subcommittees on specific chemicals and the SAB Subcommittee on Airborne Carcinogens reviewed exposure assessments as well as the health assessments. In April 1982 the Director of OAQPS decided that the exposure assessments would no longer be included in the package sent to SAB for review. OAQPS believes that exposure assessments are not scientific documents but are preliminary assessments that give estimates on types of sources and numbers of people exposed. According to the Deputy Director of the Strategies and Air Standards Division of OAQPS, EPA does not obtain any other independent scientific review of exposure assessments.

During the December 9, 1982, Environmental Health Committee review of health assessment documents, three members expressed concern about SAB's not being able to review the exposure assessments. The Director of SAB told us that the Environmental Health Committee should review exposure assessments and that he has expressed that view to officials in OAQPS.

CHAPTER 5

DELAYS IN SETTING STANDARDS AFTER SAB REVIEW

EPA has not made a listing decision on two substances for which the Science Advisory Board has written letters of closure even though written closure on one of them--cadmium--was obtained in 1978.

Of the seven substances EPA has listed, it has promulgated regulations on only four and has been sued for missing congressionally mandated 180-day deadlines to propose or promulgate regulations on the remaining three substances. In order to meet the deadlines outlined in court orders, EPA has had to shift a significant amount of resources away from work on other substances.

In developing regulations, EPA interprets the Clean Air Act to provide that costs of compliance may be taken into account when EPA sets standards for pollutants for which there is no safe level established. According to EPA officials, obtaining the necessary cost data contributes to delays and the difficulty in meeting the 180-day deadlines. We believe that under section 112 the Congress intended the EPA Administrator to establish emission standards at a level that eliminates significant risk to the public health and that economic and technological feasibility were not intended to be relevant considerations.

EPA has not completed reviews of the standards that have been set for three of the four pollutants that are already regulated under section 112.

EPA HAS NOT MADE A LISTING DECISION AFTER OBTAINING SAB CLOSURE

EPA has not made a listing decision on either of the two chemicals for which it has received a written letter of closure from SAB. SAB sent EPA a letter of closure on cadmium on September 15, 1978, and on toluene on September 29, 1982; as of June 1983, no decision had been made as to whether to list either substance.

Decision process after SAB review

After SAB gives written closure attesting to the scientific validity of the health assessment document, OAQPS combines that information with exposure assessment data and prepares a decision--or action--memorandum. The decision memorandum accompanies a proposed Federal Register listing notice and is sent from the Assistant Administrator for Air, Noise and Radiation to the EPA Administrator. The decision memorandum summarizes the information contained in the exposure assessment and the health

assessment document and includes a recommendation to the Administrator. Before the memorandum and Federal Register package reaches the Administrator, it is reviewed by a Steering Committee and is subjected to the "red border" review process.

The Steering Committee consists of representatives of the six assistant administrators, the Office of Legal and Enforcement Counsel, and office directors on the Administrator's staff who provide an intermediate-level policy review for all EPA proposed or final actions. After Steering Committee review, the listing package is sent through EPA's "red border review," which is an internal review at a senior level by the Office of Legal and Enforcement Counsel, the Associate Administrator for Policy and Resource Management, and any assistant administrator who requests participation. Finally, the decision package, as modified by the Assistant Administrator for Air, Noise and Radiation, the Steering Committee, and the red border review group, is referred to the EPA Administrator for a listing decision.

Cadmium

EPA's health assessment document for cadmium was given closure by SAB in September 1978. In the almost 5 years since that closure, EPA still has not published a list/no list decision on cadmium. OAQPS took over 3 years to develop the Federal Register package and forward it to the Steering Committee. According to the Chief of the Pollutant Assessment Branch in OAQPS, the delay resulted because OAQPS did not receive the final published health assessment document until late 1981; it took OHEA that amount of time to incorporate SAB comments.

There are several factors behind the delay of the cadmium health assessment. After SAB closure, OHEA delayed the document for about 1 year waiting for OAQPS to provide revisions of some exposure tables. OHEA then incorporated several studies to update the document and, according to the Director of the Environmental Criteria and Assessment Office in Research Triangle Park, held the document pending agreement within OHEA over preliminary findings to a cadmium study. The document was finally provided to OAQPS in July 1981 and published in October 1981. SAB no longer will give written closure to a health assessment document until it first receives the final document from EPA.

Steering Committee comments--due on November 9, 1981--were received between November 15, 1981, and February 10, 1982. OAQPS incorporated those comments into the package and transmitted the "red border" package to the Office of Air, Noise and Radiation on March 16, 1982. After considering the comments received, the Assistant Administrator for Air, Noise and Radiation forwarded the Federal Register package to the Administrator on August 24, 1982. The decision memorandum recommended that the Administrator sign the attached Federal Register notice announcing the proposed determination not to regulate cadmium as an air pollutant. The Assistant Administrator for Air, Noise and Radiation concluded that the general public was not at significant risk of kidney

dysfunction from exposure to the highest ambient air concentrations of cadmium or from combined exposure to the highest levels of cadmium in food, drinking water, and the ambient air.

On September 10, 1982, the Administrator sent a memorandum to the Assistant Administrator for Air, Noise and Radiation requesting that additional information be examined, including a reassessment of cadmium carcinogenicity. On December 14, 1982, OHEA responded that a new study had been found that could significantly change EPA's qualitative evaluation of cadmium's carcinogenicity. As of June 1983, OHEA was preparing an addendum to the health assessment document to be reviewed by SAB in the fall of 1983.

Toluene

SAB reviewed the health assessment document for toluene in August 1982 and wrote a letter of closure the next month stating that there is no evidence that toluene presents any significant health hazard to the public at current ambient exposure levels. OAQPS selected toluene for examination because of the chemical's structural similarity to benzene.

The decision memorandum on toluene was submitted for Steering Committee review in early May 1983. According to the Chief of the Pollutant Assessment Branch in OAQPS, the reason for the delay in moving forward after obtaining SAB closure was that OAQPS coordinated the proposed Federal Register package extensively with other EPA offices. He said that OAQPS wanted to be very careful because EPA had not previously proposed a notice stating that it was not going to regulate a substance.

DELAYS IN PROPOSING AND PROMULGATING REGULATIONS

EPA has not met the Clean Air Act's 180-day deadline to propose regulations after the pollutants have been listed or the 180-day deadline to promulgate final regulations after they have been proposed.

Since listing five substances as hazardous air pollutants by 1977, EPA has been slow to act on other pollutants and has done so only under the pressure of congressional deadlines or litigation. EPA listed radionuclides and inorganic arsenic in response to Section 122 of the 1977 Clean Air Act which required the Administrator to determine within 1 year (2 years for radioactive pollutants) from enactment whether radionuclides, arsenic, cadmium, and polycyclic organic matter "cause or contribute to air pollution which may reasonably be anticipated to endanger public health." EPA has not yet made a listing decision on cadmium or polycyclic organic matter.

According to the Clean Air Act, within 180 days after the Administrator lists a pollutant,

> "* * * The Administrator shall publish proposed regulations establishing emission standards for such pollutant together with a notice of a public hearing within thirty days. Not later than 180 days after such publication, the Administrator shall prescribe an emission standard for such pollutant * * *. The Administrator shall establish any such standard at the level which in his judgment provides an ample margin of safety to protect the public health from such hazardous air pollutant."

EPA did not meet the 180-day deadline for proposed regulations for benzene, radionuclides, and inorganic arsenic or the 180-day deadline for final regulations for benzene. As a result EPA has been sued by several different parties to force action on the three substances.

According to EPA officials, the 180-day deadlines are impossible to meet. The Chief of the Standards Development Branch in OAQPS told us it takes about 2 years to propose standards because of the time required to identify the sources, obtain technical and cost information from the regulated industry, and get the proposed package reviewed in EPA. He stated that it takes at least 1 year to promulgate final regulations after their proposal because of the time required to obtain and analyze public comments, obtain additional technical and cost data, and obtain and incorporate EPA comments.

Radionuclides

In Sierra Club v. Gorsuch, Civ. No. 81-2436 (N.D. Calif., Sept. 30, 1982), EPA was sued for failing to publish proposed regulations establishing emission standards for radionuclides within 180 days after EPA listed the substance. EPA listed radionuclides as a hazardous air pollutant in December 1979, and according to the decision dated September 30, 1982, "No such proposed regulations have been published in the nearly three years since the date of listing." In presenting its proposal for issuing standards, EPA stated that it could have taken until 1989, or more than 9 years after the statutory 180-day deadline, to issue proposed regulations for "some" emission sources.

The U.S. district court opinion stated that

> "to accept EPA's proposal for further, indefinite and virtually open-ended extension of the time for compliance without a more convincing demonstration of evident impossibility, would be to, in effect, repeal the Congressional mandate."

The court ruled that EPA shall issue the proposed regulations, together with the notice of public hearing therein, within 180 days of the filing of the court order. The order was filed September 30, 1982, and EPA published proposed standards for radionuclides in about 6 months on April 6, 1983.

Inorganic arsenic

In New York State v. Gorsuch Civ. No. NY-81-3151 (Jan. 12, 1983), EPA was also sued for failing to propose standards for inorganic arsenic. Citing the radionuclides decision, the U.S. district court ordered that EPA publish proposed regulations establishing emissions standards for inorganic arsenic within 180 days of the date of the opinion and order (Jan. 12, 1983).

The court's opinion stated that in the 1977 amendments to the act, the Congress directed the EPA Administrator to determine within 1 year whether airborne arsenic may reasonably be anticipated to endanger public health. The opinion noted that it was not until almost 2 years later than required that the Administrator listed inorganic arsenic as a hazardous air pollutant. The order also stated that more than 2 years had passed since the Administrator was required to publish proposed regulations.

In response to the court's decision, EPA published proposed standards for arsenic in the Federal Register in July 1983.

Benzene

On July 14, 1983, the Environmental Defense Fund and the National Resources Defense Council filed a complaint to compel the EPA Administrator to propose and promulgate emission standards for benzene as required by the Clean Air Act.

In 1980 and early 1981, EPA issued proposals to regulate four source categories of benzene and drafted but never issued a fifth draft proposal limiting emissions from transferring gasoline, which contains benzene, from bulk storage to service stations (gasoline marketing). EPA also identified coke oven byproduct recovery plants and several types of chemical manufacturing plants as sources of benzene emissions. According to the complaint filed by the environmental groups, EPA's failure to promulgate standards for four categories and propose standards for gasoline marketing, coke oven byproduct plants, and chemical manufacturing plants is a violation of EPA's non-discretionary duty under section 112.

EPA sent the four proposed standards to its Steering Committee in May 1983 and is projecting final promulgation for October 1983. EPA also plans to release proposed standards for coke oven byproduct recovery plants about October 1983. As of July 1983, EPA was still in the process of evaluating benzene emissions from gasoline marketing and chemical manufacturing plants to determine what, if any, standards should be issued.

Use of contractors in standards development

In developing standards for hazardous air pollutants, OAQPS utilizes contractors as well as in-house staff. According to the Director of the Emissions Standards and Engineering Division in OAQPS, contractor dollars comprise about 60-70 percent of the

Division's expenditures on national emission standards for hazardous air pollutants.

OAQPS uses contractors for three functions--standards development, source tests, and economic analysis. According to EPA, contractors working on standards development assist EPA in preparing information to help determine if standards are to be developed for any process in a source category. If EPA determines that a standard should be developed, the contractor inspects plants, analyzes alternative emission control systems, evaluates potential impacts associated with standards and, following EPA guidance, drafts the preamble and the standard selected by EPA. For source tests, contractors usually presurvey candidate test sites, prepare site-specific test plans, conduct the field testing, analyze the data, and write the test reports. Contractors helping in economic analyses develop descriptions of industry structure, conduct cost analyses of technical control options, analyze the ability of the regulated industry to raise the capital required by the various control options, and provide support to public hearings on proposed regulations.

The contractors involved in standard-setting for hazardous air pollutants are shown below for fiscal years 1982 and 1983 (estimated).

EPA Expenditures on Contractors for Standard-Setting
1982 and 1983 (estimated)

	Standards development	Source test	Economic analysis	Total
	(000 omitted)			
Midwest Research Inst.	$ 247	-	-	$ 247
Pacific Environmental Sciences	448	-	-	448
Radian Corporation	466	-	$135	601
Research Triangle Institute	1,027	-	63	1,090
TRW	216	-	-	216
GCA Corporation	20	-	-	20
PEDCo Environmental, Inc.	5	-	-	5
Monsanto Chemical	-	$ 42	-	42
JACA, Inc.	-	-	177	177
Development & Planning Research Association	-	-	47	47
Undecided	-	425	-	425
Total	$2,429	$467	$422	$3,318

Source: EPA.

About half of the money spent for emission standards development by contractors in fiscal year 1982 went toward work on benzene.

EPA estimates that almost two-thirds (or $1,368,000) of the funds spent on regulation development by contractors for fiscal year 1983 will be for work on the arsenic standards.

RESOURCES SHIFTED TO MEET COURT DEADLINES

Both OHEA and OAQPS have shifted resources away from work on other hazardous air pollutants in order to help meet the deadlines for the pollutants outlined in the court decisions. According to the Director of the Environmental Criteria and Assessment Office, the lawsuit on arsenic forced OHEA to rearrange its priorities and defer work on other health assessment documents in order to meet the arsenic deadline.

The lawsuits have also affected OAQPS. The Chief of the Pollutant Assessment Branch in OAQPS told us that he has had to utilize three staff members to work on arsenic and benzene and to monitor work by the Office of Radiation on radionuclides. He said that two of these individuals would have been working on other candidate pollutants.

The arsenic lawsuit has also affected the Emission Standards and Engineering Division of OAQPS. The Division has delayed the review of the mercury emission standards. The lawsuits have also had a major impact on the Division's work on new-source performance standards (standards to limit emissions of air pollutants from new and modified sources) under Section 111 of the Clean Air Act. According to a March 24, 1983, memorandum from the Director of OAQPS to the Assistant Administrator for Air, Noise and Radiation, the arsenic work has resulted in shifting $1,300,000 in fiscal year 1983 contract funds and 6 staff years that had been budgeted for new-source performance standards projects. The memorandum stated that to complete promulgation of the arsenic hazardous air pollutant standards in fiscal year 1984, another $400,000 and 4 staff years would be required. Specifically, the reassignment of personnel to the arsenic work will have the following impacts:

- --Delay the start of three new-source performance standards from fiscal year 1983 to fiscal year 1984.
- --Delay the promulgation of one new-source performance standard from fiscal year 1986 to fiscal year 1987 and two new-source performance standards from fiscal year 1987 to fiscal year 1988.
- --Delay the completion of reviews for three issued new-source performance standards from fiscal year 1983 to 1984 and for 5 issued new-source performance standards from fiscal year 1984 to 1985.

The impacts of the lawsuits may have other, more far-reaching effects on the regulation of hazardous air pollutants because of

the disruption the lawsuits have caused within EPA. In order to avoid similar future problems caused by not proposing or promulgating standards, EPA may be reluctant to list pollutants until OAQPS has already prepared the proposed regulation packages. Officials in OAQPS told us that, as a result of the lawsuits, they plan to obtain much of the standard-setting information prior to listing. Because the Clean Air Act does not specify a time frame forcing the Administrator to list a substance, EPA can wait to list for several months or years until proposed regulations are nearing completion.

For example, the listing decision for acrylonitrile may be delayed as a result of the recent lawsuits. SAB gave conditional oral approval to the acrylonitrile health assessment document in December 1982. The Emission Standards and Engineering Division has not drafted any proposed regulations for acrylonitrile and, according to the Division Director, does not have the resources to begin work on such standards until fiscal year 1984. Even though the listing package could be prepared, EPA may wait several months or years until the acrylonitrile proposed regulations are prepared before it is willing to list the substance.

EPA INTERPRETS SECTION 112 TO INCLUDE COST CONSIDERATIONS

In interpreting section 112's "ample margin of safety" criterion, EPA has taken the position that, while it must focus primarily on health risks, it may also consider economic and technological factors in adopting a regulatory control strategy. EPA has recognized, however, that section 112 could be construed to require the Administrator to prohibit any emission of hazardous air pollutants--i.e., establish a "zero-emission standard"--if EPA cannot identify a threshold below which emissions would not be expected to cause adverse health effects.

According to the attorney in EPA's Office of General Counsel responsible for Section 112 of the Clean Air Act, it has never been EPA's policy to interpret the "ample margin of safety" clause to mean that standards should require zero emissions, thereby forcing the shutdown of a source. He said that EPA's policy has always been that best available technology--which allows for the consideration of costs and technological factors--is required as a minimum to establish standards. Additional control may be required, after consideration of the health risks, costs, benefits, and other factors, to eliminate unreasonable residual risks. EPA's consideration of costs and technological factors in setting standards has also contributed to delays and the difficulty that EPA has had in meeting the 180-day deadlines.

According to a November 5, 1982, Status Report on Hazardous Air Pollutants prepared by OAQPS, EPA has been reluctant to list pollutants as hazardous under section 112 without a reasonable assurance that subsequent regulations would result in health benefits that are not grossly disproportionate to the costs of control.

The question of section 112's proper interpretation is a difficult one, raising complex regulatory issues. EPA takes the position that economic and technological factors may be considered in establishing standards and, therefore, that zero-emission standards need not be imposed where they would have dire economic consequences grossly disproportionate to the benefits of completely eliminating the risk.

While only the courts can resolve definitively the scope of EPA's discretion under section 112, we find little support for EPA's position. As we read section 112, its legislative history, and applicable case law, the Congress intended that the Administrator establish emission standards at a level that eliminates significant risks to the public health posed by hazardous air pollutants. Moreover, economic and technological feasibility do not appear to be relevant considerations in the standard-setting process. (Lead Industries Inc. v. E.P.A., 647 F. 2d 1130 (D.C. Cir., 1980); cf., Union Electric Co. v. E.P.A., 427 U.S. 248 (1976).) Instead, it appears that the Administrator must evaluate the health risks posed by the hazardous pollutant and set the emission standard based solely on an examination of the appropriate health data. In effect, this would require the Administrator to establish zero-emission standards for hazardous pollutants that may pose significant health risks even at low levels of exposure.

We recognize the potentially severe economic consequences that may result from zero-emission standards. However, when interpreting analogous statutes, the Supreme Court has made clear that it is for the Congress to adjust the competing concerns of regulatory objectives and economic well-being. (See T.V.A. v. Hill, 437 U.S. 153 (1978); Union Electric Co. v. E.P.A., supra). (See app. I.)

EPA HAS NOT REVISED ANY PROMULGATED STANDARDS

EPA has not completed the review of any standards of three of the four substances already regulated under section 112--asbestos, mercury, and beryllium. EPA has reviewed and is in the process of revising the vinyl chloride standards.

According to the Director of the Emission Standards and Engineering Division in OAQPS, although section 112 does not require such action, it is EPA's policy that the existing section 112 regulations should be reviewed about every 4 years. Standards reviews should be conducted to determine if recent technological developments or new health effects information indicate a need to change the standard.

Some standards are 10 years old; standards for mercury, beryllium, and asbestos were established in 1973. EPA promulgated standards for additional source categories for mercury and asbestos in 1975 and established vinyl chloride standards in

1976. EPA has initiated efforts to review and possibly revise the standards established for these four chemicals, but none have been completed to date. The Director of the Emission Standards and Engineering Division said that the standards reviews for beryllium, asbestos, and mercury are scheduled to be completed in fiscal year 1984.

EPA completed a review of the vinyl chloride standards in 1981 and is planning to publish a revised standard in June 1985.

The problem--non-threshold pollutants

A central issue in the development of an emission control strategy for hazardous air pollutants is identifying the amount of exposure reduction needed to provide an "ample margin of safety" for the public health. Where an adverse effects threshold can be identified, i.e., a level below which exposure would not be expected to result in adverse health effects, an emission standard that provides an "ample margin of safety" conceivably can be set at or below that level. However, where hazardous air pollutants such as airborne carcinogens have no identifiable adverse effects threshold,[2] there is considerable debate concerning how to translate section 112's mandate that any emission standard provide an "ample margin of safety" for the public health into a regulatory control strategy. Hence, some commentators have argued that the Administrator's inability to identify an adverse effects threshold for a hazardous air pollutant requires him to eliminate entirely emissions of the hazardous substance in order to provide the public with an "ample margin of safety."[3] Under this view, the only factor for the Administrator's consideration in setting an emission standard under section 112 is the health effects of a particular hazardous pollutant; the standard's economic impact and technological feasibility are irrelevant.

EPA concedes that "it is possible to read section 112 as requiring regulation designed to protect the public health absolutely." Proposed Airborne Carcinogens Policy, 44 Fed. Reg. at 58652 (1979).[4] Nonetheless, EPA has taken the position that "the most reasonable interpretation of [section 112]

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[2]See Proposed National Emission Standards for Hazardous Air Pollutants; Policy and Procedures for Identifying, Assessing and Regulating Airborne Substances Posing a Risk of Cancer (hereafter Proposed Airborne Carcinogens Policy), 44 Fed. Reg. 58641 (Oct. 10, 1979).

[3]See Currie, Direct Federal Regulation of Stationary Sources Under the Clean Air Act, 128 U.Pa. L. Rev. 1391, 1460 (1980); 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 Submitted by Environmental Defense Fund and Natural Resources Defense Council dated February 21, 1980.

[4]For purposes of this analysis, we relied heavily on EPA's legal explanation of its proposed regulatory policy for airborne carcinogens. See 44 Fed. Reg. at 58659-58661. Although the proposed policy was never formally adopted, we understand that the proposed policy's legal explanation continues to reflect EPA's general legal position on this issue.

requires [the Administrator] to focus principally on health protection in regulating carcinogens but does not require the total elimination of risks from such substances." Id. In EPA's view, economic, technological, and other social factors may be incorporated into an emission control strategy for a particular pollutant. Id. at 58650, 58661.

EPA's past actions regulating asbestos, 38 Fed. Reg. 8820 (1973), and vinyl chloride, 40 Fed. Reg. 59532 (1975), 41 Fed. Reg. 46560 (1976), both accepted the existence of residual risks.[5] With respect to the vinyl chloride standard, EPA found that no level of exposure was safe. 38 Fed. Reg. 595. Yet the Administrator explicitly construed section 112 to authorize

> "emission standards that require emission reduction to the lowest level achievable by use of the best available control technology in cases involving apparent non-threshold pollutants, where complete emission prohibition would result in widespread industry closure and EPA has determined that the cost of such closure would be grossly disproportionate to the benefits of removing the risk that would remain after imposition of the best available control technology." 40 Fed. Reg. 59534 (1975).[6]

More recently, EPA specifically rationalized its proposal to regulate the emission of airborne carcinogens in light of the economic consequences of a zero-risk emission standard. 44 Fed. Reg. at 58642, 58660. EPA concluded that when the Congress enacted section 112, it did not foresee or address the problems inherent in translating section 112's "ample margin of safety" standard into emission standards for non-threshold pollutants. 44 Fed. Reg. at 58660-61. In the absence of clear direction from the Congress on this issue,

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[5]National emission standards also have been promulgated for beryllium, 40 C.F.R. 61.30 et seq., 61.40 et seq., and mercury, 40 C.F.R. 61.50 et. seq. In addition, EPA has included benzene, 42 Fed. Reg. 29332 (1977), and radionuclides, 44 Fed. Reg. 76738 (1979), on the list of hazardous substances to be regulated.

[6]The Environmental Defense Fund challenged the legality of EPA's vinyl chloride standards in the Court of Appeals for the District of Columbia Circuit. Environmental Defense Fund v. Train, No. 76-2045 (D.C. Cir.) (settled and dismissed June 24, 1977). To settle the suit, EPA agreed to a zero-emission "goal" and to periodically review and adjust the vinyl chloride emission standard to reflect advances in control technology. 42 Fed. Reg. 29005 (1977).

EPA believes it is unreasonable to presume that the Congress intended the drastic economic consequences that would flow from a zero-risk emission standard. Id. Thus, according to EPA, the Congress must have intended that the Administrator accept a reasonable level of residual health risks when implementing section 112. If this proposition is accepted, EPA argues that limited consideration of factors other than the level of risk is necessary to assess whether a control strategy provides an "ample" margin of safety. Id. at 58661. To this end, the Administrator may consider technological and economic (cost) factors. Id. For these reasons, a control strategy that accepts a reasonable amount of residual risks (evaluated in light of the above-mentioned factors) remaining after the application of best available control technology is consistent with section 112. Id.

GAO analysis

While only the courts can resolve definitively the scope of EPA's authority under section 112, we find little support for EPA's position. As we read section 112 and its legislative history, we conclude that the Congress intended that the Administrator establish emission standards for hazardous pollutants at a level that eliminates any significant health risks. In effect, this means that the Administrator may have to set zero-emission standards for hazardous pollutants that may pose significant health risks even at low levels of exposure.

The Clean Air Act Amendments of 1970 "were a drastic remedy to what was perceived as a serious and otherwise uncheckable problem of air pollution." Union Electric Co. v. E.P.A., 427 U.S. 246, 256 (1976). To overcome the industry's repeated claim that available pollution control technologies were economically or technically infeasible, the Congress adopted a "technology-forcing" approach. Id. at 257. Although the technology-forcing concept was not without risks, the Congress considered those risks and "decided that the dangers posed by uncontrolled air pollution made them worth taking." Id. at 270.

By 1970, the Congress had become aware that previous efforts designed to protect the public health against only the known effects of air pollution were inadequate. The realization by the Congress that relatively little was known about the health effects of air pollutants required a new approach if the public health was to be safeguarded. See S. Rep. No. 91-1196 at 1, 2-3 (1970); 116 Cong. Rec. 32920-23 (1970) (remarks of Sen. Muskie). The Congress addressed the uncertainty by requiring the Administrator to promulgate primary air quality standards and hazardous emission standards that, respectively, provided for an "adequate" or "ample" margin of safety to protect the public health. The Senate Report accompanying S. 4358, the Senate version of the Clean

Air Act Amendments of 1970, explained the purposes of the margin of safety requirement:

> "Margins of safety are essential to any health-related environmental standard if a reasonable degree of protection is to be provided against hazards which research has not yet identified." S. Rep. No. 91-1196 at 10 (1970).

Applicable case law construing margin of safety requirements in the Clean Water Act and the Clean Air Act emphasizes this precautionary and protective purpose. As read by the courts, the purpose of such requirements is to permit the Administrator to protect the public health to the greatest extent possible from health hazards which research has not yet uncovered or whose medical significance may be shrouded in uncertainty and controversy. Lead Industries Ass'n v. E.P.A., 647 F.2d 1130, 1150, 1153-54 (D.C. Cir. 1980) (construing §109 of the Clean Air Act); Environmental Defense Fund v. E.P.A., 598 F.2d 62, 81 (D.C. Cir. 1978) (construing §307 of the Clean Water Act).

As noted earlier, many hazardous air pollutants are thought to be carcinogens for which no safe level of exposure has been identified. Hence, once EPA determines that a substance poses some risks to health as specified in section 112's definition of hazardous pollutant, a literal application of the "ample margin of safety" standard argues for a prohibition on the emission of such substance in order to protect the public health.

In other words, where the Administrator's assessment of the level of risks presented by a particular carcinogen indicates that significant health risk may exist even from a low level of exposure, a zero-emission standard may be necessary to provide the public a reasonable degree of protection from such health risks, let alone an "ample" degree of protection.

EPA apparently takes the position that the Administrator may consider other factors besides the health effects of the particular substance when determining whether any additional controls are necessary to control residual risks remaining after the application of best available control technology when determining the appropriate level of emission control. Thus, as in the case of vinyl chlorides, where the costs of reducing the health risks below the point obtained by the application of best available control technology outweigh the benefits therefrom, the Administrator would conclude that that particular control technology may provide "an ample margin of safety." Apart from this use of cost and technical factors to evaluate residual risks, the Administrator would rely heavily on economic and technical factors to determine in the first instance what is the best available control technology. 44 Fed. Reg. at 58650-51.

This interpretation of the Administrator's authority appears at odds with section 112. The language of section 112 does not qualify the Administrator's duty to provide an ample margin of safety from significant health risks by consideration of economic or technological feasibility. The Clean Air Act viewed as a whole carefully distinguishes between health standards and technology standards. Union Electric Co. v. E.P.A., 427 U.S. at 257, n.5 (1976); compare, for example, sections 109 and 112 of the act with section 111. And, as the courts have repeatedly recognized, when the Congress intended that the Administrator consider economic and technological feasibility, the Congress expressly so provided. Lead Industries Ass'n v. E.P.A., 647 F.2d 1130, 1150 (D.C. Cir. 1980); American Petrol. Inst. v. Costle, 665 F.2d 1176, 1185 (D.C. Cir. 1981); cf. American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 510 (1981).

Even more on point, the United States Court of Appeals for the District of Columbia rejected a lead industry argument that the Administrator must consider the economic or technological feasibility of ambient air quality standards. The industry petitioner asserted that the Administrator's mandate to consider these factors was to be found in section 109's requirement that air quality standards provide an "adequate margin of safety," but the court disagreed:

> "* * * We are unable to discern here any congressional intent to require, or even permit, the Administrator to consider economic or technological factors in promulgating air quality standards. And when Congress directs an agency to consider only certain factors in reaching an administrative decision, the agency is not free to trespass beyond the bounds of its statutory authority by taking other factors into account. American Overseas Airlines, Inc. v. CAB, 254 F.2d 744, 748 (D.C. Cir. 1958). A policy choice such as this is one which only Congress, not the courts and not EPA can make * * *." Id.

EPA relies heavily on the fact that the economic consequences of zero-risk standards are so drastic that the Congress could not have intended EPA to pursue such a regulatory approach. We agree with EPA that such an intention should not be presumed lightly. Industrial Union Dept. v. American Petroleum Inst., 448 U.S. 607, 645 (1980). Here, however, section 112's legislative history suggests that the Congress in fact was aware that zero-emission standards may be necessary under section 112's mandate and that the result of such standards may be the closure of an industrial emitter. See S. Rep. No. 91-1196 at 2-3 (1970). Senator Muskie's summary of the conference bill submitted in the record of the debate thereon clearly reflects this view:

> "Under section 112, the administrator must set emission standards for hazardous pollutants, after public hearings on proposed standards. 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 measureable emissions."

Along the same lines, section 112 itself reflects the Congress' awareness that emission sources may have to shut down because of a hazardous emission standard. In this regard, section 112(c)(2) permits the President to

> "[E]xempt any stationary source from compliance * * * for a period of not more than two years if he finds that the technology to implement such standard is not available and the operation of such source is required for reasons of national security." 42 U.S.C. § 7412(c)(2).

Illustrative of the "technology-forcing" nature of section 112, the limited national security exemption clearly suggests that where an emission source is not required for reasons of national security, the availability of technology to comply with an emission standard is irrelevant. Although the choice may appear "draconian," Union Electric Co. v. E.P.A., 427 U.S.C. at 272 (J. Powell concurring), the emitter must either develop the technology needed to comply with section 112's health standard or close down. In addition, the Congress' recognition of the relevance of "technology" in granting exemptions under section 112(c)(2) reinforces the view that the Congress' exclusion of technology or economic factors from section 112's standard-setting mandate to the Administrator was purposeful. Cf. Union Electric Co. v. E.P.A., 427 U.S. at 257, or 5 (1976); Lead Industries Ass'n v. E.P.A., 647 F.2d at 1150 (D.C. Cir. 1980).

Although it may be that the Congress would not insist on zero emission standards if faced with the dire economic consequences that EPA predicts, we are not free to rewrite section 112 to conform to our views of reasonable social or environmental policy. T.V.A. v. Hill, 437 U.S. 153 (1978); Union Electric Co. v. E.P.A., 427 U.S. 248, 270-71 (1976) (J. Powell concurring). As Chief Justice Warren observed in T.V.A. v. Hill, 437 U.S. at 185, "it is not for us to speculate, much less act, on whether Congress would have altered its stance had the specific events of this case been anticipated."

Here the Congress authorized the Administrator to act in the face of uncertainty to provide ample protection from significant risks to the public health. This interpretation in effect may require the Administrator to prohibit any emissions of certain substances. The balance the Congress struck between competing health and economic concerns is a legislative determination, and it is for the Congress to adjust the balance struck in section 112.

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