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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

RESOURCES, COMMUNITY,
AND ECONOMIC DEVELOPMENT
DIVISION

B-220242

SEPTEMBER 30, 1985


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

Dear Mr. Chairman:

Subject: Status of EPA's Efforts To Regulate Chemical Substances As Hazardous Air Pollutants Under the Clean Air Act (GAO/RCED-85-168)

The Environmental Protection Agency (EPA) is required under Section 112 of the Clean Air Act of 1970 to (1) develop a "listing" of hazardous air pollutants and (2) propose standards for regulating emissions of those pollutants within 180 days of the date a pollutant is listed. In August 1983, we reported[1] to you that since passage of the act, EPA had listed only seven substances as hazardous air pollutants and had established emission standards to regulate four of them. As of August 1985, the figures were eight and six, respectively. During November 1983 hearings before the Subcommittee on this matter, the EPA Administrator agreed to improve the Agency's progress in this area and said that the Agency would decide by the end of 1985 whether an additional 20 to 25 chemical substances should be regulated.

In your four letters to EPA between January and March 1985, you indicated that GAO would be asked to review and comment on EPA's responses to a variety of questions concerning EPA's hazardous air pollution program and other related matters. In subsequent meetings with your office, it was agreed that we would initially review the status of EPA's efforts to fulfill its commitment to your Subcommittee regarding the 20 to 25 substances. As a result, we limited our review to determining what EPA had done and what remained to be done before EPA would

[1]Delays in EPA's Regulation of Hazardous Air Pollutants (GAO/RCED-83-199, Aug. 26, 1983).

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announce its decisions to regulate or not to regulate the chemicals. Our review did not include reviewing the adequacy or appropriateness of EPA's decisions. The results of our review are summarized below and detailed in enclosures I, II, and III of this letter report.

Subsequent to its commitment to you, EPA developed a new strategy to issue notices of intent to list or regulate for specific chemicals where regulation seems warranted. EPA advised the Subcommittee of this new strategy in a March 9, 1984, letter. According to EPA, a notice of intent allows the Agency to announce its tentative conclusions in a more timely fashion. However, EPA does not consider these notices to be legally binding regulatory decisions because additional technical and cost information would be needed to support formal listing decisions. EPA's Associate General Counsel for Air and Radiation contends that because the notices are not formal listing decisions, they do not require EPA to propose emission standards within 180 days as is required when formal listing decisions are announced. Based on our analysis of the Clean Air Act, we also believe that a notice of intent to list or regulate is a step preliminary to the regulatory process required by section 112 and does not constitute a legally binding regulatory decision.

EPA believes that the notices of intent to list or regulate satisfy its commitment to the Subcommittee, but that the Clean Air Act still requires the Agency to publish regulatory listing decisions before the substance is considered "listed" within the context of the law. According to EPA's Chief of the Pollutant Assessment Branch--who is responsible for administering EPA's hazardous air pollution program--EPA will publish legally binding regulatory decisions when the Agency believes it is within 180 days of publishing proposed emission standards. This could take from 2 to 4 years after the notices of intent to list or regulate are published. (This strategy is discussed on page 7, enclosure II.)

EPA's Pollutant Assessment Branch Chief is optimistic that by the end of 1985 EPA will publish in the Federal Register either notices of intent or final decisions to regulate or not to regulate 23 chemicals under Section 112 of the Clean Air Act. The Chief also told us that he expects EPA to regulate 11 of the 23 substances and not to regulate the remaining 12 substances under section 112. In fact, as of September 1985, EPA had already made 16 announcements--5 announcements to regulate and 11 not to regulate. EPA expects to publish notices in the Federal Register within the next 3 months regarding its intentions to regulate (or not to regulate) the seven additional substances. (See table III.1, enclosure III.)

Also worth noting is a change in EPA's procedure for deciding whether to list and regulate a substance. Prior to mid-1984, EPA submitted a document assessing the health effects resulting from exposure to all candidate pollutants to the Science Advisory Board for its review and comment. The Board is an advisory group of independent scientists who review the quality and sufficiency of scientific data underlying regulatory development of some EPA actions. In mid-1984, however, EPA decided to submit health assessment documents to the Board for only those substances EPA would probably regulate. According to EPA, the change was made to streamline the regulatory decisionmaking process. In accordance with the new policy, the Board was not requested to review the health assessment documents for four chemicals that EPA does not intend to regulate. Based on our discussions with EPA officials and members of the Board and our review of the Clean Air Act and the Board's enabling legislation, we believe that EPA's decision to be more selective in submitting health assessments to the Board for review is consistent with the legislation.

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As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of issuance. At that time we will send copies to interested parties and make copies available to others upon request.

Sincerely yours,

J. Dexter Peach
Director

Enclosures - 3

ENCLOSURE I

OBJECTIVES, SCOPE, AND METHODOLOGY

Our objective was to assess the status of EPA's efforts to fulfill its commitment to the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, to decide whether to regulate 20 to 25 chemical substances by the end of 1985.

To understand and document EPA's decisionmaking process and to determine what work had been done and what remained to be done to reach regulatory decisions by the end of 1985, we discussed the status of various substances with the Chief of the Pollutant Assessment Branch at EPA's Office of Air Quality Planning and Standards in Durham, North Carolina, and 10 project managers on his staff. These project managers were responsible for evaluating chemicals in detail and ultimately recommending whether or not chemical substances should be regulated as hazardous air pollutants under the Clean Air Act. We also reviewed the files for 23 chemicals--those which EPA had assessed in detail. Our review, however, did not include reviewing the adequacy or appropriateness of EPA staff recommendations or decisions.

As part of its decisionmaking process, EPA relies on scientific analyses prepared by its Office of Research and Development on the health effects of various substances. EPA also generally has the Science Advisory Board--a group of independent scientists--review and comment on these analyses. To substantiate the status of work underway by these groups, we talked with EPA's Director of Environmental Criteria and Assessment Office (within the Office of Research and Development) in North Carolina and a project officer in its Ohio office because these offices prepared the health analyses for the 23 chemicals. We also met with the Science Advisory Board's Director and members of the Board's Environmental Health Committee, which reviews the analyses mentioned above.

In early to mid-1984, EPA announced changes regarding the Science Advisory Board's review of health assessment documents and the manner in which listing decisions would be published. To determine whether these changes were in compliance with the law, we reviewed the legislative history of the Environmental Research Development and Demonstration Authorization Act--the Board's enabling legislation--and the Clean Air Act. In addition, we met with EPA's Associate General Counsel for Air and Radiation to obtain the Agency's interpretation of relevant sections of these acts.

Our audit work was conducted between March and July 1985. In accordance with your request, we did not request EPA to review and comment officially on a draft of this report.

STATUS OF EPA's EFFORTS TO REGULATE HAZARDOUS AIR POLLUTANTS UNDER THE CLEAN AIR ACT

During November 1983 hearings before the House Subcommittee on Oversight and Investigations concerning delays in EPA's regulation of hazardous air pollutants, EPA told the Subcommittee that it would decide by the end of 1985 whether to regulate 20 to 25 chemical substances. At the Subcommittee Chairman's request, we determined the status of EPA's efforts to fulfill its commitment. The results of that review are presented in this enclosure.

BACKGROUND

Section 112 of the Clean Air Act of 1970, entitled "National Emission Standards for Hazardous Air Pollutants" is designed to protect the public from air pollutants that are not regulated under other sections of the act. Accordingly, the act defines a "hazardous pollutant" as an air pollutant for which no air quality standards are applicable but which "may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness." Section 112 requires EPA to periodically publish a list of each hazardous air pollutant for which it plans to establish an emission standard. This is known as "listing" a substance. 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 and to promulgate final regulations within 180 days of publishing proposed regulations.

To carry out its responsibilities under section 112, EPA established a multistep process to review a hazardous air pollutant candidate before listing and regulating it. EPA periodically conducts an extensive chemical-by-chemical and source-by-source analysis in which it identifies candidate pollutants and prepares a health assessment document which evaluates the health effects of the candidate substance. This document is normally reviewed by the Science Advisory Board--a group of independent scientists who review the quality and sufficiency of scientific data underlying regulatory development of some EPA actions. Simultaneously with preparing the health assessment document, EPA prepares a preliminary source/exposure assessment on the candidate pollutants to determine whether the substance is emitted and to estimate whether it is present in the air to a degree that significant human exposure results. Through the preliminary source/exposure assessment, EPA also determines the approximate number of people exposed to differing levels of a candidate pollutant and estimates the risk. Based on the health assessment document, the exposure assessment, and the risk assessment, EPA determines whether or not to list the pollutant and regulate various emission sources.

In August 1983 we reported[1] to you on delays in EPA's regulation of hazardous air pollutants. At that time, we stated that since passage of the Clean Air Act in 1970, EPA had only listed seven substances as hazardous air pollutants and established emission standards for four of them. (As of August 1985, these figures had risen to eight and six, respectively.) We found that various policy shifts at EPA and uncertainty over the type and amount of scientific data needed to support a regulatory action were major factors contributing 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. At hearings held on this subject in November 1983, EPA agreed to improve the Agency's track record and made a commitment to the Subcommittee to decide by the end of 1985 whether to regulate an additional 20 to 25 chemical substances.

EPA officials told us that a number of changes have been made to correct problems noted in our August 1983 report. Specifically, they told us that EPA has given the highest priority to making the 20 to 25 listing decisions by the end of 1985 and established milestones and a tracking system to monitor progress. In addition, the Science Advisory Board tries to review health assessment documents in a single meeting rather than having multiple reviews.

EPA HAS MADE PROGRESS AND PLANS TO MAKE ANNOUNCEMENTS REGARDING REGULATION OF 23 CHEMICALS BY THE END OF 1985

EPA plans to make announcements regarding regulation of 23 chemical substances by December 1985 to fulfill its commitment. As of September 1985, 16 of the 23 announcements had been made and EPA expects to make the remaining seven by the end of 1985.

A breakdown of the 16 chemicals already announced is presented below.

--EPA decided to list and regulate coke oven emissions.

--EPA published notices of intent to list in the Federal Register for chromium and carbon tetrachloride and announced that notices of intent to list will be published for chloroform and ethylene oxide.

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[1]Delays in EPA's Regulation of Hazardous Air Pollutants (GAO/RCED-83-199, Aug. 26, 1983).

--EPA decided not to list or regulate seven chemicals as hazardous air pollutants. These chemicals are: (1) acrylonitrile,[2] (2) chlorofluorocarbon-113, (3) manganese, (4) methyl chloroform, (5) polycyclic organic matter, (6) toluene, and (7) vinylidene chloride.

--EPA published notices of intent not to regulate in the Federal Register for chlorinated benzenes and epichlorohydrin and announced that notices will be published for chloroprene and hexachlorocyclopentadiene.

The Pollutant Assessment Branch Chief is optimistic that EPA will publish notices regarding regulation of the seven remaining substances by December 1985. More specifically, for the remaining substances, preliminary source/exposure assessments had been done, and the Science Advisory Board had offered its comments when requested by EPA on the scientific sufficiency of draft health assessment documents and all assessment documents had been finalized. Further, a draft Federal Register notice to announce the results of EPA's assessments had been prepared for all seven chemicals and decisions to regulate were reviewed by the Office of Management and Budget to determine their implications on the public and federal government. Consequently as of September 1985 an internal agency review to obtain the Administrator's approval was underway for the remaining seven--the final step in the process.

Of the 23 chemicals, EPA has decided or recommended regulating 11 of them. EPA has also announced or the Agency staff has recommended not regulating the 12 other substances. The Assessment Branch Chief told us that although health evidence and/or exposure data on the 12 chemicals may not warrant regulation at this time, EPA can reassess a substance at any point in the future should new data become available. A list of the 23 substances and their status as of September 23, 1985, is presented in enclosure III.

REGULATORY MEANING OF NOTICES OF INTENT TO LIST OR REGULATE (OR NOT TO REGULATE)

In a March 9, 1984, letter, EPA informed the Subcommittee Chairman that the Agency planned to fulfill its commitment to make listing decisions on 20 to 25 substances by the end of 1985 by issuing either a notice of intent to list or regulate or, if the decision is not to list or regulate, issuing a public announcement of that decision. In that letter, EPA stated that

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[2]It is also important to note that although acrylonitrile is not being listed and regulated under Section 112 of the Clean Air Act, EPA is conducting a pilot project with 15 states to determine the feasibility of state/local regulation of acrylonitrile-emitting sources.

it was considering using the new medium of notices of intent because it offered the Agency the opportunity to fulfill its commitment to the Subcommittee in a timely manner. In subsequent meetings with EPA, we were also told that EPA chose this strategy because these notices are not considered regulatory decisions within the context of the Clean Air Act, which would have started the rulemaking process and required EPA to propose emission standards within 180 days of publishing the listing decision. EPA's Associate General Counsel for Air and Radiation also told us that these notices are not required by law and are preliminary to an actual listing. In June 1985, EPA published its first notice of intent to list or regulate. At that time, EPA also issued a notice of intent not to regulate--also a new medium which EPA plans to use when the health effects document for a substance has not been reviewed by the Science Advisory Board. (See p. 9 for detailed discussion.)

EPA told the Subcommittee in its March 9, 1984, letter that the notice of intent to list (which had not been used but was under consideration at that time) would generally be issued after the Science Advisory Board review and the completion of the health assessment document and exposure assessment. According to EPA, the notice would announce EPA's tentative conclusions based on these studies in a timely fashion and would generally be used to initiate the emission standard development activity. EPA said that the notice would outline the principal emission sources of concern, solicit comments on the need for regulations and the priorities for source regulation, and solicit additional technical data. EPA said that this approach has the advantages of prompt public notification of its intent, provides opportunity for additional public input to the listing decisions, and solicits additional data that could be useful in developing emission standards.

The Assessment Branch Chief told us that another important benefit of the "notice of intent to list" approach is that it gives EPA more time to comply with provisions of the law requiring proposed standards within 180 days after listing because the notice of intent to list does not start the 180-day clock. The Chief told us that EPA will not issue the proposed or final listing decisions until it believes it is within 180 days of proposing standards. He said that it could take EPA 2 to 4 years (from the time EPA publishes the notice of intent to list or regulate) to develop and promulgate standards because of the time required to identify the sources, obtain cost and technical information from the affected industries, get the proposed regulation package reviewed within EPA, and obtain and analyze public comments.

To obtain EPA's view on the legal significance of a notice of intent to list or regulate, we met with EPA's Associate General Counsel for Air and Radiation. He told us that the notice of intent to list or regulate is equivalent to an advance

notice of a proposed rulemaking and is not legally binding on the Agency. He said that these notices are not required by law and are an extra step the Agency has taken to obtain public input to its listing decision. He also said that a notice of intent to list or regulate is not based on the same kind or amount of information that would be necessary to support a listing decision and therefore could not be considered a listing. The Associate General Counsel also said that additional technical and cost information would be needed before EPA would be ready to formally list or regulate a substance. He said further that because the notice is not a listing it does not begin the rulemaking process, and in turn, does not require EPA to publish emission standards within 180 days.

EPA believes that the notices of intent to list or regulate satisfy its commitment to the Subcommittee, but the Clean Air Act still requires EPA to list and propose standards for those substances considered to be hazardous air pollutants. Based on our discussions with EPA program and legal staff, and our analysis of the Clean Air Act, we also agree with EPA's views that a notice of intent to list or regulate is a step preliminary to the regulatory process required by section 112 and represents EPA's findings to date regarding a particular substance without constituting legally binding regulatory decisions.

According to the Assessment Branch Chief, EPA now plans to publish notices of intent not to regulate and solicit public comments in cases where it does not plan to regulate and did not request a Science Advisory Board review of the health assessment document because regulation was not warranted. (This change from EPA's prior practice of submitting all health assessment documents to the Board for its review is further discussed below.) Four of the 23 substances fell in this category and, as mentioned on page 7, as of September 1985, EPA had published or will publish notices of intent not to regulate for all of them. EPA has noted, however, that it is not required by law to make public the results of its assessment in cases where it decides not to regulate, but EPA plans to do so because the Agency believes the public should be informed and given a chance to comment. We agree with EPA's views that a notice of intent not to regulate is a means of informing the public of the results of EPA's assessment of potentially hazardous pollutants. While the law does not require these notices, it does not preclude EPA from publishing them either.

EPA NO LONGER ASKS THE SCIENCE ADVISORY BOARD TO REVIEW ALL HEALTH DOCUMENTS

As noted on page 5 of this enclosure, EPA normally prepares health assessment documents for substances it is considering regulating and has the Science Advisory Board review these

documents for scientific sufficiency of the data. To streamline the listing process, a review group consisting of representatives of several EPA offices concluded in June 1984 that only those health assessment documents for pollutants that EPA would probably list or those considered controversial should be submitted to the Board for review. EPA believed this change was needed if the Agency was going to meet its commitment of making 20 to 25 listing decisions by the end of 1985. Also, according to the Chief, Pollutant Assessment Branch, EPA's Associate General Counsel for Air and Radiation, and the Executive Secretary of the Board's Environmental Health Committee--the committee responsible for reviewing health assessment documents--EPA needed to better prioritize issues requiring the Board's involvement. In accordance with its new policy, EPA did not ask the Board to review the health assessment documents for four chemicals. As explained below, this change in EPA's decisionmaking process is, in our opinion, consistent with the Clean Air Act and the Board's enabling legislation.

According to Section 117(c) of the Clean Air Act, prior to publishing any listing decision or proposed emission standard under section 112 of the act, 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." In addition, Section 8(a) of the Environmental Research, Development and Demonstration Authorization Act of 1978, which formally established the Board, states that EPA shall establish a Science Advisory Board which shall provide such scientific advice as the Administrator requests. Under section 8(e) of this act, at the time EPA provides any proposed criteria documents, standards, limitations, or regulations to any other agency for formal review and comment, EPA shall make such proposals available to the Board for its advice and comments on the adequacy of the scientific and technical basis of the action under consideration.

Until mid-1984, EPA's policy was to request the Board's review of health assessment documents for all chemicals under review by the Pollutant Assessment Branch regardless of the likelihood of regulation. The Board's review was conducted to insure that the documents were scientifically accurate and adequately represented the latest knowledge on health effects. In accordance with the new policy instituted in 1984, the Board was not asked to review the health assessment documents for four chemicals--epichlorohydrin, hexachlorocyclopentadiene, chlorinated benzenes, and chloroprene--because EPA recommended not regulating them. It should be noted that even though the Board did not review the four health assessment documents, they were submitted for peer review outside EPA.

On June 11, 1985, and August 13, 1985, EPA announced that it was not necessary to regulate epichlorohydrin and chlorinated benzenes, respectively, because of the limited potential for exposure and their relatively low risk of cancer (about one case every 700 years). On September 23, 1985, EPA also announced that it does not intend to regulate chloroprene or hexachlorocyclopentadiene under the Clean Air Act because of very limited potential for human exposure to the chemicals and inadequate or insufficient information to determine their cancer-causing potential. As mentioned on page 9, these decisions were or will be announced as notices of intent not to regulate because the health assessment documents had not been reviewed by the Board.

We interviewed the Board's Director as well as the Executive Secretary and the Chairman of the Board's Environmental Health Committee to obtain their views on EPA's decision to be more selective in deciding what matters should be submitted to the Board for review and comment. They generally supported this change. For example, the Executive Secretary said that the Board's Environmental Health Committee spent too much of its time reviewing health assessment documents and many of them were not significant health problems. Further these officials said that they did not foresee any problem with not having the Board review all health assessment documents. The Chairman of the Health Committee also said that EPA could solicit public comments on the health documents as a form of peer review which could take the place of the Science Advisory Board review.

Further, on June 25, 1985, the EPA Administrator issued a memorandum on improving the Agency's use of the Science Advisory Board. The memorandum stated that EPA/Board interactions could be improved by (1) developing a more formal process for selecting which issues the Agency should submit to the Board, (2) establishing more uniform rules for Board participation in the Agency's decisionmaking processes and developing a more consistent approach to the form and content of scientific analyses which the Board will review, and (3) streamlining the Board's review process to avoid unnecessary delays in meeting the Agency's commitments. In addition, the memorandum stated several general criteria which should be met in assessing whether to submit a particular issue for Board review. For example, this would include instances of widespread population exposures to a pollutant, cases where the pollutant is associated with adverse effects to humans or the environment, or if the issue is scientifically controversial. EPA expects that no more than 50 to 55 issues will be submitted to the Board by all EPA offices during a fiscal year and plans to issue further guidance to enhance the Agency's compliance with section 8(e) of the Board's enabling legislation.

ENCLOSURE III

Table III.1

STATUS OF 23 CHEMICALS EPA IS CONSIDERING FOR REGULATION AS OF SEPTEMBER 23, 1985

List of 23 chemicals	Final or Tentative Decisions: To list or regulate	Final or Tentative Decisions: Not to list or regulate	Date decisions announced
1. Acrylonitrile		X	June 1985
2. 1, 3-Butadiene	X		September 1985 (P)
3. Cadmium	X		September 1985 (P)
4. Carbon Tetrachloride	X		August 1985
5. Chlorinated Benzenes		X	August 1985
6. Chlorofluoro-carbon-113		X	June 1985
7. Chloroform	X		September 1985
8. Chloroprene		X	September 1985
9. Chromium	X		June 1985
10. Coke Oven Emissions	X		September 1984
11. Epichlorohydrin		X	June 1985
12. Ethylene Dichloride	X		September 1985 (P)
13. Ethylene Oxide	X		September 1985
14. Hexachlorocyclo-pentadiene		X	September 1985
15. Manganese		X	August 1985
16. Methyl Chloroform		X	June 1985
17. Methylene Chloride	X		September 1985 (P)
18. Nickel		X	September 1985 (P)
19. Perchloroethylene	X		November 1985 (P)

ENCLOSURE III

List of 23 chemicals	Final or Tentative Decisions: To list or regulate	Final or Tentative Decisions: Not to list or regulate	Date decisions announced
20. Polycyclic Organic Matter		X	August 1984
21. Toluene		X	May 1984
22. Trichloroethylene	X		November 1985 (P)
23. Vinylidene Chloride		X	August 1985

P = Projected dates