ABSTRACT


In 1970, Congress passed Amendments to the Clean Air Act which included a provision requiring the EPA to reduce emissions of hazardous air pollutants (HAPs). The Amendments required the agency to promulgate emission standards that would provide an ample margin of safety to protect public health. The EPA was largely unsuccessful in promulgating rules under this framework. In 1990, Congress passed new Amendments to the Clean Air Act. These Amendments significantly changed the way the EPA was to develop emission standards for HAPs. The new Amendments require the agency to first set standards based on existing methods to emissions reduction, then evaluate remaining public health risks, within eight years, and set risk-based standards if necessary.

The 1990 Amendments attempted to removed major impediments to standard setting under the former program: listing chemicals as HAPs was largely eliminated; setting health-based standards was postponed and may not be necessary in all cases; and deadlines were extended. The EPA has made some internal progress as a result of these changes but it still far behind its mandated regulatory schedule. How the agency succeeds as implementation proceeds will depend on how it manages the intractable regulatory process, and how it prepares for the second, risk-based phase of the program.
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CHAPTER 1: BACKGROUND AND PURPOSE

1.0 Background

The most proximate goal of any air toxics program is to protect public health from exposure to emissions of chemicals that are considered hazardous to human or environmental health\(^1\). One way to achieve this goal is for a government to regulate emissions of certain chemicals considered to be dangerous. Historically, in the case of the U.S. air toxics program, Congress has passed laws that require the promulgation of rules in the form of emissions standards, in order to limit the emission of chemicals determined to be hazardous air pollutants (HAPs), and thereby protect public health.

Congress first required regulations limiting emission of HAPs in 1970, by passing the 1970 Clean Air Act Amendments (1970 CAAA)\(^2\). This first-ever U.S. air toxics provision was a health-based program, which required the regulating agency to identify and list HAPs based on criteria in the Amendments, then promulgate standards for each HAP that would ensure the protection of public health\(^3\). The 1970 Amendments required these tasks to be completed within extremely short statutory deadlines.

The Environmental Protection Agency (EPA) failed to produce many regulations under the 1970 program. In the 20
years following the enactment of this legislation, the EPA identified only 8 pollutants as HAPs and regulated only 7 HAPs. Impediments to regulation included: the amount and type of data needed to establish a chemical as a HAP; basing emissions standards on what the agency interpreted to be solely human health effects considerations; extremely short statutory deadlines; and disagreements over how health effects should be assessed (see also Appendix A).

Congress attempted to change this regulatory approach by passing the 1990 Amendments to the Clean Air Act (1990 CAAA). These new Amendments updated and significantly changed the former air toxics provision by requiring the EPA to first regulate air toxics not on the basis of adverse human health effects, but on the basis of available approaches to emissions reduction. The Amendments then require the EPA to revise these standards, within eight years, based on risk, and revise them if necessary. The Amendments also require the EPA to regulate emissions of all HAPs from sources, rather than emissions of individual pollutants as was the approach in the 1970 Amendments.

Further, the new Amendments are more prescriptive than their 1970 counterpart; Congress chose to increase its dictate over the EPA in passing a more agency-forcing law than it did in 1970. The 1970 air toxics provision, while agency-forcing in that it required standards to be based on public health, and in that rules were to be promulgated
quickly, left most of the details to the EPA. The 1990 version leaves less discretion to the agency with regards to what chemicals to regulate, how to regulate them, and the pace of regulation.

The Clean Air Act Amendments of 1990 embody a two-tiered approach to air toxics regulation. The theme is: apply technology-based standards first, to achieve at least some level of health protection, then assess risk later, and if necessary, strengthen the standard to achieve additional health protection. The first phase of the new program requires standards be set based on the Maximum Achievable Control Technology (MACT)\(^\text{10}\). In the second phase, the residual risk to human health is to be assessed within eight years after the promulgation of each MACT standard. If an unacceptable risk remains after MACT has been implemented, the standard may be revisited and made more health protective. As this paper will show, the new regulatory approach presents many challenges to the regulatory agency as it implements the program.

1.2 Purpose

This paper addresses the issue of regulation development under the national air toxics program from the specific perspective of implementation. That is, the analysis conducted on this topic is conducted from the point of view that the EPA has been twice handed an agency-forcing
type of legislation which mandates it to protect the public health from hazardous air pollutants by promulgating emission standards. The perspective from which this paper is written is: Congress gave the EPA a legally mandated tool with which to do its job; how has the agency fared, and how can it better succeed?

The purpose of this paper is to provide the reader with insights to the development, success and failure of the air toxics provision under the Clean Air Act Amendments of 1970; to describe the present program in terms of its purpose and its core regulatory components; to analyze the EPA's current progress toward implementation with specific regard to the factors that contributed to the failure to promulgate rules under the 1970 Amendments; and finally, to recommend to the agency how it might maximize the potential for successful implementation of the 1990 air toxics program.

This paper's approach is to first conduct a retrospective review of the development of the first air toxics provision in 1970 (Chapter 2). By understanding how the air toxics program came about, it is easier to understand why the regulatory agencies charged with its implementation had a difficult time promulgating rules. The next step is to document the main factors that led to the EPA's difficulty in implementing the regulatory portion of that initial program (Chapter 3). The third step is to outline the core components of the 1990 regulatory program.
This chapter will show how Congress changed the Amendments in an attempt to promulgate more rules, and, will provide the reader with necessary background with which to read the remainder of the paper. The next step is to assess the EPA's progress in implementing the 1990 version of the national air toxics program, paying particular attention to those aspects of the program that failed before (Chapters 5, 6). The goal here is to identify and document implementation challenges associated with the new program. The final step is to discuss observations regarding the EPA's progress in implementing the new program, to offer suggestions to the agency as to how it might maximize the potential for successful regulatory development under the air toxics provision of the Clean Air Act Amendments, and to identify future research needs (Chapter 7).
CHAPTER 2: BIRTH OF THE U.S. AIR TOXICS PROGRAM

2.0 Historical Perspective

Congress first addressed the problem of air pollution in 1955, when it authorized the Public Health Service to conduct studies into the area\textsuperscript{11}. This legislation authorized the Surgeon General to conduct research and investigations upon request, to make grants, and to enter into contracts and projects regarding research and training\textsuperscript{12}. The next action Congress took was in passing the Clean Air Act of 1963, the first modern environmental law\textsuperscript{13}. This law provided federal funding for the study of air pollution, provided for grants to the states to develop air pollution control and prevention programs, and provided federal enforcement of both interstate, and intrastate programs\textsuperscript{14}. Congress acted again in 1965, passing an extension to the 1963 Act, designed mostly to deal with motor vehicle emissions\textsuperscript{15}. In 1967, Congress passed legislation which, for the first time, required standards. The 1967 Clean Air Act Amendments did not yet require federal standards, but rather required states to develop metropolitan air quality control regions and to establish standards for those areas. If the states failed, the then Department of Health, Education, and Welfare was authorized
to establish federal standards. By 1970, however, when the Amendments were required to be reauthorized, no state had put in place a complete set of standards, and the federal government had designated less than one-third of the metropolitan air quality control regions that had been projected.

2.1 Sociological Context

In 1970, during the reauthorization of the 1967 Amendments, several factors came together which resulted in the passage of a radically new, comprehensive set of Clean Air Act Amendments, that included for the first time in the history of air pollution legislation, a toxics provision. 1970 was a year of great awareness and concern for the environment: Polls showed increased concern for air, water and land pollution; Numbers of and membership in environmental groups grew; and Earth Day, held on April 22, 1970, simultaneously reflected and intensified the nation's concern for the environment. In May of 1970, Ralph Nader's Study Group on Air Pollution published a strong critique of what they saw as the government's poor response to an environmental crisis, and specifically criticized one of Congress's long time environmental leaders, Senator Edmund Muskie (D. Maine), for being more interested in politics than the environment. This public interest, as reflected in the news of the day and in the popular culture,
would influence the upcoming debate over air pollution legislation, and fuel the development of the new air toxics provision.

2.2 Overview: Passage of the 1970 Clean Air Act Amendments

The first bill to update the nation's clean air legislation was offered by Senator Edmund Muskie, on Dec 10, 1969. It was little more than an effort to refine the 1967 law and to prod administrators to move faster in getting the states to act. The House held hearings on this matter at the same time. This was unusual; up to this point environmental legislation had been the province of the Senate. Thus, from the beginning of the reauthorization process, both the House and the Senate were interested in taking the lead in reworking the Clean Air Act.

President Nixon was interested in this area as well. Some suggest that the President's interest resulted from a desire to prevent the cause of pollution control from becoming identified with the Democratic party, specifically with Muskie, a strong candidate for the 1972 democratic Presidential nomination, and a Senate leader on environmental issues since 1963. On January 1, 1970, the President signed into law the National Environmental Policy Act of 1969 in a symbolic and highly publicized ritual on New Year's day of a new decade. Further, on January 23, 1970, in his State of the Union address, Nixon stated:
"The great question of the seventies is, shall we surrender our surroundings, or shall we make our peace with nature and begin to make reparations for the damage we have done to our air, our land and to our water?... Clean air, clean water, open spaces - these should once again be the birthright of every American. If we act now - they can be." 25

Following this address, the Administration presented its legislative proposals to the House on February 10, 1970 and to the Senate on February 18, 1970. The Administration bills changed the focus of the 1967 legislation by increasing the federal government's role in pollution control and by requiring more federal standards. While the bills addressed hazardous pollutants only in a limited fashion (some prohibitions, some technology-based regulations), they were stronger than the initial Muskie bill (S.3229), and thus sent a message to Congress that the Administration wanted to control the reauthorization of the Clean Air Act.

On March 4, in response to the Administration Bill (S. 3466), Muskie introduced a second bill (S.3546) which was more stringent than the Administration's offerings. Among the differences between it and the Administration Bills was a more detailed provision to control hazardous air pollutants from stationary sources.

The House voted to amend the Administration Bill and passed it as H.R. 17255 on June 10. This bill slightly weakened the Administration's provision to address chemicals considered to be "extremely hazardous to health". The
Senate reworked the two Muskie bills and the Administration Bill into S.4358, which retained the toxics provision in the same form as it was in S. 3546, the second Muskie Bill. The Senate passed S.4358 on September 17, 1970. Both the House and Senate Bills were then sent to a Conference committee to be debated.

The Conferees passed the Senate version of the bill with a few changes, including significant alterations to the toxics provision (see discussion in section 2.3). After Conference approval, the House and Senate voted to pass the joint bill as H.R. 17225. On December 31, 1970, President Nixon signed the Clean Air Act of 1970.

2.3 Evolution of the Toxics Provision

As noted above, the initial Muskie bill, S. 3229, sought only to broaden the 1967 Act, and therefore had no air toxics provision. Before the final reauthorization bill was finalized, however, a series of bills were introduced, reworked, and debated, each with their own requirements for toxics.

The Administration Bills, introduced to Congress as H.R. 15848, and S. 3466, addressed pollutants that were "extremely hazardous to health" by stating that no new source of such emissions was to be constructed or operated, with exceptions, and that existing sources were subject to standards that considered economic and technical
feasibility, where such emissions could be prevented or substantially reduced (S. 3466, H.R. 15848). That is, emissions of "extremely hazardous chemicals" were to be prohibited, if necessary, from new sources, and regulated, if possible, based on technology and economics, when emitted from existing sources.

The House altered Administration Bill H.R. 15848, including the section pertaining to chemicals considered to be "extremely hazardous to health". The prohibition language remained the same as in the Administration's Bill (§112 (b)(1)), but the language requiring regulation of existing sources of extremely hazardous pollutants was deleted. The House Bill was changed from H.R. 15848 to H.R. 17255, and was sent to the Senate on June 10, 1970.

Senate Bill 3546, the second Muskie bill, contained a stronger air toxics provision than in either the Administration Bills or H.R.17255. The toxics provision of this bill remained unchanged after the subcommittee (where S.3546 was changed to S.4358). This bill was called the National Emission Standards for Hazardous Air Pollution Agents. Section 115 of this bill had several distinct components. It required:

1) That the Secretary of HEW would within 90 days, publish a list of those air pollution agents "which available material evidence indicates are hazardous to the health of persons" (S.4358 §115(a)(1)).

2) That either a prohibition or an emission standard (where a chemical is hazardous but where a total
prohibition is not necessary) would be proposed 180 days after the list's publication, and promulgated after public hearings (S. 4358 §115(a)).

Section 115 also defined an air pollution agent which is "hazardous to the health of persons" as:

"one whose presence, chronically or intermittently, in trace concentrations in the ambient air, either alone or in combination with other agents, causes or will cause, or contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible damage to health. (S. 4358 §115(b))."

Section 115 of the Senate bill was not intended to cover an infinite number of pollutants. The report on Senate Bill 4358 states that, based on the "information presented to the committee" the definition under §115 encompasses a "limited number of pollutants". Asbestos, cadmium, mercury, and beryllium were named in the report as potential chemicals to be regulated under this section, and the Secretary of HEW was to be responsible for determining whether there were more chemicals to be regulated under §115. The report continues, "In writing a relatively restrictive definition of hazardous agents, the Committee recognized that a total prohibition on emissions is a step that ought to be taken only where a danger to health as defined exists".

Senate bill 4358, and H.R. 17255 were sent to Conference for debate. The resulting air toxics provision was very different from either the House or Senate Bills as
they entered the Conference debates, being both stronger and broader. Some components of the Senate Bill did not change: The EPA Administrator was still to publish, within 90 days, a list of Hazardous Air Pollutants, propose regulations 180 days after publication of the list, and promulgate regulations after hearings unless the hearings proved the chemical not to be hazardous. Changes between S. 4358 and the Conference substitute are listed below:

1) Language was changed from "causes or will cause" adverse effects to "may cause" adverse effects in describing chemicals to be regulated under §112;

2) Language was added describing the justification upon which standards would be set: the Administrator was to set emission standards "at the level which in his judgment provides an ample margin of safety to protect the public health from such hazardous air pollutants";

3) New sources could be constructed only if they met the standards under §112.

Thus, section 112 of the 1970 Clean Air Act Amendments progressed from being non-existent (S. 3229); to requiring some prohibitions for some new sources, and technology based standards for existing sources (S. 3466 and H.R.15848); to requiring regulation of chemicals that "will cause" an adverse effect (S. 4358); to finally, requiring regulation of chemicals that "may reasonable be anticipated to" cause an adverse effect based solely on an "ample margin of safety to protect the public health". The specific language defining a HAP, and describing an ample margin of safety is below:
"The term 'hazardous air pollutant' means an air pollutant to which no ambient air quality standard is applicable and which in the judgement of the Administrator may cause, or contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness."

"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."

2.4 Political Components of the Legislative Process

In retrospect, it seems that both President Nixon and Senator Muskie ended up with a stronger toxics provision than either of them wanted. By the end of the legislative process the Administration did not even want a toxics provision included at all - in Conference, the Administration expressly recommended that the toxics provision be deleted. Senator Muskie, before he felt the public and political pressure, seemed content to only fine tune his 1967 law.

This process of escalating legislative proposals that lead to laws which are beyond any immediate capacity to apply, is called "speculative augmentation" by Charles Jones. Jones states that:

Normally decision-makers are expected to refine existing policy by determining what is technologically and administratively feasible...In speculative augmentation...feasibility is less important than estimating what is acceptable to a rather indistinct public perceived to be demanding strong action."
Davies and Davies refer to a similar phenomenon called "political-one-up-man-ship" where the political stakes become higher as politicians "one-up" their competitors' positions. By attempting to appease the public's outcry for environmental responsibility, in order to put public health first, and for political gains, the Administration, House and Senate participated in the game of speculative augmentation / political-one-up-man-ship, and were rewarded with the 1970 Clean Air Act Amendments.

2.5 Symbolic Legislation

The changes made in section 112 during the passage of the 1970 Amendments both increased the stringency of the provision and made it more difficult to implement. By replacing the certainty of "causes or will cause" (an adverse effect) with "may cause", Congress was stating that health impacts or even the possibility of health impacts were to be avoided. Due to this single minded focus on protecting public health, the provision grew in impact. In addition, the term "ample margin of safety" was inserted, the definition of which turned out to be the most contentious part of the statute to interpret, and was a key factor in the failure of the EPA to promulgate regulations under this provision.

It is interesting that such important changes were made to a provision in Conference. The express purpose of a
Conference is to arrive at agreements to provisions based on what is in either a House or Senate Bill, not to create new components of a provision. But in this case new language was added to the bill, during the Conference debates. It seems that political one-up-man-ship did not stop until the very end of the legislative process. The result was a law that was difficult to implement, a law that was more figurative than functional.

Dwyer has a term for the type of legislation which resulted from this process of one-up-man-ship. He terms it symbolic legislation\(^4\). Symbolic legislation results from the determination to address a single, over-riding concern to the exclusion of other concerns\(^2\). In the case of §112 of the 1970 CAAA, this was exhibited by the statute's requirement to set standards for hazardous air pollutants based solely on human health, without regard to economic or technical feasibility. Dwyer provides several reasons why politicians and others might support symbolic legislation. First there is the political. As described above, the passage of section 112 was caught up in the political power struggle for environmental leadership. Muskie was guarding against the House establishing environmental leadership, and the Administration was guarding against Democratic control of the issue, to protect the White House in the upcoming 1972 elections. Once the escalation began, it would have been politically risky for any member of Congress to oppose
strong environmental controls: "It is safer politically to vote for "safety" - or better yet, an "ample margin of safety" - and to let the agency or courts deal with the unresolved legal, ethical and political questions." In describing Congress's unwillingness to address economic, technological, or societal issues associated with section 112, Dwyer notes that very little debate took place regarding this single-minded approach to air toxics in either the House, Senate or Conference, during passage of the 1970 Amendments.

While Dwyer and others acknowledge the political forces involved in the passage of the 1970 CAAA, other insights to why Congress was motivated to support symbolic legislation exist. By passing a strict statute Congress may have been trying a "technology-forcing" and an "agency-forcing" method of air pollution control. The technology-forcing method assumes that industry would develop necessary technologies required to control hazardous air pollutants, and bear the cost of development. The agency-forcing approach seeks to achieve ambitious regulatory ends by constraining Agency discretion (e.g., by requiring health-based standards, and imposing short deadlines). One further reason for Congress to support symbolic legislation is to support the symbol itself, here, the protection of human health at any price. Such a law may be impossible to implement, but it may be important symbolically in that it
establishes the proper ideals. The goals are then set via legislation, and the only task then is to achieve those goals.

3.0 Introduction

By including section 112 into the 1970 CAAA, Congress handed the regulatory agency a mandate to protect public health from emissions of hazardous air pollutants. Congress deemed that the process by which the agency was to accomplish this goal was through regulation; the agency was to promulgate rules that limited emissions of listed HAPs. By regulating these harmful emissions, by rule, the public's health would be protected, and the mandate of the section would be fulfilled. Did Congress's mandate result in the promulgation of rules limiting emissions of toxic chemicals? Was the EPA able to work within the construct set forth in section 112?

The answer is no. Twenty years after the passage of the 1970 CAAA, the EPA had promulgated only seven regulations. While the EPA did find some ways to encourage the reduction of air toxics emissions49, the Congressionally mandated program was not the process by which this was accomplished. This chapter describes the factors in this failure to achieve emissions reductions within the given framework.
3.1 Structure of the Amendments

Recall that the structure of the 1970 toxics provision required the EPA:

1) To determine that a chemical is a hazardous air pollutant, and list it as such;

2) To regulate the emissions of the HAPs based solely on human health effects and with an ample margin of safety;

3) To propose and promulgate regulations in the span of one year, while including the opportunity for public comment.

The EPA had difficulty implementing each of these three components of the regulatory process: listing chemicals became increasingly difficult over time; the definition of ample margin of safety proved elusive to the agency; and the statutory deadlines were too short. The following sections describe the difficulties the agency experienced in attempting to work within the framework laid out by Congress.

3.2 Listing Chemicals as HAPs

The statutory language in section 112 required the agency to list a chemical as a HAP if it met the legislative definition (section 2.3). In 1971, EPA listed asbestos, beryllium, and mercury, using qualitative data it included in its Health Assessment Documents. A 1983 retrospective General Accounting Office report on the EPA's lack of progress in implementing the 1970 program stated that, as time progressed, the EPA experienced much
difficulty in listing other chemicals, due to a need to satisfy its Science Advisory Board\(^5\) (SAB) and, due to industry opposition\(^6\). Specifically, the amount and type of data needed to reach a conclusion to list a chemical became an issue both within the agency's Office of Research and Development (ORD), and between EPA and its review body the SAB. Consequently, the agency grew to believe that it must develop and present the most convincing case possible before listing a chemical\(^7\). This need to present the best case possible to avoid opposition, prompted the EPA to develop lengthy review processes, which resulted in delays in listing hazardous air pollutants\(^8\).

The GAO report also contends that delays in listing and regulating occurred due to EPA's changing methodologies\(^9\). During the first years of implementation, the agency looked at all the potential health effects associated with a particular chemical\(^10\). In 1979, the EPA published a new methodology stating that it would concentrate on assessing cancer effects in its listing decisions\(^11\). In 1981, the agency reversed itself, and went back to full scale assessments, considering both cancer and noncancer effects\(^12\). This, the GAO contends, caused even more delays because more resources were needed to study and review the data.
3.3 Defining Ample Margin of Safety

Another contributing factor resulting in the delay in and lack of regulatory action, was the mandate to set standards based on an "ample margin of safety to protect the public health". This proved to be extraordinarily difficult for the agency to address. What is an ample margin of safety, particularly as it relates to non-threshold pollutants\(^6^0\)? The agency was in a dilemma here. If it deemed that no level of exposure to a chemical could be determined to be within an ample margin of safety, the logical next step would be to ban emissions of that chemical. The EPA was, however, unwilling to take that next step, as the economic consequences could be drastic. Thus, for the early standards, the agency regulated HAPs on the basis of technology despite the language in the Amendments requiring an ample margin of safety\(^6^1\). As time passed, and outside parties became involved in the regulatory process, this method of regulating was challenged in court\(^6^2\). These challenges contributed to delays in standard setting because of lengthy court cases, which prevented the release of standards. These challenges also contributed to delays because they sensitized the agency to the possibility of being sued, and to avoid such an outcome, the agency struggled to apply the ample margin of safety language in a way that would not result in lawsuits. Again, the outcome was that standards were delayed (see section 3.3.1 below).
3.3.1 The Vinyl Chloride Case

The pivotal court case regarding the issue of an ample margin of safety was the vinyl chloride case. EPA listed vinyl chloride as a hazardous air pollutant in 1974, based on rough estimations of the projected incidence of angiosarcoma. The agency deemed that these estimations were too uncertain to be used to establish an emission rate that allowed for an ample margin of safety\(^63\), and set the vinyl chloride standard on the best available control technology, rather than on a purely health-based determination\(^64\).

Shortly after the EPA promulgated the rule, the Environmental Defense Fund requested a review of the rule by the District of Columbia courts\(^65\). The two parties worked out an agreement to amend the regulation to establish a goal of zero emissions. The amended rule included a schedule to accomplish this goal\(^66\). The EPA however, never finalized this regulation, and took no action for 8 years. On January 9, 1985, the EPA withdrew the proposal stating that the regulation imposed unreasonable costs to the industry, and that no technology could control the emissions below what the current regulation required\(^67\).

In 1985, the Natural Resources Defense Council (NRDC) sued the agency arguing that the EPA Administrator must prohibit emissions of vinyl chloride because there is no ample margin of safety associated with its emissions\(^68\). Further, the NRDC argued that the EPA's standard was
"arbitrary and capricious" because it considered cost and technical feasibility, and that the EPA was not permitted to consider such factors in setting standards69. The EPA contended that it could set an emission level for non-threshold pollutants at the lowest level achievable by best available control technology when that level is below the level of demonstrated harm and when the cost of setting a lower level is disproportionate to the remaining risk70.

In the 1987 en banc decision for the D.C. Circuit Court, Judge Robert Bork wrote that the court rejected the NRDC's "extreme position" that the proper reading of the legislative history requires vinyl chloride emissions to be prohibited71. The court, however, remanded the EPA standard saying that while the language in section 112 did not preclude the consideration of any particular factor, the agency had indeed placed too great an emphasis on technology rather than the ample margin of safety provision. The court then provided the agency with the legal framework with which to determine ample margin of safety72.

The vinyl chloride decision did not expressly define ample margin of safety, rather, it outlined a process to determine it. The decision stated that implicit in the term ample margin of safety is the need first to determine what is safe. However, Bork writes that safe does not necessarily mean risk-free73. The EPA Administrator, Bork wrote, is required to make this determination based on "the
risk to health at a particular emission level". Neither economics, technical feasibility, nor any other criteria may enter into a determination of what is safe. The second step in the process is to assess the ample margin of safety. Here, technical feasibility and economics may enter into the equation, but only to lower allowable emission levels. Economics and technical feasibility may not be used to argue for emission levels higher than what was originally determined to be safe.

The court did not mandate the use of this particular two-step process, it merely stated that the determination of what is safe must be accomplished by using human health as the sole criterion. The EPA has however, adopted this process as a matter of policy:

"In response to the vinyl chloride decision, the EPA has re-evaluated its approach to regulating hazardous air pollutants, and will, both here and in the future, make an "acceptable risk" determination based exclusively on the health effects of the substance, and then set a standard providing for an ample margin of safety." 

Thus, 17 years after the passage of the Amendments, the issue of ample margin of safety had been addressed in the courts. The EPA's next step was to interpret the decision and turn a legal decision into a regulatory reality.
3.3.2 The Benzene Standard: EPA's Application of the Vinyl Chloride Decision

In 1988, EPA proposed National Emission Standards for Hazardous Air Pollutants (NESHAP) for Benzene, which reflected the determination of ample margin of safety as put forth in the vinyl chloride decision (see section 3.3.1). The determination of a safe level of benzene emissions for certain sources was established using risk assessment, (risk assessment was commonly employed by EPA in 1988). The proposal included several options for the standard, including regulating:

1) On a case-by-case approach;

2) When the cancer incidence exceeded one case per source category (total);

3) When the Maximum Individual Risk (MIR) is 1 per 10,000 people exposed \((10^4)\) per lifetime;

4) When the MIR is 1 per 1,000,000 people exposed \((10^6)\) per lifetime\(^a\);

This standard was promulgated in 1989, based on what is called the "fuzzy bright line". This regulatory goal holds that risks are acceptable if few\(^b\), if any people are exposed to above 1 in 10,000 lifetime cancer risks, and if as much of the population as possible is below 1 in 1,000,000 lifetime cancer risk\(^b\). The EPA had no more chances further chances to set standards based on the idea of the "fuzzy bright line", President Bush signed the Clean Air Act Amendments into law on November 15, 1990.
3.4 Statutory Deadlines

The third part of the regulatory process, as set forth in the 1970 amendments, required the agency to publish proposed regulations 180 days after listing a chemical with a notice of a public hearing to be held in 30 days. The agency was to then promulgate the regulation 180 days after proposal, unless information presented at the public hearing proved the chemical not to be a HAP\textsuperscript{11}. These statutory deadlines proved impossible for the agency to meet. For example, the EPA listed asbestos, beryllium, and mercury in 1971, but did not promulgate standards until 1973\textsuperscript{12}. Even then the agency was acting under a court order\textsuperscript{13}. Congress's intent to force the agency to set standards by stipulating short time-lines was unsuccessful, and instead resulted in few standards being set at all\textsuperscript{14}.

3.5 Summary

The EPA's difficulties in implementing the 1970 Air toxics section of the CAAA arose from a combination of issues: the requirement to list chemicals, the absence of a clear implementation methodology, the definition of ample margin of safety, and some contend, short deadlines.

Listing chemicals was a problem for the EPA because of three issues: how much data are needed to list an chemical as a HAP; opposition to regulation, (lawsuits and the fear of lawsuits) and changing methodologies upon which listing
decisions were based. The first issue is one of knowledge: how much does the EPA need to know, and what specifically must it prove about a chemical before it can be listed as a HAP? The second issue is one of goals: the EPA and other players in the regulatory process (industry for example) may have different goals. This could explain the differing opinions regarding regulation, and industries opposition to some of the agency's actions.

The third issue was methodological. The EPA struggled to establish a methodology with which to list pollutants, and changed it back and forth over a period of years from dealing with all health effects to only cancer effects, then back to all effects. The reason the EPA struggled here could be explained in two ways. The change in methodology could have been a response to criticisms over the agencies methodologies and an effort to stay out of court. It could also be explained by the fact that assessing hazardous air pollutants was new for the agency and they were finding their way along a steep learning curve. Whatever the reason for the methodological shifts, they did result in delays in standard setting."

Another problem the EPA had with promulgating standards was rooted in the idea of setting standards on an ample margin of safety. This, while perhaps the "right thing" to do, or at least the "right thing" for members of Congress to support politically, turned out to be something the agency
could or would not do. The agency could not apply a strict interpretation of the language because of the difficulty in determining that data could support such a drastic action as shutting down an industry. The agency would not apply a strict interpretation because of the potential for negative economic consequences caused by shutting down industry. This attempt to regulate on one issue is arguably the largest problem the agency faced in implementing the air toxics provision, although it is not the only issue that prevented the EPA from promulgating regulations. It was difficult for the EPA to address the ample margin of safety issue because the idea of making a decision based on only one issue, even an issue as compelling as protecting human health, is inconsistent with the way this society makes decisions in general. Considerations of health are generally if implicitly balanced with other issues, including economics. The EPA understood that this was how decisions are made, but found the law difficult to interpret in this manner and found that lawsuits often awaited the agency after they arrived at a decision.

This difficulty could be described as one of each party's differing means to achieving a goal, and explained in the context of the vinyl chloride case. Both the EPA's and NRDC's goal seems to be to protect the public. In determining the means by which to accomplish this goal, the EPA wishes to avoid the economic consequences of shutting
down industry. In the case of vinyl chloride, the NRDC's means by which to protect public health seem to include the concept of zero risk\(^6\), which in turn includes the possibility of banning emissions if necessary. The conflict here caused delays in the public health being protected at all, as the rule was delayed for years.

The next type of difficulty faced by the agency, according to the GAO and Congress was one of deadlines. This was significant in two ways. First it was meaningful in that Congress's attempt at agency-forcing failed. The second point is that the deadlines were ineffectual in prompting the agency to promulgate rules, because there was little incentive (or punishment) associated with promulgating (or failing to promulgate) a rule, and even less incentive to address a rule after the deadline had passed. This may have allowed the arguments over listing chemicals and over the determination of an ample margin of safety to drag on.

The common thread through all these problems is that the agency had difficulty working within the established framework to promulgate rules, and in turn, protecting the public health. The solution then is to establish a new approach, or find a way to work through the existing one. As the next chapter will describe, the first tack was taken; Congress changed the approach the EPA was to take in regulating air toxics.
4.0 Rationale for New Regulatory Approach

Congress's motivation for revising section 112 was that the former section 112 was not working as intended; few regulations had been promulgated, and thus public health was not being adequately protected. Congress analyzed the 1970 Hazardous Air Pollutant program and drew several conclusions that led to the restructuring of section 112. The legislature stated that EPA did not use all the authority granted to it by the Clean Air Act in order to protect the public health. Congress also admitted some guilt by stating that because emission standards were to be set with an ample margin of safety to protect the public health, and that could mean the banning of some emissions, it could be very costly, in terms of closing industrial facilities. In addition, the legislature reported that the time frames for proposal and promulgation were unrealistic (see Appendix A). These and other reasons were put forth as the rationale for Congress to revise and significantly alter the nation's air toxic program.

Based on these conclusions, Congress determined that the former section 112 should be restructured to provide EPA with the authority to regulate stationary sources of
hazardous air pollutants. This chapter will describe the core components of the 1990 regulatory program for the control of emissions of air toxics. This information is presented to assist the reader in understanding the differences between the 1970 and 1990 programs, and will serve as background information for the remainder of this paper, the EPA's experience in implementing the 1990 program.

4.1 Core Components of the New Regulatory Program

4.1.1 Regulating Major Sources

Congress, working within the philosophy of agency-forcing (forcing the agency to promulgate regulations), outlined a very deliberate path for the EPA to follow in creating regulations under Title III of the 1990 Amendments. First, the Amendments include a list of 189 Hazardous Air Pollutants (see Appendix B). This list was provided by Congress in the Amendments, and consisted mostly of chemicals that other EPA programs had previously determined to be hazardous (e.g. the Superfund program). The Amendments also require the EPA to create a source category list; a list that contains sources of HAPs gathered together into appropriate categories (e.g., ship building facilities, or wood preserving operations) (See Appendix C). This list is divided into "major source categories" and "area source categories". "Major source categories" are
categories whose sources emit greater than 10 tons per year (TPY) of any one pollutant, or greater than 25 TPY of any combination of HAPs (§112(b); §112(d)). "Area source categories" are categories whose sources emit less than 10 or 25 TPY (see section 4.1.2). The Amendments require technology-based standards to be applied to all new and existing sources, provided they emit listed chemicals noted above, and were listed as part of a source category. For new major sources, the standard requires the new source to meet the emissions of the best controlled similar source (§112(d)(3)). Emission standards promulgated for existing major sources must be at least as stringent as "the average emission limitation achieved by the best performing twelve percent of the existing sources" (§112(d)(3)(A)) 88.

This provision requiring existing sources to meet the emissions of the average of the best performing twelve percent is called the "MACT floor". This concept refers to the fact that the MACT floor is the least stringent a standard can be. A standard may be set above the MACT floor, that is the standard may be more strict than the minimum represented by the floor, but it may not be set less stringent than the floor89.

The time frame for setting these standards is a period of ten years (§112(e)). Section 112(e) states:

1. Emission standards for not less than 40 source categories are to be promulgated two years after the enactment of the CAAA (November 15, 1992) (CAAA, §112(e)(1)(A));
2. Emission standards for not less than 25 percent of the listed source categories are to be promulgated four years after the enactment of the CAAA (November 15, 1994) (CAA, §112(e)(1)(C));

3. Emission standards for an additional 25 percent of the listed source categories are to be promulgated seven years after the enactment of the CAAA (November 15, 1997) (CAA, §112(e)(1)(D));

4. Emission standards for an all source categories are to be promulgated ten years after the enactment of the CAAA (November 15, 2000) (CAA, §112(e)(1)(E)).

If the EPA should miss a deadline, that is, not set a standard by the date specified in section 112 (e), a type of "penalty" is assessed. Interestingly, Congress chose to penalize the regulated community and the states, more so than the EPA, when the agency misses a deadline. Section 112(j) contains a provision called the "MACT hammer". Section 112(j) states that if 18 months has elapsed after a specific statutory deadline, and the EPA has yet to promulgate a standard, the industry and the states must take over the regulatory process and determine MACT themselves. Under this scenario each facility in the source category must submit to their state regulatory agency, a plan detailing how they will determine and meet MACT. The state is then required to approve or disapprove this plan, and provide an operating permit to the facility if the plan is approved. Penalties may be assessed to industries failing to comply, and states who fail to act could lose their state air toxics program (if they have their own). Finally, section 112(j) never releases the EPA from the
responsibility of setting a standard, however. Even if the "hammer" clause becomes applicable, and facilities and states regulate the sources, the EPA must still promulgate a federal rule.

4.1.2 Regulating Area Sources

An area source is defined as any stationary source of HAPs that is not a major source (excluding motor vehicles and non-road vehicles) (§112(a)(2)). Title III provides for the regulation of these smaller sources under several specific conditions. In one of these special cases, area sources are regulated as a source category. This occurs where the agency determines that emissions from a small facility, or combined emissions from several small facilities present "a threat of adverse effects to human health or the environment warranting regulation under this subsection" (§112(c)(3)). An area source may receive either MACT as its emission standard, or Generally Achievable Control Technology, (GACT). The agency interprets GACT as a providing a lesser amount of control (potentially), where health and costs considerations are directly addressed in the decision about whether to regulate the area source(s) in question (§112(d)(5)).
4.1.3 Residual Risk

As described above, the initial part of the new national air toxics program is to set standards based on available technology. The second phase of the program is to assess the health protective nature of those first standards, then set additional health or environmentally-based standards if the initial standards are not protective enough (§112 (f)). More specifically, the provision states that EPA will, in November of 1996, present a report to Congress containing methods of calculating risk to the public health remaining after the application of the 112(d) standards; the significance of those risks and technological availability and costs of reducing such risks; actual human health risks to persons living in the vicinity of sources, risks due to background levels of pollution, any uncertainties in risk assessment methods, any negative effects to people or the environment regarding efforts to reduce such risks; and, recommendations to Congress as to legislation regarding such remaining risks (§112(f)(1)). If Congress does not act on the recommendations, the EPA is required, by statute, to promulgate additional standards, up to 8 years after the promulgation of the MACT standards, where an ample margin of safety is needed to protect the public health. For carcinogens, these standards are to be set according to the Benzene NESHAP. (see section 3.2.1.2). Residual risk standards may also consider non-cancer health
effects, ecological effects, and cost. ($112(2)(f)(A); $112(2)(f)(B))

4.2 Summary

The major components of the air toxics provision of the 1990 Amendments include a list of 189 hazardous air pollutants and the requirement that the EPA to develop a list of source categories. The EPA is to develop regulations for major source categories (those that emit 10/25 TPY of HAPs) based on MACT. The EPA is also to develop regulations for area source categories (those that emit less than 10/25 TPY of HAPs) based on either GACT or MACT. The "hammer" falls if the agency misses a regulatory deadline by more than 18 months, and the state and source category must then determine MACT (or GACT) themselves. The residual risk of each source category must be estimated within eight years of the promulgation of a standard, and further emissions regulation must be applied if the risks are unacceptable.

This regulatory strategy provided to the EPA by Congress and requiring the promulgation of 174 standards over a period of 10 years, seems to put forth a philosophy to get many standards out relatively quickly, rather than a few perfect standards. This suggests that Congress was willing to accept the possibility of over or under regulating in the MACT part of the program. The next
chapters will discuss challenges faced by the EPA in following the new protocol to promulgate rules.
CHAPTER 5: ISSUES IN IMPLEMENTING THE 1990 REGULATORY PROGRAM

5.0 Introduction

It is presently nearly three years since the passage of the 1990 Amendments. It is too soon to declare success or admit failure with regards to regulation development under the new section 112, but it is an appropriate time to ask some basic questions regarding progress, particularly about how the new program is faring in light of the problems the EPA encountered in implementing the 1970 program. What problems that arose in the former section 112 did the 1990 program attempt to fix? What problems still exist? And, what challenges face the agency in the new program?

5.1 What the 1990 Program Attempted to Fix

5.1.1 Identifying Hazardous Air Pollutants

Congress, determined to make the new air toxics program more successful than the former program, made a series of changes to the new regulatory program under the 1990 Amendments. First, Congress changed "what" is to be regulated. Recall that, under the former section 112, the agency was to list individual chemicals considered to be hazardous air pollutants, then regulate each pollutant
separately. The 1990 program changed this procedure. The new Amendments contain a list of 189 pollutants, which consists of chemicals to be regulated under section 112(d) (see section 4.1.1). As listing HAPs was a major hurdle in the previous program, this change was intended to be a factor in enabling the EPA to promulgate regulations.

This change seems to have indeed made regulation development easier. For example, the agency proposed its first regulation, the Hazardous Organic NESHAP (National Emission Standard for Hazardous Air Pollutants), hereinafter referred to as the HON\textsuperscript{40}, without having to justify that the emitted chemicals were toxic\textsuperscript{91}. It simply identified that synthetic chemical manufacturers producing and/or emitting a listed chemical(s) in the requisite amount, are subject to the HON.

The above is the simple case. In some cases, the EPA will still need to determine whether it will list a chemical as a HAP, for example, when a source category uses substitute chemicals\textsuperscript{92}. Suppose a listed source category produces a product, and during the manufacture of that product a solvent, which is listed as a HAP, is used and is emitted in the amount of 10 TPY. This source category then comes into the MACT program; the agency must write a regulation to limit emissions from that source category. Suppose further that the industry discovers that they can replace the solvent that they are currently using with a
solvent that is not on the list of 189. The source category is no longer emitting one of the HAPs and is therefore no longer subject to regulation. Should the source category be regulated? The answer to this question will require that the EPA make a formal determination as to the hazard potential of a non-listed chemical - this harkens back to the 1970 program when the EPA had to list each chemical before regulating it. The EPA had problems with this procedure in the previous program (section 3.1.1) - listing may prove to be a stumbling block for the 1990 regulatory program as well (see discussion in section 5.3.1.1).

5.1.2 Regulatory Deadlines

The second change Congress made to the regulatory program was to change "when" regulations are due to be promulgated by extending the regulatory deadlines. Recall that the former section 112 program required that regulations were promulgated within 360 days from the date the EPA listed a chemical. Recall also that the new program contains a regulatory agenda that EPA must follow, in which the agency must regulate all 174 source categories within a period of 10 years (section 4.1.1). Thus, EPA has either 2, 4, 7, or 10 years from the date the Amendments were signed to promulgate a regulation. In essence, this extends regulatory deadlines. In real time, the EPA has not been able to take advantage of the extended deadlines, at least
so far. The EPA was mandated to promulgate standards for not less than 40 source categories by November 15, 1992. The Agency missed that deadline and has responded to a pre-litigation notice from the Natural Resources Defense Council and the Sierra Club, by agreeing to meet a stringent regulatory schedule by promulgating several regulations over the next two years (see section 6.1).

5.1.3 Basis for Regulation

The new program also changed "how" the Agency is to regulate air toxics. The 1970 air toxics program required regulations to be set on the basis of human health. As described earlier, this cornerstone of the 1970 program was also what the EPA struggled with the most in implementing the 1970 toxics provision. As chapter 4 describes, Congress changed the ample margin of safety program into the MACT - residual risk program in which regulations are initially based largely on technical and economic factors, then on health effects. Congress's intent here was to get air toxics regulations "out the door", and afford some measure, albeit indirect, of health protection. In the MACT program, health plays an implicit role; the idea is that fewer emissions lead to less exposure which protects public health. MACT standards are not meant to be the final solution in all cases; residual risk is to be the final word. The answer to the questions, of whether this largest
change to the regulatory program can assist the agency in promulgating regulations, will be posed in the final chapter.

Congress changed the new toxics program in an attempt to fix several components that were difficult for the EPA to deal with under the former program. Changing the requirements regarding listing chemicals as HAPs can be called largely successful at this time. While the agency will have to determining how it wished to deal with non-listed chemicals, for the majority of the source categories, no listing will be required. The new Amendments also extended regulatory deadlines - this may help the agency promulgate regulations down the line (e.g. those on the 4, 7, and 10 year schedules) but the agency missed its first deadline. Finally, Congress changed the basis for the program from setting standards based on health, to first setting technology-based standards, then addressing health in eight years. As the following chapters will illustrate, this successful implementation of this approach is a great challenge to the agency.

5.2 What the 1990 Program Did Not Attempt to Fix

5.2.1 Power Struggles

The 1990 Amendments did not attempt to fix all problems associated with the 1970 program. Indeed, legislation cannot solve all problems associated with the implementation
of regulatory programs because not all implementation problems are rooted in the legislation. For example, the agency does not create regulations in a vacuum; several other players are involved, including those in other parts of the executive branch of the government. As a result of several parties having input into the regulatory development process, power struggles can develop. So far, the EPA has dealt with two such power struggles, both concerning the Office of Management and Budget (OMB) (sections 5.2.1.1, 5.2.1.2)\textsuperscript{93}.

5.2.1.1 OMB and the General Provisions Rule

The General Provisions regulation establishes the implementation framework for the regulatory program under Title III\textsuperscript{94}. Specifically, this regulation lays out the principles for compliance, in describing record keeping and reporting requirements that are consistent across all standards promulgated under Title III. Further, the general provisions discuss enforcement, and preconstruction reviews. These issues are relevant to all standards under Title III. The purpose of the General Provisions is to gather all these commonalities together rather than repeat them in each standard.

During negotiations over the General Provisions, the OMB brought up for discussion a provision from Title III that had nothing to do with the General Provisions
regulatory package itself: the Source Category Deletion provision under §112(c)(9). The OMB focused on the portion of this section that allows the Administrator to initiate delisting a source category, and made a request. The OMB's initial request, in October of 1992, was that the EPA should agree, in writing, in the General Provisions preamble, to apply section 112(c)(9) before setting each MACT standard. The OMB stated that the EPA should conduct a screening level analysis before beginning the standard setting process and determine that at least one source in each source category fails the requirements for delisting. Under this scenario, if no source in the category presents a health or environmental risk, the agency would delist that source category. The intent here, according to the OMB, is to avoid setting standards for which there is minimal risk, and focus society's efforts where they are most needed. In October 1992, the EPA rejected the OMB's argument simply as a position that the agency could not agree with at the time. More specifically, the agency rejected this proposal because conducting a health screen before setting a MACT standard would place risk assessment back into the standard setting process and jeopardize the entire MACT program.

In continued negotiations over the General Provisions occurring in March and April of 1993, the OMB repeated yet softened its request by asking the EPA to place language
into the General Provisions preamble that states the agency will consider when and how it might initiate the delisting process. Once again OMB suggested that the EPA formally apply some sort of screening procedure as an explicit part of the standard setting process. This time, the EPA compromised in order to gain release of the General provisions package from OMB. The EPA placed language in the General Provisions preamble that commits the agency to include certain language in the Source Category Deletion Guidance Federal Register notice when the agency publishes the Source Category Deletion notice in the Federal Register (see Appendix D). This language will only describe when the agency itself will consider initiating the deletion of source categories. EPA made no promise to apply a health-based screen as a normal part of the MACT standard setting process.

While the OMB request is not completely devoid of merit, an EPA agreement to incorporate even the softened language into the General Provisions regulation would have been dangerous, and could potentially have stalled the MACT program. In certain cases, the EPA should explore the option of initiating the deletion provision itself, where data on hand can establish, with a reasonable amount of confidence, that no source in the category exceeds the requirements set forth in §112(c)(9). Under these circumstances, the agency would be prudent to delist such a
source category, as it would prevent unnecessary regulation. However, the practical application of a screen, which requires the EPA to find that at least one source in the category exceeds the requirements set forth in section 112(c)(9) before beginning the formal rulemaking process, is dangerous for four reasons. First, such a screen would require that the EPA conduct some sort of human health and ecological assessment before setting a MACT standard. This is in direct contrast to the goal of the MACT process as described in the Amendments. MACT is a technology-based program designed to place at least an achievable level of control for sources not already doing so, to reduce HAP emissions. The "risk" component of the program will assess residual risk and apply additional controls if the risks are unacceptable, after the agency's risk assessment methodologies are reviewed and revised, and after more health and ecological data are made available.

Second, conducting a health and ecological screen before the application of the technology-based standards is unacceptable, because it would change the philosophical base of Title III. Title III maintains that chemicals on the section 112(b) list of 189, if emitted as part of a major source, are guilty until proven innocent, not innocent until proven guilty. In other words, the sources are to be regulated unless they are proven not to pose a risk to human health or the environment (i.e. through section
112(c)(9)(b)). The EPA should not be required to prove that a certain source categoryposes a risk to human health or the environment before the standard is set. That philosophy harkens back to the previous program, which failed under the burden of proof.

Third, the OMB screen assumes that the EPA has the data on hand to determine whether or not at least one source in the category poses a risk. In correspondence submitted to the EPA\textsuperscript{7}, the OMB reminds the agency that the EPA's Office of Air Quality Planning and Standards is undertaking a major information collection effort, which will provide the EPA with relevant information including source locations and emissions characteristics. The OMB argued that such information is sufficient to conduct a screening analysis. This is incorrect on two counts. First, while the EPA is attempting to gather source category information, the results of such an effort have been less than encouraging. Many of the industries surveyed do not know the entire range of chemicals they emit, nor the amount in which they emit those chemicals, and as such, are unable to report this information to the EPA. Conducting tests at facilities in order to gather this necessary information is time-consuming and expensive. The EPA cannot request that a source conduct tests, nor can the EPA conduct all necessary tests itself, and still meet statutory deadlines. Consequently, the agency does not often have basic information on the
speciation and emission parameters necessary for even a screen. Second, human health and ecological data are often unavailable or incomplete for the purposes of determining a level which is either safe, or unsafe to breathe. Without such toxicity information, any meaningful screening level analysis, which may result in a source category not being regulated, becomes impossible.

The fourth and final reason why the EPA should reject the OMB's request for a screen, is that the "screen" has already been provided in the Amendments. If a source within a source category emits 10 TPY of a listed HAP, or 25 TPY of a combination of listed HAPs, then the agency is to apply MACT. This legislative "screen", not a health effects assessment, is the initial screen.

This power struggle was among the factors that delayed the proposal of the General Provisions rule. As the General Provision must be in place before any MACT standard is promulgated, this struggle could have delayed the entire MACT program. Fortunately, this was not the case.

5.2.1.2 The OMB and the Hazardous Organic NESHAP

Another power struggle in which the EPA and OMB were engaged was over the very first MACT proposal the agency sent to the OMB. Here, the EPA compromised on a significant point in the first MACT standards, the HON. In setting this standard, the agency discovered that certain industrial
processes within this source category were uncontrolled. Therefore, if the normal formula for regulation were to be followed, that is, setting the standards on the best performing twelve percent of sources, the level of emission reduction required would be zero. The agency determined that some of the uncontrolled processes should be controlled, and others should not. The agency then set the standards for the processes that the agency determined required them. However, since none of the sources were controlled, any regulation would be more strict than the MACT floor (e.g., the MACT floor represents no control, therefore any control is more stringent than the floor).

The OMB agreed to this in light of the fact that the EPA provided a cost-benefit analysis that left OMB satisfied that the benefits did outweigh the additional costs of compliance. More precisely, the OMB agreed to setting a standard above the floor in these cases because the EPA compromised on the following point: the agency placed language in the HON proposal, promising to conduct similar cost-benefit analyses for each standard where the EPA desires to go above the floor. As a result of this compromise, the language in the HON proposal states that the costs and benefits of setting a standard above the floor should be considered before setting a more stringent standard than the floor. Thus, for each portion of a standard where EPA wishes to set a standard that is more
stringent than the floor, benefits and costs must be estimated and documented.

This could be a potential road block for future MACT standards and may bring an old problem back into the new standard setting process. The situation is this: In order to conduct a cost benefit analysis, one must have some way to estimate costs and benefits. The first part of the equation includes costing the controls to be applied to the process units. Determining the benefits is more difficult; this is where the problem lies. In these types of situations, benefits are normally measured in terms of lives saved, or cancer cases avoided. This type of information comes from a health effects analysis. Thus, if the Agency must perform cost benefit analyses on each standard where they intend to set a standard above the MACT floor, risk assessment becomes an issue. This may cause the same kinds of logistical and methodological problems that existed in the old programs. The implications for this decision are at this time unknown as no other regulation sent to the OMB has set a standard more stringent than the floor.

5.2.2 Risk Assessment Methodology

As described above, the new air toxics program did not attempt to change the general regulatory process, that, by its nature, can lead to power struggles. Nor did the program attempt to solve the debate over risk assessment
methodologies. This issue is larger than any one regulatory program; it encompasses many regulatory agencies, the scientific community, the public, and policy-makers. As such, and, due to the language in section 112, the issue of risk assessment remains an unsettled issue in the 1990 air toxics program. Risk assessment is an issue in both the MACT program, in setting standards above the floor, in addressing substitutes, in determining whether to regulate area sources. Finally, risk is the cornerstone of the residual risk part of the program.

5.2.3 Litigation

Another potential logistical challenge in the new program that is a carry-over from the old program concerns litigation. As chapter three described, litigation impeded some regulatory development under the former section 112 (see the vinyl chloride example section 3.3.1). In the new program, the evidence so far suggests that the threat of litigation may in fact assist the agency in promulgating rules (see section 6.1).

5.3 Challenges in Implementing the MACT program

5.3.1 Risk in the MACT Program

Section 5.1 described how the reauthorized Clean Air Act attempts to, and partially succeeds in, improving the regulatory development portion of the federal air toxics
program. However, the current program brings with it its own challenges. For example, Congress determined that the issue of risk assessment was to be largely relegated to the residual risk program. As the implementation of Title III proceeds, however, it is clear that the issue of health effects cannot be so easily divorced from the process of setting MACT standards. As mentioned at previous points, health effect concerns have entered into the MACT standard setting process in a variety of ways. First, the statute itself mandates that EPA consider health effects under certain circumstances, during standard development, for example, in determining whether to regulate area sources. Second, health effects have become an issue in the MACT program because of the complex process of regulation development, specifically, during negotiations over standards between EPA and the Office of Management and Budget (sections 5.2.1.1 and 5.2.1.2). A third major issue concerns the use of substitutes.

5.3.1.1 Pollutant Substitution

Recall the discussion in section 5.1.1., regarding pollutants that are not currently on the list of HAPs, but are used or emitted in lieu of HAPs. This scenario presents a challenge to the agency that may have been unforseen by the authors of section 112.
If the replacement solvent is of low toxicity, leads to low exposure, and does not present a water or land disposal problem, then the scenario becomes a shining example of how emissions, and therefore pollution, can be prevented in the MACT program. If however, the replacement solvent is of higher toxicity, or presents exposure or cross-media transfer problem, then this scenario becomes an example of a potentially dangerous loophole in the regulatory program. Similarly, if the toxicity, or other impacts of the replacement chemical are unknown, then no one knows whether the change is positive, negative, or neither.

The EPA is currently faced with issues regarding substitution as a result of the agency-wide push for "pollution prevention alternatives" to be addressed in standard setting, and, as a result of an industry's attempt to avoid regulation. In the first case, EPA Administrator Carol Browner has issued a directive that pollution prevention alternatives are to be explored as regulatory options, and that she expects to be briefed on pollution prevention options when staff present her with regulatory packages (Appendix E). To satisfy these directives, the Agency has undertaken a study which closely examines pollution prevention options for some of the MACT standards. One pollution prevention option is to avoid emissions of HAPs by changing processes or feedstocks so HAPs are not
emitted rather than merely reducing HAP emissions by applying end of pipe controls.

The EPA is looking into this substitution option as part of MACT standard development, for example, in the Wood Furniture MACT standard. Here, the industry, (which uses many solvents, some HAPs, and some non-HAPs) can feasibly switch to using all non-HAP solvents. Some of the non-HAPs are of unknown effect, and some may be more hazardous to human health and the environment than some of the HAPs. The agency is currently negotiating with the industry and environmental groups to resolve this potential problem.

The implications of the substitution issue with regards to regulatory development under Title III are vast. The air program wants to participate in pollution prevention; it makes sense to avoid emitting HAPs rather than concentrating on end of pipe controls which may result in only reducing but not eliminating HAP emissions. However, simply replacing HAPs with non-listed chemicals may have negative environmental consequences - replacement chemicals may be just as hazardous as the HAPs. Second, the agency wants to prevent source categories from avoiding regulation by switching to potentially dangerous non HAPs. How does the agency prevent the use of these "non-listed HAPs", when their only jurisdiction is over officially listed HAPs? Must the agency examine all potential replacement chemicals and determine whether or not to place them on the HAP list
in order to insure that sources do not substitute equally hazardous chemicals for listed HAPs? The Amendments allow for this under 112(b), which states that the Administrator may add a chemical to the list, upon his/her own motion, or upon a showing by a petitioner, if the chemical meets the requirements in section 112(b)(3)(B). The burden on the agency to assess the potentially long list of replacement chemicals (if history provides some insight) could stifle the entire MACT program.

The EPA has at least 3 options to consider in dealing with the substitution issue. Under the first option, the agency could ignore health effects of the replacement chemicals altogether; sources would then be able to avoid regulating HAPs by switching to substitutes, even if those substitutes are hazardous. This is not advisable for several reasons. First, it is simply not health protective to ignore regulating a potential HAP when the agency is clearly given authority to add pollutants to the list of HAPs. Second, in rules developed through the technique called regulatory negotiation¹⁰⁰, certain parties involved in the negotiations might hold up the rule if substitutes were not adequately addressed.

The next option is for the EPA to make a formal determination about whether to list each of the proposed replacement chemicals, thus regulating those that fall under section 112's definition of hazardous air pollutant. This
option, while health protective, might prove to be too burdensome for the agency to realistically pursue. The agency may not have the human or financial resources to commit to such a rigorous examination of substitutions. The agency is struggling to gather and assess data on the existing 189 HAPs for residual risk - whether the EPA could conduct even modest analyses on all potential replacement HAPs, for each standard considering substitutions, and still meet statutory deadlines is not certain. The list of potential substitutes for the Wood Furniture standard alone numbers nearly fifty. Even if the agency attempted to assess the hazard of potential replacements, arguments over methods used to determine hazard could stall standards. Taking this tact could lead the agency back into the same problems with listing chemicals it faced under the former section 112.

The third option is for the agency to develop a list of potential substitutes and publish a notice in the Federal Register stating that specific source categories are using or considering using the following chemicals in their processes. The agency could state that it is concerned about the potential human and environmental health impacts of the chemicals, and ask for information as to the hazard potential of each of the chemicals. This may encourage sources to determine the hazard (or lack thereof) of replacement chemicals before changing their processes, and
supply the EPA with data. Similarly, other individuals may offer the EPA pertinent information regarding the hazard or safety of a chemical. At the same time the EPA could embark on a limited and concentrated evaluation of the replacement chemicals of most concern from either a toxicity or exposure standpoint. The agency could then attempt to list, as a HAP, any chemical that met the listing criteria under section 112(b).

The agency has just begun to address this latest test of the 1990 program. Its challenges are to write regulations that incorporate progressive, pollution prevention practices, while at the same time preventing a greater hazard from the use of a non-listed chemical and, to discourage industry's use of non-HAPs to avoid regulation.

5.3.1.2 Determining Whether to Regulate Area Sources

Another issue where risk comes up in the MACT standard development is in identifying area sources to regulate. Here, the agency may identify area sources in addition to major sources during MACT standard development, or it may identify an entire source category that contains only area sources. In either case, the agency must make a determination that the sources present a threat to human health or to the environment (section 112(c)(3)). The agency will attempt to determine whether or not a threat exists by using a risk assessment approach. If the EPA determines
that, in its opinion, a risk exists, then the agency will attempt to list, then regulate the sources. This may prove difficult as the agency passes regulations through the OMB, and considers carefully the OMB's opinions. Past listing attempts have proved difficult: after negotiations with OMB ended up with seven area source categories, but attempted to list more. Based on this experience, and the fact that since the EPA last held discussions of this type with the OMB the Administration has changed, it is difficult to predict how the agency will fare in trying to list and regulate area sources in the future.
CHAPTER 6: PROGRESS TOWARD DEVELOPING STANDARDS

Congress changed the federal air toxics program, in order to allow the EPA to more easily implement the statute and achieve reductions on HAP emissions. As chapter 5 discussed, the changes in section 112 have so far prevented some of the old implementation issues from arising, and have created some new issues for the agency to address. Where have these changes gotten the new program nearly three years into its implementation? What progress has the agency made in terms of rulemaking and meeting deadlines under the new Amendments? What is the agency doing to meet the deadlines?

6.1 Missed Deadlines

The schedule for promulgating MACT standards requires EPA to have promulgated standards for not less than 40 source categories by November 15, 1992. The EPA missed this first deadline, and proposed its first MACT standard, the HON, on December 31 of that year. The agency will promulgate the HON by February 1994 (see Appendix F).

Not only did the EPA miss its first statutory deadline, environmental groups contend that the agency misinterpreted the meaning of the first deadline, to promulgate 40 standards by November 15, 1992. The EPA, in interpreting
the schedule for standards, attempted to promulgate only the HON by the regulatory deadline and count it as 40 source categories. The reason for this is that the source category to be regulated by this rule consists of different facilities producing and emitting many chemicals within the Synthetic Organic Chemical Manufacturers Industry. In the initial list of source categories that EPA was charged with creating under section 112(c)(1)\textsuperscript{101} the EPA had the HON source category separated into 400 categories, based on differences in chemicals emitted and production processes. During negotiations with the OMB over the content of the final source category list, the agency agreed to shorten the source category list by combining the 400 chemical producing source categories into one, very large category\textsuperscript{102}. According to the EPA, the HON regulation, since it covered so many different types of chemicals, could feasibly be interpreted to account for at least 40 source categories. If the EPA could count this regulation as 40, when it promulgated the HON, it could say that it met the first regulatory hurdle. At the time the HON was proposed, the agency felt that it had Congressional backing to state that in promulgating the HON, they would meet the statutory deadline\textsuperscript{103}. However, the Natural Resource Defense Council (NRDC) and the Sierra Club presented the EPA with a pre-litigation motion claiming that the HON could only represent 8 source categories, and that, even after the HON is
promulgated, the agency would still have missed the first regulatory deadline by 32 source categories. Thinking that the agency would at least partially miss the 1994 deadline (to promulgate 25% of the standards by November 15, 1994), the environmental groups requested in the pre-litigation notice that the EPA and themselves come to an agreement regarding a schedule for some of the MACT standards. Appendix F presents the regulatory schedule agreed to by the EPA and the potential litigants.

6.2 The "Futures Concept"

While the EPA has missed the initial MACT deadline, the agency appears to be taking the challenge of promulgating the numerous MACT standards seriously. The Emission Standards Division, responsible for producing the standards themselves has instituted a plan to promulgate the standards within a reasonable time-frame. This plan, referred to as the "Futures Concept" prioritizes the standards based on the effort needed to produce a MACT standard\textsuperscript{104}. The plan was born out of the realization that the agency is mandated to produce 174 standards in ten years on a shrinking budget\textsuperscript{105}. The goal of this plan is to meet what the EPA interprets as the primary intent of the new standard setting program: to achieve maximum levels of emissions reductions across the nation by placing initial, technology-based controls on many sources, within the mandated time-frame.
There are three parts to the "Futures Concept". First, each listed source category is to be placed into one of three categories, A, B, or C. The amount of time and resources allotted to the development of a standard is dependent on which category it was assigned, with source categories in the A category being allotted more resources than those in the B category, and the B categories more than the C's. Source categories that fall into the A category tend to have high emissions, large numbers of facilities across the nation and are predicted to be the more complicated standard. These source categories also have some political interest. A source category would be placed into the B category if it has medium levels of emissions, a large number of facilities, and/or HAPs, and peaks little political interest. A source category is labeled C if there are low emissions, few sources in the nation and no political interest.

The second step in the new approach to standard setting requires the EPA to set the scope of the project up front; to address technical, economic, and any health issues at the beginning of the standard setting process to identify potential issues that may arise during standard development. Not all issues can be foreseen, but the agency's intent here is to determine as many potential issues as possible up front.
The third step is to obtain agency approval on the scope of the project. The intent here is to get the decision-makers' attention early on in the project, and get their "buy-off" on the scope and direction of a project. This is intended to prevent surprises later that often lead to re-analysis and consequently delays in the standard setting process. Also in this step, the agency intends to obtain outside participation early on in the process. Involvement by the regulated community, State and local air pollution control agencies, and environmental groups is essential in producing a standard that is both implementable and that will truly achieve real reductions in the emissions of hazardous air pollutants. Whether this new plan will aid the agency in actually meeting the deadlines remains to be seen as implementation progresses.
CHAPTER 7: DISCUSSION AND CONCLUSIONS

7.0 Discussion

As this paper has discussed, several factors impeded the EPA's ability to promulgate regulations under the 1970 air toxics program. These included:

- Listing chemicals as Hazardous Air Pollutants
- Setting health-based standards with an ample margin of safety
- Deadlines that carried no incentive

A common thread through these issues was the regulatory process itself: delays occurred where the agency tried to satisfy the SAB or industry (section 3.2), and litigation often resulted when the agency did make decisions (section 3.3.1). Another commonality was that the agency struggled to apply risk assessment in listing and setting standards and was met with opposition.

Congress recognized these weaknesses of the 1970 program, and made some changes in the 1990 Amendments. First, since the agency had trouble listing HAPs, Congress removed that provision almost entirely. Congress handed the EPA a list of 189 HAPs with which to regulate (and provided provisions to added and delete chemicals from the list).
Only under circumstances where the EPA wishes to regulate non-listed chemicals from a source category, must the agency list a chemical as a HAP.

The second problem, that of regulating on an ample margin of safety to protect the public health, was put off in to the future by the creation of the two-phased approach to regulating air toxics. The first set of standards would not be set on health but on the basis of existing methodologies to emissions reduction. The second phase of the program would address risks remaining after application of the first standards, and set further standards only if health risks still exist.

The issue of deadlines was addressed in two ways. First, they were lengthened. The first set of standards were due two years after the Amendments were signed into law, and subsequent sets of standards are due 4, 7, and 10 years later. Second, a new provision pertaining to deadlines, was added, perhaps to encourage states, industry and the EPA to work together in setting standards under the new timetable. This "hammer" provision requires industry and the states to regulate sources themselves if the federal EPA misses the statutory deadline.

Some problems remained after the passage of the 1990 Amendments. Congress did not, in fact could not, change other problems that may still hamper the EPA in getting standards out under the current legislative framework.
Specifically, Congress could do little to change the regulatory development process by which standards are set. As discussed in section (5.2.1), there are and should be several players in a regulatory development process: the Congress, the regulatory agency (EPA, states, EPA Regions, Local agencies), the regulated community (Industry), experts (SAB, other scientists inside and outside the agency), the public (Environmental groups), the Administration (OMB). Each of these players may have different objectives, and different motivations for their actions. Where the objectives differ, issues arise that may need to be resolved; this takes time and may delay standards (e.g., the EPA's current experience in the wood furniture MACT standard regulatory negotiation - if not satisfied, either the environmental groups or industry might pull out of the negotiations, thus bring the development of the standard to a halt). Where the EPA goes ahead and sets standards, they may be sued (there is no current example, but the EPA has been sued for "arbitrary and capricious standards in the past, see section 3.3.1).

As discussed in Chapter 5, Congress did enjoy some success in revising specific aspects of the air toxics program. In general, the agency does not have to list chemicals before regulating them. Also, in the first phase of the program, the MACT standard is a less controversial target than ample margin of safety. The EPA is however,
still behind in its responsibilities to promulgate regulation under the new program. Are the remaining impediments to successful regulation intractable, or could Congress, if it revised the current air toxics program, improve the process further?

Of the remaining impediments to air toxics regulation, under any legislative scenario, including and beyond the 1990 program, the one intractable element is the regulatory process. Short of absolutely dictating that the regulatory agency has the right to regulate unchallenged from any party, however, Congress cannot create legislation that will avoid the risk of being tested either within the regulatory development process itself, or in the courts. Such a dictatorial process would be inappropriate in a democracy such as the United States. Congress can give "incentives" to encourage the parties to work together (e.g. the 112(j) "hammer" which requires industry and the states to regulate sources when the EPA misses a deadline). It can also specify some section of legislation that cannot be subject to litigation (e.g. the 112(e) schedule for standards). These small actions can help the EPA meet its mandates, but the over-arching issues of politics and the differing agendas of those involved in the regulatory development process, are permanent.

The issue of controversies over risk assessment become intractable to the extent that Congress chooses this
particular process to play a part in specific environmental policies. If Congress wishes to legislate control of air toxics by means of risk assessment (in whole or in part), then the problem of controversies over risk assessment methodologies becomes an issue within that specific framework. Conflicts over assumptions, extrapolation, and data, for example, cannot be solved through legislation - these are scientific issues.

Congress can, however, establish mandates with regards to risk management. For example, legislation can require that standards be set at the level which is most cost effective for the amount of risk reduced, or it can require that standards be set at some specific numeric risk level. The 1990 CAAA in fact do address risk management issues in a limited fashion, first by establishing a one in a million risk level to be achieved for carcinogens (plus other more vague requirements) before a source category is exempt from a MACT standard, and second, by stating that residual risk standards for carcinogens must be set according to the Benzene NESHAP that resulted from the vinyl chloride decision (section 3.3.2). This, of course, is not without potential pitfalls, as the risk assessments from which these decisions are made, will be scrutinized.

Congress, in an attempt to further improve legislation regarding air toxics, could step away from the traditional command-and-control type environmental policy and legislate
in a different fashion, for instance an incentive approach (e.g. market-based, tax-based incentive approaches). Any change, however must address three issues. The first issue is that new legislation must avoid resurrecting a problem already resolved. For example, the problem of listing chemicals as HAPs was solved (for the purposes of setting standards), by removing that provision. This component of any new air toxics program might be improved but it must not be reintroduced as a impediment to regulation. Second, any new legislation must clearly identify what issues can be changed and what cannot. For example, the issue of risk assessment may be malleable; there may be a way to bring out the advantages of that type of analysis without becoming paralyzed by the process itself. Opportunities to make positive changes must nor be overlooked. The third issue any legislative revision must identify and address is that which is not repairable by legislation. Here, the example is the regulatory process - this process's strengths and weaknesses are present in the development of all regulations. In designing a future air toxics program Congress must be certain not to merely trade one problem, or a set of problems, for another by changing the components of the legislation or changing the policies on which the legislation is based. This is key.

The above discussion takes a broad view of the air toxics program and considers improvements to the current
legislation. The current situation for the EPA is that they are required to meet the mandate of promulgating rules under the framework provided in the 1990 amendments. How can the agency accomplish this?

7.1 What Can EPA do to Maximize Chances for Successful Implementation?

From the empirical evidence presented in chapter 5, it is clear that the new federal air toxics program solves some old problems, and creates some new challenges to the EPA as to how to successfully implement the 1990 program. Given that the agency missed the initial deadline, but is making some progress in proposing rules under the MACT program, an important question to ask is, what can the agency do to better meet future deadlines and to promulgate responsible and health-protective rules within a reasonable time-frame?

One approach the agency can take is to steer a narrow course through the first phase of the program, the MACT program. The EPA may choose to focus on promulgating the maximum number of standards possible under the limited time-frame and not concentrate as much on using all the power in section 112(d) to achieve as much emission reduction as possible in the short-term. Under this scenario, the agency may choose to set most standards at the MACT floor, and not attempt to make arguments to set more stringent standards except in extreme cases where, for example a portion of a source category is not controlled at all, or where going
above the floor actually saves money. Also under this scenario, the agency may choose to eliminate any issues regarding risk that may be pertinent (e.g., area sources, substitutions) from most standards. It is unclear at this time the success the EPA will have at steering an extremely narrow course through the MACT standards, but since going beyond the very core of the MACT requirements is a discretionary action and not mandated by the Act, the agency may be able to push through an agenda that focuses on the core requirements. Steering a narrow course through the MACT standard setting process could result in greater air toxics emissions nationwide, more reductions than if the agency concentrated all its resources on a few comprehensive standards.

Another approach the EPA could take, and from the evidence so far in the rulemaking the tactic it seems to be taking is to address issues like area sources and substitutions, but in a manner that does not lose sight of the strict deadlines imposed by the statute. For example, the EPA has established a policy to determine whether to regulate area sources (where they exist) for each standard. The agency developed a protocol to accomplish this called Regulatory Options for Area Sources. The agency follows this protocol and determines whether to make the case for regulating area sources during the development of each MACT standard. Such a determination is to be documented in the
docket, and discussed in the preamble to MACT rules (ESD position as of Aug. 1993 - magnetic tape standard). While this protocol is followed in MACT standard development, the agency interpretation of what constitutes a need to regulate area sources remains a high hurdle. So, while the EPA may address a potentially controversial issue, it still may do so with a narrow interpretation of the requirements under section 112(d).

Whether the agency sets MACT standards in either of the ways mentioned above, it still must accomplish some specific tasks in order to have a chance at achieving success in the residual risk portion of the air toxics program. First and foremost, the agency must prepare for the residual risk part of the program now. One of the problems in the 1970 program was that the agency had no chance to develop a vision of how to carry out the toxics program. As chapter three discusses, the toxics provision was finalized near the end of the development of the 1970 Amendments, and carried with it such short deadlines that the brand new agency had no time to prepare a sound plan on how to implement the program. The luxury of the new program is that by the time the residual risk program is required to go into effect, the EPA will have had eight years to develop an implementation plan. Whether the agency realistically has the resources, or chooses to use its resources to fully prepare for the
residual risk program is another question, that can be answered in five years.

The agency has made some progress in preparing for residual risk. What the agency has done to date to prepare for residual risk is that it is identifying chemicals for which more data is needed to be able to determine the risks. Further, the agency is prioritizing these chemicals and spending time and resources on toxicological studies to gain needed data through the test rules program\(^{197}\). The air program is also benefitting from risk assessment research that the agency and outside parties are conducting for the larger purpose of risk assessment methods development. Such efforts include risk assessment for non-cancer endpoints, and the revision of the EPA cancer guidelines which have the goal of more accurately identifying the true risks to the public from environmental toxins.

So, the agency is making at least some efforts to provide itself with the toxicological data and methods it will need to assess residual risk. What the agency needs to concentrate on now, in addition to the science, is the policy development aspect of the residual risk program. Given that the main reason for the delay in rule promulgation in the former air toxics program was largely due to lack of data and standard methodologies (see chapter 3), and given that eight years is not enough time to solve both of those problems, the agency needs to develop a
thoughtful plan to implement the residual risk program in the face of uncertainty. To accomplish this, the agency may want to consider the following path. The agency could develop the residual risk plan in a truly public forum, and sell the plan to those who have an interest and play a role in the regulatory process. This would prepare the environmental groups, states, industry, and the OMB for how the agency plans to implement the program. If the EPA can satisfy all the players with the plan, then it might have an easier time in implementing the standards when the time comes to do so.

This idea of selling the new program is based in the hindsight of Bob Kellam, Acting Director of the Technical Support Division in the Office of Air Quality Planning and Standards, who directly experienced the difficulties in implementing the air toxics program under the former section 112. His point of view is that the EPA's attempt to implement the Amendments was unsuccessful partially due to the Agency's lack of salesmanship to the players involved with the process. Those players (industry, environmental groups) sued the Agency over various attempts to implement specific provisions, thus throwing rules into the courts for resolution. Kellam's point is that by not including these other groups in the policy planning, the agency ultimately lost in its attempts to reduce air toxic emissions.
The statute already requires the agency to present Congress with a report on how they plan to assess residual risk (due November 15, 1996), and requires the EPA to consult with the Surgeon General, and include an opportunity for public comment before submitting recommendations to Congress (section 112(f)). However, Congress gets no more specific about the review process than that. The agency should consider developing the residual risk guidance by consulting a range of expertise and interests. In this way, the agency can increase its chances that the residual risk guidance will be based in solid science, include progressive policies and methodologies, and be as implementable as possible. If the agency is successful in this endeavor, then it can implement residual risk in a way that will truly protect the public health.

7.2 Recommendations for Future Research

This paper has examined the EPA's attempts, to date, to develop regulations under section 112 of the 1990 Clean Air Act Amendments. It has focused exclusively on implementation, that is, it has focused on assessing how the agency is carrying out the Congressional mandate of section 112, as opposed to dissecting and analyzing that mandate. This paper is but a first step in analyzing the U.S. air toxics program.
Opportunities for further research abound. There is a need for researchers to further develop many of the ideas presented here. For instance, the proper role of risk assessment both in the MACT program, and in the residual risk program might be explored in depth. Further, the role of litigation and politics in current EPA policies in the air toxics program and beyond is worthy of examination. In addition and importantly, a researcher may want to broaden the view here and discuss if this type of command-and-control policy is an appropriate way to legislate the control of toxic air pollutants, and examining other, alternative to the MACT - residual risk program. A question to ask here is, given the fact that Congress's first attempt to mandate a command and control approach to regulating air toxics failed, why did it continue in that direction in passing Title III? Did Congress consider other options? Are there any other workable options?

Finally, the issue of the need for resources to be spent on controlling air toxics might be explored. Where does the problem of air toxics rank among risks that face society today? Is the 1990 Clean Air Act sufficient to address the problem? Is it overkill? These and other research opportunities arise as the dynamic process of implementing the national air toxics program continues.
REFERENCES

1. While the consideration of both human health and environmental health effects are important, this paper will focus solely on human health.


3. The terms "hazardous air pollutants" and "air toxics" will be used throughout this paper synonymously. See section 2.3 for the legislative definition of hazardous air pollutant.


7. 1990 CAAA, §112(d).

8. 1990 CAAA, §112(f).

9. 1990 CAAA, §112(c).

10. The 1990 CAAA clearly state that emission reductions may be achieved by measures other than traditional control technologies (pollution prevention measures, for example). The terms "technology based standards" and "MACT" have come to represent the greater range of options, and will be used throughout this paper to refer to any valid means of achieving emission reductions.

11. 1970 CAAA.


23. Vogel, p.327; Ingram p. 33.


26. This provision was part of the Stationary Sources Emission Standards section (S. 3466 and H.R. 15848 §112) which would later be changed to address pollutants which "may contribute significantly to air pollution which causes or contributes to the endangerment of public health or welfare". This provision under the 1970 Amendments is referred to as New Source Performance Standards (NSPS) (CAA 1970, §111 (b)(1)(A)).


31. §112(a)(1); Conference Report No. 90-1783, Dec 17, 1990 to Accompany H.R. 17255.

32. §112(b)(1)(B); Conference Report No. 90-1783, Dec 17, 1990 to Accompany H.R. 17255.

33. §112(c)(1)(A); Conference Report No. 90-1783, Dec 17, 1990 to Accompany H.R. 17255.


37. Graham, p. 106.

38. Also, in debates over §112, Muskie was the only legislator to acknowledge that the ample margin of safety standard could close factories (see note 41, Dwyer, p.241.) His intent here is unclear, however, as he did not push his point.


42. Dwyer, p. 233.

43. Dwyer, p. 245.

44. See also discussions in Ingram, Vogel, and Jones.

45. Dwyer, p. 248; Graham, p. 100.

46. Graham, p.100; Dwyer, p.247.

47. A question to ask in 1993 is whether these are the ideal goals, or more of a naive notion? Should we perhaps acknowledge that it's impossible in this society to regulate on just one issue; that we might we need to address the difficult issue of balancing economic and social costs with benefits of regulations? Apparently Congress thought so and in 1990 determined that "at any price" was
a price too high by passing amendments reflecting a change to a more cost-benefit philosophy (see chapter 4).

48. Dwyer, p. 249.

49. In the mid-1980's, the EPA decided to assist the states in starting their own air toxics programs. The agency had not been able to promulgate the number of rules it deemed necessary to appropriately reduce the emissions of harmful chemicals, and tried a new tactic: helping the states help themselves (see U.S. EPA, Office of Air Quality Planning and Standards, 1985. A Strategy to Reduce Risks to Public Health from Air Toxics.)


52. Health Assessment Documents are comprehensive evaluations of the known health data, including carcinogenicity, mutagenicity, developmental and reproductive effects, pharmacokinetics, and metabolism, from exposure to particular chemicals. HADs are developed for the Office of Air Quality Planning and Standards, and under the 1970 program often served as technical documentation for regulatory decisions.


54. GAO p. 17 report; While the GAO report makes this claim, it does not document instances where industry opposition forced this reaction in the agency. The Federal Register notice announcing the promulgation of asbestos, beryllium and mercury does state that the agency received comments on the rule from industry, universities, governments, and environmental groups, yet no comments were addressed in the notice.

54. GAO report, p. 17.

55. Under the 1970 Amendments, the EPA's legal burden was to list chemicals that "may cause or contribute to" various health effects (1970 CAAA §112(a)(1); see also section 2.3). The law was amended in 1977 and the definition of a HAP was amended to include the term "may reasonably anticipated to cause" various health effects (42 U.S.C. §7412(a)(2) (1982). Thus it seems that the EPA's burden was not to prove unequivocally that a chemical caused an effect. Despite this language, the EPA found it difficult to list chemicals as HAPs.

57. Graham, p. 119.


60. Non-threshold pollutants are those chemicals the agency believed to have no safe exposure level associated with them, for example, many carcinogens.


62. One of these challenges resulted from the initial vinyl chloride standard. See Environmental Defense Fund v. Train No 76-2045, 7 ELR 20,547 D.C Cir., filed November 19, 1976, settled and dismissed June 24, 1977.

63. No risk numbers were available, as risk assessment was not yet formally developed and used by the agency.


79. The term "few" was left undefined by the agency.

80. NESHAP for Benzene, Final. 54 Federal Register 177, 1989.


84. From 1970 to 1990, the EPA set standards for only seven chemicals: asbestos, beryllium, mercury, cadmium, arsenic, radionuclides, and benzene.

85. GAO Report pgs. 18-21.


88. For source categories containing less than 30 sources, standards will be based on the emission limitation achieved by the best performing five sources (§112(d)(3)(B)).

89. See exceptions in 1990 CAAA, §112(d)(4)), §112(d)(3).

90. The HON is directed at those facilities that manufacture synthetic organic chemicals. The source category is called the Synthetic Organic Chemical Manufacturers Industry (SOCMI).

91. This "simple" way of identifying chemicals to regulate is, of course, imperfect and may lead to either over or under-regulation. Sections 112(b)(2), 112(b)(3), do however, allow for additions and deletions from the list, either upon the administrator's motion, or by outside petition.

92. In the context of Title III, a substitute is a chemical that replaces one of the 189 listed HAPs, either in use, or as an emitted pollutant.
93. In order for a standard to be promulgated, the agency follows a precise protocol, which includes presenting the regulatory package to OMB for economic analysis. While this protocol is only required by executive order for "major" regulations (see Executive Order 12291, Weekly Compilation of Presidential Documents, vol.17, (February 23, 1981), pp.124-30.), and is not required for non-major regulation, the EPA customarily presents each package (major and non-major) to the OMB for review and approval. Even though the EPA presents regulatory packages to the OMB, the EPA Administrator is not bound to obtain the OMB's approval before s/he signs, and therefore finalizes, a regulation. The EPA however, traditionally negotiates with the OMB and gains their approval, before the EPA Administrator signs a rule.


95. This section allows any person to petition the Agency to delete a source category, and, allows the Administrator her/himself to delete a source category, if no source in the category emits HAPs in amounts which may 1) result in an excess lifetime cancer risk of one in one million 2) exceed ample margin of safety to protect the public health (for HAPs that are non-carcinogens) or 3) result in adverse environmental effects.

96. Briefing notes on file with the author.

97. Language on file with the author.


99. Although the HON is a proposal at this time, EPA is proceeding as if the promulgated rule includes this requirement by incorporating an analysis of the benefits versus the costs of setting a standard more stringent than the floor.

100. The term regulatory negotiation refers to a method of rule development where the EPA meets regularly with the affected industry, states, and environmental groups. This larger group creates the rule by consensus.


105. The OAQPS received a 40% budget cut in 1993.


APPENDIX A  CONGRESSIONAL RATIONALE FOR REVISING THE U.S. AIR TOXICS PROGRAM
1. Routine and episodic releases of hundreds of non-criteria air pollutants pose a significant health threat to public health in the United States.

2. The risk of adverse health effects, principally excess cancers, from exposure to toxic air pollutants is not distributed evenly across the population. Americans living in the vicinity of concentrated industrial activity, or in highly polluted urban areas may face relatively high risks.

3. Air toxics may also be causing severe environmental damage though deposition and run-off, bioaccumulation in the food chain, or disruption of climatic or atmospheric processes.

4. The Environmental Protection Agency has not made sufficient use of the existing authorities available under section 112 of the Clean Air Act to protect public health.

5. To some extent, the statutory language itself may be responsible for the slow pace of the Nation's air toxics program as it requires emissions standards which provide an ample margin of safety to protect health even for carcinogenic air pollutants for which no level of exposure may be considered safe. If interpreted to required standards prohibiting emissions, regulations under section 112 could be very costly for some source categories or pollutants.

6. The regulatory time frames included in the existing law requiring the proposal of emission standards within 180 days of listing a pollutant as hazardous and promulgating a standard 180 days later are unrealistic.
7. A recent court opinion (NRDC v. EPA 824 F2nd 1146), invalidated basic premises used by the Agency in the standard setting-setting process for hazardous air pollutants. Although listing and regulatory decisions had been scheduled for several other pollutants in the near-term, this decision is likely to cause additional significant delay as the Agency reassesses its basic policies.

8. Some measures proposed by the Agency in its 1985 air toxics strategy offer promise for addressing non-traditional sources of air toxics emissions. However, these proposals are not currently recognized within the structure of section 112 and have no other statutory authorization.

## APPENDIX B

### SECTION 112(b) LIST OF HAZARDOUS AIR POLLUTANTS

<table>
<thead>
<tr>
<th>CAS NUMBER</th>
<th>POLLUTANT NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>75070</td>
<td>Acetaldehyde</td>
</tr>
<tr>
<td>60355</td>
<td>Acetamide</td>
</tr>
<tr>
<td>75058</td>
<td>Acetonitrile</td>
</tr>
<tr>
<td>98862</td>
<td>Acetophenone</td>
</tr>
<tr>
<td>53963</td>
<td>2-Acetylaminofluorene</td>
</tr>
<tr>
<td>107028</td>
<td>Acrolein</td>
</tr>
<tr>
<td>79061</td>
<td>Acrylamide</td>
</tr>
<tr>
<td>79107</td>
<td>Acrylic acid</td>
</tr>
<tr>
<td>107131</td>
<td>Acrylonitrile</td>
</tr>
<tr>
<td>107051</td>
<td>Allyl chloride</td>
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<tr>
<td>92671</td>
<td>4-Aminobiphenyl</td>
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<tr>
<td>62533</td>
<td>Aniline</td>
</tr>
<tr>
<td>90040</td>
<td>O-Anisidine</td>
</tr>
<tr>
<td>1332214</td>
<td>Asbestos</td>
</tr>
<tr>
<td>71432</td>
<td>Benzene (including benzene from gasoline)</td>
</tr>
<tr>
<td>92875</td>
<td>Benzidine</td>
</tr>
<tr>
<td>98077</td>
<td>Benzotrichloride</td>
</tr>
<tr>
<td>100447</td>
<td>Benzyl chloride</td>
</tr>
<tr>
<td>92524</td>
<td>Biphenyl</td>
</tr>
<tr>
<td>117817</td>
<td>Bis (2-ethylhexyl)phthalate (DEHP)</td>
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<tr>
<td>542881</td>
<td>Bis(chloromethyl)ether</td>
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<td>Bromoform</td>
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<td>156627</td>
<td>Calcium cyanamide</td>
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<td>Caprolactam</td>
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<td>133062</td>
<td>Captan</td>
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<td>63252</td>
<td>Carbaryl</td>
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<td>Carbon disulfide</td>
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<td>Carbon tetrachloride</td>
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<td>463581</td>
<td>Carbonyl sulfide</td>
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<td>120809</td>
<td>Catecol</td>
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<tr>
<td>133904</td>
<td>Chloramben</td>
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<tr>
<td>57749</td>
<td>Chlordane</td>
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<tr>
<td>7782505</td>
<td>Chlorine</td>
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<tr>
<td>79118</td>
<td>Chloroacetic acid</td>
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<td>2-Chloroacetophenone</td>
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<td>Chlorobenzene</td>
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<td>510156</td>
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<td>107302</td>
<td>Chloromethyl methyl ether</td>
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<td>126998</td>
<td>Chloroprene</td>
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<td>1319773</td>
<td>Cresols/Cresylic acid (isomers and mixture)</td>
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<td>95487</td>
<td>o-Cresol</td>
</tr>
<tr>
<td>108394</td>
<td>m-Cresol</td>
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<tr>
<td>106445</td>
<td>p-Cresol</td>
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<tr>
<td>98828</td>
<td>Cumene</td>
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<tr>
<td>94757</td>
<td>2,4-D (including salts and esters)</td>
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<tr>
<td>72559</td>
<td>DDE</td>
</tr>
<tr>
<td>334883</td>
<td>Diazomethane</td>
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<tr>
<td>132649</td>
<td>Dibenzofuran</td>
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<td>96128</td>
<td>1,2-Dibromo-3-chloropropane</td>
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<tr>
<td>84742</td>
<td>Dibutylphthalate</td>
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<tr>
<td>106467</td>
<td>1,4-Dichlorobenzene (p)</td>
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</tbody>
</table>
3,3'-Dichlorobenzidine
111444  Dichloroethyl ether (Bis(2-chloroethyl)ether)
542756  1,3-Dichloropropene
62737   Dichlorvos
111422  Diethanolamine
121697  N,N-Dimethylaniline
64675   Diethyl sulfate
119904  3,3'-Dimethoxybenzidine
60117   Dimethyl aminoazobenzene
119937  3,3'-Dimethylbenzidine
79447   Dimethylcarbamoyl chloride
68122   Dimethyl formamide
57147   1,1-Dimethylhydrazine
131113  Dimethyl phthalate
77781   Dimethyl sulfate
534521  4,6-Dinitro-o-cresol (including salts)
51285   2,4-Dinitrophenol
121142  2,4-Dinitrotoluene
123911  1,4-Dioxane (1,4-Diethyleneoxide)
122667  1,2-Diphenylhydrazine
106898  Epichlorohydrin (1-Chloro-2,3-epoxypropane)
106887  1,2-Epoxybutane
140885  Ethyl acrylate
100414  Ethylbenzene
51796   Ethyl carbamate (Urethane)
75003   Ethyl chloride (Chloroethane)
106934  Ethylene dibromide (Dibromoethane)
107062  Ethylene dichloride (1,2-Dichloroethane)
107211  Ethylene glycol
151564  Ethylenimine (Aziridine)
75218   Ethylene oxide
96457   Ethylene thiourea
75343   Ethyldene dichloride (1,1-Dichloroethane)
50000   Formaldehyde
76448   Heptachlor
118741  Hexachlorobenzene
87683   Hexachlorobutadiene
77474   Hexachlorocyclopentadiene
67721   Hexachloroethane
820250  Hexamethylene-1,6-diisocyanate
680319  Hexamethyleneposphoramidate
110543  Hexane
302012  Hydrazine
7647010  Hydrochloric acid (hydrogen chloride (gas only))
7664393  Hydrogen fluoride (Hydrofluoric acid)
123319  Hydroquinone
78591   Isophorone
58899   Lindane
10831   Maleic anhydride
67561   Methanol
72435   Methoxychlor
74839   Methyl bromide (Bromomethane)
74873   Methyl chloride (Chloromethane)
71556   Methyl chloroform (1,1,1-Trichloroethane)
78933   Methyl ethyl ketone (2-Butanone)
60344   Methyl hydrazine
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<td>Methyl methacrylate</td>
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<td>Methyl tert-butyl ether</td>
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<td>Methylene chloride (Dichloromethane)</td>
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<td>Polychlorinated biphenyls (Aroclors)</td>
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<td>1,3-Propane sultone</td>
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<td>96093</td>
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<td>1746016</td>
<td>2,3,7,8-Tetrachlorodibenzo-p-dioxin</td>
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<td>1,1,2,2-Tetrachloroethane</td>
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<td>Titanium tetrachloride</td>
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<td>95954</td>
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<tr>
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<td>2,4,6-Trichlorophenol</td>
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<tr>
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<td>Triethylamine</td>
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<tr>
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<td>Trifluralin</td>
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<tr>
<td>540841</td>
<td>2,2,4-Trimethylpentane</td>
</tr>
<tr>
<td>108054</td>
<td>Vinyl acetate</td>
</tr>
</tbody>
</table>
593602  Vinyl bromide
75014  Vinyl chloride
75354  Vinylidene chloride (Dichloroethylene)
1330207  Xylenes (isomers & mixture)
  95476  o-Xylene
  108383  m-Xylene
  106423  p-Xylene

0  Antimony Compounds
0  Arsenic Compounds (inorganic including arsine)
0  Beryllium Compounds
0  Cadmium Compounds
0  Chromium Compounds
0  Cobalt Compounds
0  Coke Oven Emissions
0  Cyanide Compounds
0  Glycol Ethers
0  Lead Compounds
0  Manganese Compounds
0  Mercury Compounds
0  Fine Mineral Fibers
0  Nickel Compounds
0  Polycyclic Organic Matter
0  Radionuclides (including radon)
0  Selenium Compounds
0  Glycol ethers
APPENDIX C

CATEGORIES OF SOURCES OF HAZARDOUS AIR POLLUTANTS AND REGULATION PROMULGATION SCHEDULE BY REGULATORY DEADLINES
APPENDIX C

CATEGORIES OF SOURCES OF HAZARDOUS AIR POLLUTANTS AND REGULATION PROMULGATION SCHEDULE BY REGULATORY DEADLINES

Source Categories with Emission Standards Due by November 15, 1992

SYNTHETIC ORGANIC CHEMICAL MANUFACTURING
COMMERCIAL DRYCLEANING (PERCHLOROETHYLENE) - DRY-TO-DRY MACHINES *
COMMERCIAL DRYCLEANING (PERCHLOROETHYLENE) - TRANSFER MACHINES *
COMMERCIAL DRYCLEANING (PERCHLOROETHYLENE) - TRANSFER MACHINES
INDUSTRIAL DRYCLEANING (PERCHLOROETHYLENE) - DRY-TO-DRY MACHINES
INDUSTRIAL DRYCLEANING (PERCHLOROETHYLENE) - TRANSFER MACHINES

Source Categories with Emission Standards Due by November 15, 1994

ACRYLONITRILE-BUTADIENE-STYRENE PRODUCTION
AEROSPACE INDUSTRIES
ASBESTOS PROCESSING *
BUTYL RUBBER PRODUCTION
CHROMIC ACID ANODIZING
CHROMIC ACID ANODIZING *
COKE OVENS: CHARGING, TOPSIDE AND DOOR LEAKS (CAA MANDATED PROMULGATION BY DECEMBER 31, 1992)
COMMERCIAL STERILIZATION FACILITIES
COMMERCIAL STERILIZATION FACILITIES *
DECORATIVE CHROMIUM ELECTROPLATING
DECORATIVE CHROMIUM ELECTROPLATING *
EPICHLOROHYDRIN ELASTOMERS PRODUCTION
EPOXY RESINS PRODUCTION
ETHYLENE-PROPYLENE RUBBER PRODUCTION
GASOLINE DISTRIBUTION - STAGE 1
HALOGENATED SOLVENT CLEANERS
HALOGENATED SOLVENT CLEANERS *
HARD CHROMIUM ELECTROPLATING
HARD CHROMIUM ELECTROPLATING *
HYPAHON (TM) PRODUCTION
INDUSTRIAL PROCESS COOLING TOWERS
MAGNETIC TAPES (SURFACE COATING)
METHYL METHACRYLATE-ACRYLONITRILE-BUTADIENE-STYRENE PRODUCTION
METHYL METHACRYLATE-BUTADIENE-STYRENE TERPOLYMERS PRODUCTION
NEOPRENE PRODUCTION
NITRILE BUTADIENE RUBBER PRODUCTION
NON-NYLON POLYAMIDES PRODUCTION
PETROLEUM REFINERIES - OTHER SOURCES NOT DISTINCTLY LISTED
POLYETHYLENE TEREPHTHALATE PRODUCTION
POLYBUTADIENE RUBBER PRODUCTION
POLYSTYRENE PRODUCTION
POLYSULFIDE RUBBER PRODUCTION
PRINTING/PUBLISHING (SURFACE COATING)
SECONDARY LEAD SMELTING
SHIPBUILDING AND SHIP REPAIR (SURFACE COATINGS)

Source Categories with Emission Standards Due by November 15, 1997

4-CHLORO-2-METHYLPHENOXYACETIC ACID PRODUCTION
2,4-D SALTS AND ESTERS PRODUCTION
4,6-DINITRO-O-CRESOL PRODUCTION
ACETAL RESINS PRODUCTION
ACRYLIC FIBERS/MODACRYLIC FIBERS PRODUCTION
AEROSOL CAN-FILLING FACILITIES
AMINO RESINS PRODUCTION
AUTO AND LIGHT DUTY TRUCK (SURFACE COATING)
BUTADIENE DIMERS PRODUCTION
CAPTAFOL PRODUCTION
CAPTAN PRODUCTION
CELOPHANE PRODUCTION
CELLULOSE FOOD CASING MANUFACTURING
CHELATING AGENTS PRODUCTION
CHLORONEB PRODUCTION
CHLOROTHALONIL PRODUCTION
CHLORINE PRODUCTION
CHROMIUM CHEMICALS MANUFACTURING
CHROMIUM REFRACTORIES PRODUCTION
CYANURIC CHLORIDE PRODUCTION
DACTHAL (TM) PRODUCTION
FERROALLOYS PRODUCTION
FLEXIBLE POLYURETHANE FOAM PRODUCTION
HYDRAZINE PRODUCTION
HYDROCHLORIC ACID PRODUCTION
HYDROGEN CYANIDE PRODUCTION
HYDROGEN FLUORIDE PRODUCTION
INTEGRATED IRON & STEEL MANUFACTURING
IRON FOUNDRIES
MINERAL WOOL PRODUCTION
MUNICIPAL LANDFILLS
NON-STAINLESS STEEL MANUFACTURING - ELECTRIC ARC FURNACE (EAF) OPERATION
NYLON 6 PRODUCTION
OIL AND NATURAL GAS PRODUCTION
ORGANIC LIQUIDS DISTRIBUTION (NON-GASOLINE)
PETROLEUM REFINERIES - CATALYTIC CRACKING (FLUID AND OTHER) UNITS,
   CATALYTIC REFORMING UNITS, AND SULFUR PLANT UNITS
PHARMACEUTICALS PRODUCTION
PHENOLIC RESINS PRODUCTION
PHOSPHATE FERTILIZERS PRODUCTION
PHOSPHORIC ACID MANUFACTURING
PLYWOOD/PARTICLE BOARD MANUFACTURING
POLYCARBONATES PRODUCTION
POLYESTER RESINS PRODUCTION
POLYETHER POLYOLS PRODUCTION
PORTLAND CEMENT MANUFACTURING
PRIMARY ALUMINUM PRODUCTION
PRIMARY COPPER SMELTING
PRIMARY LEAD SMELTING
PUBLICLY OWNED TREATMENT WORKS (POTW) EMISSIONS (CAA MANDATED
   PROMULGATION BY NOVEMBER 15, 1995)
PULP & PAPER PRODUCTION
RAYON PRODUCTION
REINFORCED PLASTIC COMPOSITES PRODUCTION
RUBBER CHEMICALS MANUFACTURING
SECONDARY ALUMINUM PRODUCTION
SODIUM CYANIDE PRODUCTION
SODIUM PENTACHLOROPHENATE PRODUCTION
STAINLESS STEEL MANUFACTURING - ELECTRIC ARC FURNACE (EAF) OPERATION
STEEL FOUNDRIES
STEEL PICKLING - HCL PROCESS
TORDON (TM) ACID PRODUCTION
WOOD TREATMENT
Source Categories with Emission Standards Due by November 15, 2000

ALKYD RESINS PRODUCTION
ALUMINA PROCESSING
AMMONIUM SULFATE PRODUCTION - CAPROLACTAM BY-PRODUCT PLANTS
ANTIMONY OXIDES MANUFACTURING
ASPHALT CONCRETE MANUFACTURING
ASPHALT PROCESSING
ASPHALT ROOFING MANUFACTURING
ASPHALT/COAL TAR APPLICATION - METAL PIPES
BAKERS YEAST MANUFACTURING
BENZYLTRIMETHYLAMMONIUM CHLORIDE PRODUCTION
BOAT MANUFACTURING
BUTADIENE-FURFURAL COTRIMER (R-11)
CARBONYL SULFIDE PRODUCTION
CARBOXYMETHYLCELLULOSE PRODUCTION
CELLULOSE ETHERS PRODUCTION
CHLORINATED PARAFFINS PRODUCTION
CLAY PRODUCTS MANUFACTURING
COKE BY-PRODUCT PLANTS
COKE OVENS: PUSHING, QUENCHING AND BATTERY STACKS
DODECANEIOIC ACID PRODUCTION
DRY CLEANING (PETROLEUM SOLVENT)
ENGINE TEST FACILITIES
ETHYLIDENE NORBORNENE PRODUCTION
EXPLOSIVES PRODUCTION
FLAT WOOD PANELING (SURFACE COATING)
FUME SILICA PRODUCTION
HAZARDOUS WASTE INCINERATION
INDUSTRIAL BOILERS
INSTITUTIONAL/COMMERCIAL BOILERS
LARGE APPLIANCE (SURFACE COATING)
LEAD ACID BATTERY MANUFACTURING
LIME MANUFACTURING
MALEIC ANHYDRIDE COPOLYMERS PRODUCTION
MANUFACTURE OF PAINTS, COATINGS & ADHESIVES
METAL CAN (SURFACE COATING)
METAL COIL (SURFACE COATING)
METAL FURNITURE (SURFACE COATING)

METHYLCELLULOSE PRODUCTION
MISCELLANEOUS METAL PARTS & PRODUCTS (SURFACE COATING)
OBA/1,3-DIISOCYANATE PRODUCTION
PAINT STRIPPER USERS
PAPER AND OTHER WEBBS (SURFACE COATING)
PHOTOGRAPHIC CHEMICALS PRODUCTION
PHTHALATE PLASTICIZERS PRODUCTION
PLASTIC PARTS AND PRODUCTS (SURFACE COATING)
POLYMERIZED VINYLIDENE CHLORIDE PRODUCTION
POLYMETHYL METHACRYLATE RESINS PRODUCTION
POLYVINYL ACETATE EMULSIONS PRODUCTION
POLYVINYL ALCOHOL PRODUCTION
POLYVINYL BUTYRAL PRODUCTION
POLYVINYL CHLORIDE AND COPOLYMERS PRODUCTION
PRIMARY MAGNESIUM REFINING
PRINTING, COATING & DYING OF FABRICS
PROCESS HEATERS
QUATERNARY AMMONIUM COMPOUNDS PRODUCTION
ROCKET ENGINE TEST FIRING
SEMICONDUCTOR MANUFACTURING
SEWAGE SLUDGE INCINERATION
SITE REMEDIATION
SPANDEX PRODUCTION
STATIONARY INTERNAL COMBUSTION ENGINES
STATIONARY TURBINES
SYMmetrical TETRACHLOROPYRIDINE PRODUCTION
TACONITE IRON ORE PROCESSING
TIRE PRODUCTION
URANIUM HEXAFLUORIDE PRODUCTION
VEGETABLE OIL PRODUCTION

* Denotes area source category
APPENDIX D SOURCE CATEGORY DELETION LANGUAGE IN THE GENERAL PROVISIONS PREAMBLE
F. Compliance Certification Requirements under Title VII

Section 702(b) of title VII of the Clean Air Act Amendments of 1990 amends section 114(a) of the Act to require the periodic submission of compliance certifications by owners or operators of major stationary sources and, at the discretion of the Administrator, other sources as well. This section of title VII also requires monitoring by a source to certify compliance with relevant emission standards or limitations. The EPA is developing regulations under 40 CFR part 63 that will specify the enhanced monitoring requirements for all existing sources that affect stationary sources of air pollutants. Under new rules, such as those developed under part 63, the EPA will specify the enhanced monitoring requirements in the individual rule. This approach is being adopted because the EPA believes it is not possible at this time to define generic enhanced monitoring requirements for each future part 63 emission standard. Enhanced monitoring requirements developed in the part 63 rules will be directly enforceable under the requirements of section 114(a). As the individual part 63 standards are developed, the enhanced monitoring requirements for the standards will utilize the part 63 general provisions to the maximum extent possible. At some future date, as experience is gained with the enhanced monitoring program, generic requirements for enhanced monitoring may be added to the part 63 general provisions.

G. Deletion of Source Categories from the Source Category List

On July 15, 1992, the EPA published an initial list of categories of major and area sources of HAP, as required under amended section 112(c)(1), that would allow the Agency to promulgate emission standards for each listed category of major sources and area sources. (See 57 FR 31576, July 15, 1992, "Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990"). The July 15, 1992 notice did not constitute completion of the listing requirements under sections 112(c)(3) or 112(c)(6), nor does it contain guidance or procedures for petitioning to delete listed categories of sources as allowed under section 112(c)(9)(B). Moreover, because of uncertainty in the available data bases concerning sources and emissions of HAP, all categories of major and area sources meeting the listing criteria in section 112(c)(1) may not be included in the list in order to direct the sections 112(d) and 112(f) regulatory efforts for sources affecting human health. Implementing section 112(c)(9)(B) would assure that the EPA’s resources— as well as society’s—are directed toward those source categories exceeding the risk criteria identified by Congress in that subsection.

The EPA is currently developing guidance to establish the procedures for source owners or operators, or other members of the public, in the petitions to delete listed categories of sources as allowed under section 112(c)(9)(B). The Agency intends to publish the "delisting" guidance in the Federal Register as expeditiously as possible. Toward that end, the Agency intends to consider recommendations about improving current risk assessment methodologies that will be developed pursuant to various studies required by Congress in the CAA. Because of uncertainties in the risk assessment process as it has been used to regulate HAP emissions under section 112 in the past, the EPA and the National Academy of Sciences (NAS) are each charged with studying the EPA’s risk assessment methodology and making recommendations to Congress about revisiting such methodology. The following paragraphs provide a short history of how risk assessment has been used under section 112 in the past and describe some of the CAA’s new requirements for evaluating existing risk assessment methodologies.

Prior to being amended in 1990, section 112 of the CAA required the EPA to regulate HAP individually on a health basis. Before establishing emission standards, the EPA listed individual air pollutants as hazardous and codified the list in 40 CFR part 61. The basis for the listing was the potential of each pollutant to "cause or contribute to air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness." After listing HAP, the EPA established emission standards to regulate the emissions of the listed HAP. The standard of protection required under former section 112 was to protect the public health with an "ample margin of safety." This involved a two-step process. First, a "safe" level had to be determined (without considering the economic costs); then, in a second step, considering cost, the standard was set at a level providing an "ample margin of safety." The process of setting emission standards under section 112 often involved conducting a detailed risk assessment to determine that the emission standard met the
statutory requirement to protect the public health with an ample margin of safety. Relatively few standards were set under section 112 because disagreements over risk assessment methodologies and depths of analyses led to long delays in the standard-setting process.

In 1980, Congress amended section 112 in part to circumvent the lengthy and controversial risk assessment process for each MACT and each emission standard. To facilitate the rapid regulation of the 189 HAP listed by Congress in section 112(b)(1), amended section 112 requires the EPA to establish standards for categories of sources that emit these HAP based on "achievable technology" rather than on an assessment of health risk. Section 112 includes statutorily mandated deadlines for when these standards must be established. All the listed source categories are to be controlled according to a schedule that ensures that all technology-based control standards will be established within 10 years of enactment of the 1980 CAAA. On September 24, 1982, the EPA published a draft schedule for the promulgation of emission standards under amended section 112. (See 57 FR 44417, September 24, 1992, "National Emission Standards for Hazardous Air Pollutants: Availability: Draft Schedule for the Promulgation of Emission Standards.") In establishing this schedule, as required under section 112(a), one of the factors the EPA considered in prioritizing promulgation dates for emission standards was the potential of sources in each category to cause adverse effects on public health and the environment. (The September 24, 1992, notice explains how the Source Category Ranking System addresses health effects and exposure data.)

While section 112 requires emission standards initially to be technology-based, Congress maintained a role for the use of risk assessment to control HAP emissions. Eight years after promulgation of MACT standards pursuant to section 112(d) for each category of major sources, the EPA must examine the health risk levels posed by such regulated major sources and determine whether additional controls are necessary to reduce unacceptable "residual risk" from exposure to emissions from these facilities. Under section 112(f), the EPA is required to establish "residual risk" standards for such categories of major sources to provide an "ample margin of safety to protect public health" in accordance with the health-based standard-setting criteria of section 112 as in effect before November 15, 1990, unless the EPA determines that a more stringent standard is necessary to prevent (taking into consideration costs, energy, safety, and other relevant factors) an adverse environmental effect.

Specifically, the health-based criterion that would trigger standard setting under section 112(f) is whether any source in a category of major sources regulated under section 112(d) emits a pollutant (or pollutants) classified as a known, probable, or possible human carcinogen such that the individual most exposed to emissions from the source has a lifetime excess cancer risk of greater than one in one million. If such a condition exists, and if Congress does not act on recommendations from the EPA regarding the need for or the practicality of setting residual risk standards, the EPA must promulgate a residual risk standard for that source category.

In the interim, before residual risk standards are set, under section 112(f), the EPA has the NAS charged with studying the EPA's risk assessment methodology and making recommendations to Congress about revising such methodology for the explicit purpose of preparing to develop health-based standards under section 112(f). Section 112(o) requires the NAS to conduct a review of: (1) the risk assessment methodology used by the EPA to determine the carcinogenic risk associated with exposure to HAP from source categories subject to regulation under section 112; (2) improvements in such methodology; and (3) the extent to which the methodology for assessing the risk of adverse human health effects other than cancer for which safe thresholds of exposure may not exist.

Section 112(f) requires the EPA to investigate and report on: (1) methods of calculating the risk to public health remaining, or likely to remain, from sources subject to regulation under section 112 after the application of MACT standards; (2) the public health significance of such estimated remaining risk and the technologically and commercially available methods and costs of reducing such risks; (3) the actual health effects with respect to persons living in the vicinity of sources, any available epidemiological or other health studies, risks presented by background concentrations of HAP, any uncertainties in the risk assessment methodology or other health assessment technique, and any negative health or environmental consequences to the community of efforts to reduce such risks; and (4) recommendations as to legislation regarding such remaining risk.

As mentioned earlier, the EPA currently is developing procedures for source owners or operators, or other members of the public, to file petitions to delete listed categories of sources as allowed under section 112(c)(9)(B). After the various risk assessment studies are completed, the EPA will consider what to do regarding having the Administrator initiate the delisting process. While the Agency could rely solely on petitions from the public as a way of implementing section 112(c)(9)(B), the Agency recognizes the benefits of having the Administrator initiate the delisting process, where the Agency seems it appropriate to avoid setting unnecessary standards. Such a process would enable the Agency to focus its resources—as well as societal resources—on those sources posing risks intended to be regulated under section 112. For many source categories, the Agency already has or is in the process of obtaining, the source-specific data needed to make such a determination. Further, the process envisioned by the Agency may require less data to make its determination because it could be structured on a positive finding that at least one source within the category exceeds these risk thresholds. The data collection costs may be lower for Agency-initiated deletions than would be if the Agency relied solely on petitions from the public, especially when there are few sources in the category and the Agency has sufficient data to perform this determination.

The Agency will consider initiating the delisting process if, during the development of a MACT standard, the Agency determines that a particular source category may meet the decision criteria. The Agency will address this issue in the forthcoming Federal Register notice to establish the petitioning procedures and guidelines. Today, the Agency is soliciting comments on all aspects of this issue.

IV. Proposed General Provisions Based on Revisions to the Existing General Provisions

A. Introduction

The majority of the proposed general provisions have been developed directly from the existing general provisions in parts 60 and 61. However, in response to requests made during the development of this rulemaking by representatives of affected industries and State and local agencies, the EPA is proposing to clarify a few aspects of the compliance and reporting procedures in the general provisions. The EPA's responses to these requests are
APPENDIX E

MEMO FROM ADMINISTRATOR BROWNER TO EPA STAFF REGARDING
POLLUTION PREVENTION
MEMORANDUM

SUBJECT: Expectations for Briefings: Source Reduction Review Project Rules

TO: See Below

I want to congratulate the Office of Water and the Office of Water and Radiation for an excellent job in addressing pollution prevention issues at the May 7th briefing on proposed rules for the pulp and paper industry. I thought it might be useful to establish consistent expectations for future briefings regarding other proposed rules covered by the Source Reduction Review Project. Accordingly, I would like programs to be prepared to address the questions identified below, which generally fall into three categories: how pollution prevention options were considered during the rule development process; how multi-media issues are being addressed in option selection; and what plans, if any, we have for rule implementation that will foster the use of pollution prevention measures.

A. Rule Development

1) What pollution prevention options were developed/considered during workgroup deliberation? Is a pollution prevention option the basis of the standard? If not, why not? What can we do to encourage its use?

2) Does the rule include particular incentives for pollution prevention, particularly for facilities that go beyond compliance?

3) Does the format of the limit (i.e. concentration-based, percent reduction) allow for accurate measurement of reductions from source reduction practices? If the limit is concentration-based, how are we preventing dilution?

4) What role have other offices (e.g. ORD, OPPT) played in developing the rule? Was their participation timely and helpful?

5) Were the cost-savings (e.g. from solvent recovery) of the pollution prevention options included in the cost analysis? How did the cost of the pollution prevention options compare to the end-of-pipe options?
B. Multi-Media Issues

1) How were multi-media impacts considered in determining the recommended workgroup option? Was an option rejected because of multi-media impacts? For example, have we considered how substituting to aqueous solvents to meet an air emission limit might affect water quality?

2) What other regulations and activities are now underway which will affect these facilities? Were these other rules developed simultaneously with this rule? If not, what was done to coordinate these rules so that facilities can plan an integrated compliance strategy?

C. Rule Implementation

1) What type of outreach do you have planned for permit writers and the regulated community to inform them about the pollution prevention options? Are pollution prevention approaches discussed in the preamble and development document?

2) Are there avenues for providing pollution prevention technical assistance to this industry to help meet expected compliance requirements?

D. General Issues

1) Since we are considering expanding the SRRP process to future rulemakings, what areas of this process could be improved?

2) What resources would be needed to improve the Agency's SRRP effort?

Carol M. Browner

Addressees:

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APPENDIX F  COURT ORDERED DEADLINES