

NLWJC - Kagan

Counsel - Box 026 - Folder 008

**Counsel: Regulatory Working
Group 1995 [3]**

EXECUTIVE OFFICE OF THE PRESIDENT

Washington, D. C.

FAX TRANSMITTAL COVER SHEET

DATE: 01-May-95

TO: ABNER J. MIKVA

SUBJECT:
SCIENCE AND TECHNOLOGY MATERIALS

FROM:
LORRAINE DAY 395-3085
OFFICE OF MGMT AND BUDGET, OIRA

If there are any problems receiving this transmission,
please call the sender, or (202) 395-7370.

April 28, 1995

MEMORANDUM

TO: Regulatory Working Group

FROM: Sally Katzen

SUBJECT: Science and Technology Materials

In preparation for the upcoming session with the Vice President on the topic of Science and Technology (currently scheduled for May 9), we are circulating the attached two drafts. These drafts reflect very thoughtful work by the OSTP team over the past several months. We understand that some of you have been active participants in the development of these papers; others of you may have a passing interest in at least some of the topics addressed and still others may have no interest at all.

If you have comments on these materials, please relay them to Julie Swisshelm in Dr. Gibbons' office (456-6041, OEOP Room 423, Internet SWISS@OSTP.EOP.GOV) — by close of business, Wednesday, May 3. If you offer comments, you will be invited to the agenda-setting meeting (which will take place in advance of the meeting with the Vice President). Even if you have no comments on these drafts, you may be included in the agenda-setting meeting by contacting Phyllis Kaiser-Dark of my office (202-395-4852). Thank you.

**RECOMMENDED APPROACHES TO REGULATORY AND
RELATED ISSUES IN
SCIENCE AND TECHNOLOGY**

Draft

April 28, 1995

draft — April 28, 1995

RECOMMENDED APPROACHES TO REGULATORY AND
RELATED ISSUES IN
SCIENCE AND TECHNOLOGY

National Performance Review Phase 2

The Office of Science and Technology Policy has played an important support role in coordinating the reinvention efforts of the Federal agencies with significant science and technology portfolios. These agency initiatives have met with considerable enthusiasm and expectations are high that they will spell success in making the Federal S&T enterprise more efficient, more effective, and more responsive to National needs.

There is a small subset of issues, however, that is not agency-specific. These issues have broad applicability across the research and development spectrum, and they are the focus of the recommendations laid out in this document.

The attached two documents are a briefing agenda and a background document with additional programmatic detail. A table of contents is included with the background document.

The issues include **simplifying approval of the products of biotechnology**, particularly useful drugs; **streamlining procurement and private-sector funding processes** and **streamlining the university research process** to make sure that each Federal dollar invested yields maximum returns both in research and in the time and energy of researchers. This latter category also emphasizes harnessing the **national information revolution** to reduce the burden of paperwork and free up researcher time for teaching, writing, research, and scholarly activity; the attached report addresses only a small part of this topic, which is to be the subject of a separate briefing at a later date.

There is one outstanding issue that we had intended to include in this document: **reform of export regulations**. Achieving consensus on this issue has proved even more difficult than it seemed at the outset, but — working with NSC and CEA — we believe progress is being made within the agencies to resolve outstanding differences. We hope to be able to present this information in a separate briefing or as part of our upcoming briefing, as appropriate.

The attached two documents are a briefing agenda and a background document with additional programmatic detail. A table of contents is included with the background

document.

DRAFT

4/28/9

**Briefing for
Regulation of Science and Technology**

Scope: Regulatory issues which affect business incentives to conduct R&D or the productivity of business, university, and federal research and development, and which have not been covered in other regulatory review sessions.

The proposals discussed here include (1) reform efforts already underway that we should highlight as a part of our regulatory reform program, (2) reforms that can be accomplished under existing authority, and (3) reforms that require new legislation.

Reform Efforts Underway**I. Conduct of Research and Development****A. Streamlining the University Research Process**

1. Reform the Treatment of Research Costs
2. A System for Continuous Quality Improvement

II. Federal Leadership in Coordinating Federal, State, and Local Regulatory Activities**III. Biotechnology****A. Simplify Approval of Biotechnology Drugs and Biologics****Outstanding Issues****I. Conduct of Research and Development****A. Streamlining the University Research Process**

1. Standardizing the Grant Process
2. Electronic Communications in the Grants Process
3. Easing the Burden of Laboratory Waste Disposal

B. Streamline the Private Sector Research Funding Process**C. Expand "Other Transactions" Authority for Certain Types of Procurement**

DRAFT

4/28/9

- D. Extend Non-Disclosure Protection to Additional Technology Partnerships
- E. Specific Example of Targeted Regulatory Reform: Galvin Commission Recommendations

II. Biotechnology

- A. Facilitate Bioremediation Field Trials and Commercialization

III. Export Regulations

- A. Create an Acceptable and Effective Commodity Jurisdiction Dispute Resolution Procedure (not included in this document)

DRAFT

4/28/9

I. Conduct of Research and Development**A. Streamline the University Research Process****1. Streamline the Grant Process**

Differences in practice and policy across Federal agencies oblige institutions of higher education to maintain separate internal operating procedures for each agency w which they do business. This increases the time spent on paperwork and correspondingly reduces the return on the taxpayers' investment in scientific research.

The Federal Demonstration Project (FDP), a cooperative effort among more than fifty universities or research institutes and nine federal agencies, is designed to improve management of federally-funded research. The FDP has developed and tested the following recommendations concerning the grants process.

Recommendation

Direct all agencies to adopt the FDP General Terms and Conditions and the expanded authorities included in OMB Circular A-110 for all research and research-related project grants as a matter of agency policy. Where not inconsistent with statute, all agencies shall prescribe the General Terms and Conditions tested by the FDP as the default for all research and research-related project grants.

These defaults may be overridden in rare and exceptional circumstances, only when there are compelling reasons to do so.

Pros

? Uniform policies and procedures for the administration of federal research projects

ject grants free faculty from paperwork and allow them to spend more time research. Between 1988 and 1990, the FDP evaluated the impact of the "expanded authorities" at over 28 universities. Responses from over 2500 principal investigators indicated that these streamlined procedures saved more than annually per investigator, permitting over 50 additional person-years of activity in this sampling. No cases of mismanagement have been attributed to implementation of the FDP terms and conditions at 50 institutions by 9 federal agencies since the inception of FDP in 1988. Grants office

DRAFT

4/28/9

cers from the six major funding agencies (NIH, DOE, DOD, NSF, USDA, NASA) with these recommendations.

Cons

? Agencies without major research activity may resist the effort necessary to implement the changes in terms and conditions necessary to achieve uniformity. Major research-sponsoring agencies, including the NIH and the NSF, are in compliance with these procedures now.

DRAFT

4/28/9

2. Use Electronic Communication to Make the Grants Process More Efficient

A number of federal agencies are experimenting with various forms of electronic grants applications and reporting to speed communications, lessen the paperwork burden and significantly lessen the amount of paper used in the process. Agencies will need to establish common data requirements for their grants submissions and reporting; commit adequate resources and effort to develop, pilot, and adopt a common electronic standard and ensure that sufficient technological options are available to institutions to allow flexibility in selecting the approaches that are most useful and cost effective to the

NSF estimates that they annually receive approximately 7,500 feet of stacked proposals (about 15 Washington Monuments high) and that 24 Washington Monuments worth of paper could be eliminated by electronic submission of just the repetitive data (civil rights, drug-free workplace, non-delinquency on Federal debt, etc.).

Recommendations

Direct agencies to develop and adopt a common set of data elements for use in proposal submission as an initial step in the development of standards and means for electronic submission and processing of proposals and awards.

Direct agencies to develop and demonstrate electronic commerce systems for the administration of federal financial assistance, including assessments of the efficacy of electronic data interchange public standards such as ANSI X12 for computer-to-computer exchange of information.

Direct OMB, working with the FDP and the Federal Business Practices Working Group, to determine, test and implement the best means of establishing electronic access profiles of recipients receiving federal financial assistance.

Pros

- ? These recommendations would greatly simplify the administration of grants.
- ? NSF has begun a project to re-engineer and automate all processes related to grant proposals, awards and related business practices. NSF and NIH have client/serve database systems to permit electronic communication with grantee organizations. Both of these systems utilize the Internet, enable grantees using any computer type to access the database to enter or modify

DRAFT

4/28/9

Cons

? Protocols and standards for electronic submission, processing and reporting of proposals are in an early stage of development and have numerous "kinks" to be resolved.

DRAFT

4/28/9

3. Ease the Burden of Laboratory Waste Disposal

Regulatory requirements unnecessarily drive up the costs incurred by government university, and industrial laboratories when handling hazardous wastes during research testing. That is because the applicable regulations, which focus on large volume industrial processes such as chemical manufacturing, are unwieldy when applied to research-testing procedures, which characteristically involve only tiny volumes of chemicals. One-size-fits-all rules and inflexible interpretations preclude laboratory oriented innovations that could increase work-place safety and enhanced environmental protection at lower cost, e.g., recovery and reuse of lab chemicals.

For research-intensive universities, expenditures associated with handling hazardous and low level radioactive laboratory waste can account for a significant fraction (above 10%) of total project costs and, in many institutions, are the fastest growing component of overhead.

Recommendations

Short Term. Simplify the process for obtaining a RCRA permit for on-site storage and treatment of hazardous laboratory waste. To achieve effective waste handling, laboratories need only a small fraction of the authorities normally included in a Treatment, Storage, Disposal (TSD) permit under RCRA. If a simplified TSD and streamlined application and review procedure were introduced, qualifying universities and other organizations that operate research facilities would be able to store small quantities of hazardous wastes on site for up to one year (currently 90 days) and to treat certain classes of wastes on the bench top or in other specified locations.

Long Term. Establish a continuing national forum to address and promote other innovations with respect to reduction, management, and treatment of hazardous laboratory wastes. In addition to encouraging reforms within existing statutes and regulations, the forum would seek to foster increased reliance on performance standards when regulating laboratory waste management and accelerated development of environmentally benign laboratory procedures.

Pros

- ? Reduces administrative costs and non-productive time requirements for bench scale researchers permitting more resources to be applied to R&D
- ? Would facilitate waste solvent recovery and waste "neutralization" that would reduce the waste burden on the environment.
- ? Essentially no down-side risks.

DRAFT

4/28/9

Cons

? Would require the EPA to develop an additional set of rules
and forms
for small volume facilities.

DRAFT

4/28/9

B. Streamline the Private Sector Research Funding Process**CRADAs**

Much research with industry partners is accomplished through the use of Cooperative Research and Development Agreements (CRADAs), which allow government laboratories to conduct cost-shared R&D projects with industry in areas consistent with laboratory missions. These CRADAs are used extensively by the federal labs and by many different agencies.

Currently, agencies use a variety of different forms of agreements, include a variety of provisions in their CRADAs. CRADAs often do not have a constant format even within the same agency. In addition, projects involving several agencies often must require that industry partner deal with all the agencies' various procedures and agreements.

While certain differences are required by statute, many are simply a function of custom and can be streamlined or eliminated. For example, the Department of Energy has developed a general-use modular CRADA and a short-form, fill-in-the-blanks CRADA. These changes have permitted DOE to cut its CRADA processing time in half -- from about 32 weeks to about 16 weeks. It appears likely that other agencies could achieve similar results.

Recommendations

The following recommendations were developed in consultation with NASA, DOE, DOC, and ARPA, which support these recommendations. Other agencies are not affected. The recommendations do not involve legislative change.

The affected agencies should be directed to begin efforts to ensure, to the extent consistent with statute and mission requirements, that all agencies develop standard form, general use, CRADAs that are consistent within each agency and as similar as possible across agency lines. The inherent tensions between standardization and flexibility in use will dictate innovative solutions, such as modular CRADA agreements. The Partnership for a New Generation of Vehicles (PNGV) can be cited as a demonstrative project that is underway in this area. All participating agencies in that project reviewed and conformed their CRADA documents to the extent possible for use in the project.

If, as is likely, it is not possible to completely standardize practices across agencies, the affected agencies should be directed to consider the possibility in multiple projects of assigning a lead agency to manage the agreement. This would provide a single approach to negotiation and processing. Statutory considerations that affect agency

DRAFT

4/28/9

specific can be noted in the multi-party agreements without the elements common to a agencies having to be negotiated afresh for each agency. The lead agency will act as single point of contact for dealing with the industry partner. This will minimize th multiplicity of effort required of industry.

DRAFT

4/28/9

B. Streamline the Private Sector Research Funding Process (continued)**Other Research Agreements**

With respect to research agreements other than CRADAs, there is a similar problem inconsistency within agencies and across agency lines, as well as substantive requirements that pose unnecessary barriers to research with the private sector. No pilot work has been done to determine the extent to which these inconsistencies or barriers can be eliminated within current statutory requirements.

Should the agencies be given expanded "other transactions" authority (see next section) all such barriers should be eliminated, although work may remain to be done to make the form of agreements more uniform across agency lines. Prior to enactment of such legislation, the agencies should begin the process of identifying any such barriers which are not required by statute and working toward their removal.

Recommendations

The PNGV, an existing, interagency R&D effort with the private sector, should be designated as a reinvention laboratory in this area of research agreements. Agencies involved in PNGV should be directed to (1) review their existing statutory authorities to determine the degree of flexibility available to them in negotiating research agreements, particularly in the areas of cost accounting, intellectual property, and multi-part "partnership" arrangements; (2) recommend any necessary changes in policy or statute in order to allow them to streamline the negotiation of R&D agreements; and (3) identify inconsistencies in current practices or requirements among those agencies and the basis for those differences.

The PNGV reinvention laboratory should be directed to report its findings to all agencies involved in research agreements with recommendations for improvement in agency practices.

Pros

? The inefficiencies in the current process affect the federal agencies' ability to work with industry and to effectively utilize the taxpayers' considerable capital investment in research facilities. These changes will improve the agencies' ability to effectively work with industry and leverage that investment for U.S. economic and social benefit.

Cons

? Agencies currently control their own procedures and have different statutory constraints. Changes that move toward uniformity are difficult to implement without strong interagency consensus (which has to date been hard to achieve).

DRAFT

4/28/9

? In addition, any effort to give one agency the lead in multi agency projects be careful to maintain agencies' compliance with the requirements of the Econom Act.

? If consistency is emphasized above all other goals it can lead to acceptance the "lowest common denominator." Care must be taken to preserve agencies' abilities to seek creative solutions.

DRAFT

4/28/9

C. Expand "Other Transactions" Authority for Certain Types of Procurement

Note: This issue is still under review by the SBA and other agencies.

The National Performance Review recommended that heads of civilian agencies be granted authority similar to that provided the Department of Defense in 10 U.S.C. 2371, so-called "other transactions" authority. This expansion of "other transactions" authority would be limited to agreements for research and development, and would not extend to procurement of goods and services. "Other transactions" authority is currently available to DOD, NASA, and DOT in funding certain research and development work, and it replaces standard procurement requirements with considerable flexibility to the project manager to craft a contract that contains only those provisions necessary to the particular project to revise the working arrangement as research projects evolve. It would eliminate, for example, rigid mandatory intellectual property requirements and use of government accounting principles.

Without this authority, firms which have not been government contractors and are accustomed to flexible, unencumbered negotiations and accounting procedures for research projects are deterred from engaging in government research programs because of the inflexible accounting requirements and agreement provisions. DOE, for example, has experienced specific problems negotiating with commercial firms for conducting joint, cost-shared, research projects to demonstrate environmental remediation solutions. In one case, DOE had to go through ARPA at DOD to fund a cost-shared demonstration project with six major chemical companies. This project could lead to significant savings in up costs, but without "other transactions" authority DOE was unable to negotiate a workable agreement with multiple parties.

Recommendation

The statutory change recommended by the National Performance Review, to extend "other transactions authority" to civilian research agencies for use in negotiating research and development agreements, should be pursued. Any legislative change would be drafted to allow, but not require, use of this authority by agencies entering into research agreements and would include a statement of principles to ensure public understanding and appropriate oversight of the increased discretion to be provided to agency managers.

Pros

- ? It is appropriate for R&D work, where the project evolves significantly over lifetime, in contrast to standard procurement of goods and services.
- ? It will greatly improve the government's ability to enter into effective research projects with the private sector unencumbered by unnecessary regulations.

Cons

DRAFT

4/28/9

? Eliminating the requirements for compliance with standard procurement regulations in these projects opens these projects to particular scrutiny and the potential for criticism about mismanagement.

? Expansion of this authority will likely require additional employee training oversight to ensure that the agencies use this authority only for R&D work, and not extend its use to procurement of goods and services in an attempt to avoid procurement requirements generally.

DRAFT

4/28/9

D. Extend Non-Disclosure Protection to All DOE Federal Technology Partnerships

There are several statutes that provide for the protection from disclosure, including disclosure under the FOIA, for a period of up to 5 years, of information produced under DOE's collaborative agreements for research, development and demonstration with industrial partners (e.g., the Energy Policy Act of 1992 [12 U.S.C. 1320], the National Competitiveness Technology Transfer Act of 1989 [5 U.S.C. 3701], the Department of Interior Appropriations [P.L. 102-381], and the Metals Initiative legislation [P.L. 100-680 and 5 U.S.C. 5101]). The language in these statutes is not uniform, the date from which information can be protected varies depending on which statute applies, and the statute not apply to the entire spectrum of agreements in which DOE enters with industrial partners (particularly in most of the agreements under DOE's defense programs). This protection from disclosure is important to industrial partners who ultimately plan to commercialize products resulting from the research with federal agencies. This inconsistency of statutory authority does not appear to be a problem for agencies other than DOE.

Recommendation

Seek a statutory change that brings uniformity to DOE's authority in this area and extends the protection of information produced under all federal research development demonstration agreements in all agencies from disclosure for a period of five years, in order to unify the ad hoc approach that has been taken to date. However, it should be made clear that protection from disclosure does not apply to the research agreement itself, that absent extraordinary circumstances information on the nature of the agreement will be publicly available.

Pros

- ? would provide consistent treatment of all DOE's Federal partners for all research, development and demonstration agreements and address a significant concern of industry about their ability to protect commercially valuable information developed as partners with the government.
- ? Since the protection under the Energy Policy Act is limited to 5 years, federal R&D efforts would afterwards be made public allowing others to benefit by taking those results (obtained in part with taxpayer dollars) and build on them.

Cons

- ? The Atomic Energy Act of 1954, section 31d states that DOE's research agreements shall not prevent the dissemination of scientific or technical information except as otherwise provided by law. This reflects the policy judgment of some that, absent exceptional circumstances, research funded with taxpayer dollars should be publicly available.

DRAFT

4/28/9

available. The extension of current non-disclosure provisions to additional rese
may be criticized on those grounds, with the claim that a few preferred contrac
are allowed to tie up research funded with taxpayer support for a period of tim
long enough to obtain all reasonable commercial potential from that research.
? There may be some increased administrative burden involved in protecting
additional information from disclosure.

DRAFT

4/28/9

E. Specific Example of Targeted Reform: Calvin Commission Recommendations

As part of the regulatory review, we have identified one additional specific area in which administrative reform would be well-received by the affected communities. DOE issues its own orders to laboratories relating to environment, safety and health. These orders are often far more restrictive than those imposed by regulatory agencies such as EPA, FDA, and OSHA. In addition DOE laboratories are subject to a multitude of audits and reviews, some imposed by organizations outside the control of DOE management (e.g. the Congress), but many are inspired by DOE. The Calvin Commission report clearly documents the excessive burden on DOE laboratories resulting from DOE orders, directives and audits (see Appendix A of the report). The Secretary of Energy concurs that the existing system is costly, bureaucratic, and inefficient. Activities now ongoing within the Department are addressing some of the issues raised in the Calvin Report. Given the budget pressures DOE is under, we recommend that attention be directed toward achieving the large savings and increased efficiency achievable by reducing the excesses identified in the Calvin Report.

Recommendation

Department of Energy recognizes the seriousness of the situation and has steps underway to correct the deficiencies including revising their Directive system. Since 1994, the Department has eliminated about 25 percent of its orders (312 to 236). An accelerated order reduction effort is currently underway to reduce 103 of the remaining orders to 42 including 24 orders considered to be the most burdensome by field offices and contractors. This accelerated effort will be completed by July 31, 1995. This will lead to a reduction in contractor requirements and overhead dollars. Orders that merely repeat external regulatory requirements are planned to be eliminated with the understanding that these external requirements must be followed. Any new orders that are developed (or revisions to existing orders) are to include statements of resource impact and justification for issuance. DOE should be directed to complete this process with timelines and deliverables. At a minimum, DOE Orders should be done away with in cases where other federal agency regulations apply. In otherwise unregulated areas, the process should be that permits only those new orders deemed essential to be promulgated. This should lead to a significant reduction in the Federal work force and allow the labs to reduce overhead and devote more of their resources to R&D.

Pros

- ? Removes what is generally recognized as excessive and costly oversight
- ? Responsive to findings of a prestigious review committee

DRAFT

4/28/9

? The DOE Lab Directors are unanimous in their belief that the Orders represent a seriously misguided oversight effort

Cons

? Some Orders are required to fulfill Congressional requirements of DOE's oversight responsibility

? The labs are more interested in carrying out their missions than adhering to regulations hence strenuous oversight is required

? This level of control is necessary to protect the public interest

DRAFT

4/28/9

II. Biotechnology

A. Facilitate Bioremediation Field Trials and Commercialization

There presently exists a reluctance to employ bioremediation in the U.S., largely because it is perceived as unproved technology, regulatory hurdles discourage applicat and the purveyors of conventional technology control the market. This reluctance will diminish substantially if large scale trials can be easily established to demonstrate e This proposal recommends a plan that would facilitate a scientifically objective evalu of bioremediation as a predictable, safe, and cost effective clean-up option.

There are currently two primary regulatory constraints on the development and application of bioremediation as a clean-up option. The first constraint comes from t Resource Conservation and Recovery Act (RCRA) and it's regulation of hazardous wastes administered by the EPA. Although EPA issued new rules for treatability studies in 1 they are still not conducive to long-term research. There needs to be a mechanism fo expediting RCRA rules when they apply to research applications on secure government land. The second constraint involves the use of recombinant (genetically altered) microorganisms in open field clean-up. This application of recombinant organisms come under the purview of the Toxic Substances Control Act (TSCA) also administered by the EPA. There needs to be a mechanism for expediting TSCA clearances when they apply t research applications on secure federal land. Accordingly, dedicated federal field site include both contaminated and clean areas need to be made available to academic, government and private sector scientists and engineers. Specific examples of secure si that also have access to appropriate analytical instrumentation include Oak Ridge Nat Laboratory, Pacific Northwest Laboratory, and selected National Environmental Research Parks.

Recommendations

Dedicate one or more secure Federal field sites to coordinated, long-ter research to underpin effective bioremediation of contaminated surface and subsurface environments.

Develop minimal state and Federal regulations to govern such restricted site fi trials.

Pros

DRAFT

4/28/9

? Will accelerate the development of new technology to clean up the environment

? Will stimulate the biotechnology industry and academics to devote more attention and creative thought to the subject.

Cons

? Will require EPA to develop a new, less stringent clearance for these test sites

? Will create some controversy among environmental public interest groups if not handled properly.

DRAFT

04/28/95 09:03

Regulation of Science and Technology

Scope

This group focuses on regulatory issues which affect business incentives to conduct R&D or the productivity of business, university, and federal research and development.

The administration has gone to great lengths to work with business, universities, and other organizations in structuring its science and technology policy. Concerns about federal regulation are always a major theme. While some concerns target the purposes of the regulation, many center on blizzards of paperwork and record keeping, as well as on confusion, contradictions, delays, and outright rudeness in the way the regulations are administered. While many of these concerns are chronic in nature, there are good reasons to take a new look.

? The rapid rate of technical change in many key industries often means that competitive advantage grows out of moving quickly to the market. This makes it essential that regulatory decisions be fast and efficient without compromising the goal of the regulations, the quality of the decisions, or public safety. There will always be a tension between the need for public scrutiny and the need for speed. But clearly the need for regulatory efficiency has grown.

? The Federal government supports over 40% of all U.S. research and development and two thirds of its fundamental research. The skill with which federal research funds are managed is therefore critical to the health of the entire U.S. R&D enterprise. The Clinton Administration has placed heavy emphasis on research conducted in close partnership with businesses. The technology supported in these partnerships can lead to profitable commercial products for the private firms while supporting the mission objectives of the federal agencies. This relationship has worked well, but it has also highlighted flaws in federal research management that can be minimized through regulatory reform.

Most of the concerns heard from business and universities focus on environmental, OSHA, FDA, financial, or other regulatory issues covered by other groups in the Vice President's regulatory task force. Our purpose here is to take the broad themes developed in

DRAFT

04/28/95 09:03

the task force as a whole and apply them to a set of issues that have not been exten covered elsewhere.

As a result, the discussion that follows focuses in three areas:

1. Increasing the effectiveness and efficiency with which the federal governme funds research and development in universities and industry.
2. Using federal leadership to encourage greater coordination between state, local, and federal regulators.
3. Biotechnology

Contents

I. Conduct of Research and Development

A. Streamlining the University Research Process

1. Reform the Treatment of Research Costs
2. Standardizing the Grant Process
3. Electronic Communications in the Grants Process
4. Easing the Burden of Laboratory Waste Disposal
5. A System for Continuous Quality Improvement

B. Streamline the Private Sector Research Funding Process

C. Improve Treatment of Intellectual Property

D. Expand "Other Transactions" Authority for Certain Types of Procurement

E. Extend Non-Disclosure Protection to Additional Technology Partnerships

F. Specific Example of Targeted Regulatory Reform: Calvin Commission Recommendations

II. Federal Leadership in Coordinating Federal, State, and Local Regulatory Activities

III. Biotechnology

A. Simplify Approval of Biotechnology Drugs and Biologics

DRAFT

04/28/95 09:03

B. Facilitate Bioremediation Field Trials and Commercialization

DRAFT

04/28/95 09:03

I. CONDUCT OF RESEARCH AND DEVELOPMENT

The proposals discussed here include (1) reform efforts already underway that we should highlight as a part of our regulatory reform program, (2) milestones for reforms can be accomplished under existing authority, and (3) reforms that require new legislation--most of which is already included in the procurement reform legislation.

A. Streamline the University Research Process**1. Reform the Treatment of Research Costs (A21)**

The cost reimbursement system for overhead or "indirect costs" for research grant has been harshly criticized and allegedly provides federal reimbursement that is widely variant and too generous. There are proposals in Congress to cap the rates used by universities to calculate federal reimbursement and use the resulting "savings" for other federal needs. A legislated cap setting an arbitrary limit on rates would repudiate the principles stated in OMB Circular A-21, under which the government has negotiated reimbursement rates with individual universities for decades. Such a cap could deny millions of dollars of reimbursement to universities for research facilities built to support federally funded research based on long-standing principles and agreements.

We propose to implement a number of revisions to OMB Circular A-21, which were published in the Federal Register on February 6. OMB and OSTP, working in collaboration with federal agencies and universities, and building on prior work, have completed their study of the system and will recommend the following changes.

Develop uniform methods and procedures. Discard past notions of "direct and indirect" costs which were needlessly complicated and poorly understood. Instead, the new categories of costs, all necessary to the conduct of fundamental research, will be research activities, research facilities, and research administration. Standardize methods for determining utility costs and eliminate special studies to reduce the variation in the portion of overhead rates across universities. Develop a methodology to determine uniform treatment of special services (such as hazardous waste facilities), to ensure that similar activities are treated consistently by universities. Include other new policies for research as: useful life for research equipment, consistent federal agency transition policies for university changes from use-allowance to depreciation, appropriate federal policies for interest costs, uniform accounting methodology, make total costs part of competitive bidding process.

DRAFT

04/28/95 09:03

Make use of cost efficiencies. Force down the average rate universities charge facilities. Tough federal review of facility construction costs, utilization, and operation and maintenance will be imposed to ensure that federal science agencies are paying on efficient and reasonable use of university research space. Benchmarks would be established by research and construction experts for different classes of facilities -- which could apply to new construction and existing facilities

Pros

? These changes would reinvent the system of cost reimbursement in the spirit of the National Performance Review. They would achieve greater uniformity and cost efficiencies while retaining the core principles of negotiated cost reimbursement based on the government-university sharing actual costs. The necessary stability would be retained to stimulate universities and their governing boards to invest in world class research education facilities.

? The chief alternatives to these revisions, a cap on reimbursement rate (or an across the board cut of reimbursement), would have serious consequences to the excellence and future vitality of U.S. academic science. Universities presently receiving federal reimbursement for their substantial investments in research facilities would suffer immediate and significant decreases in their federal recovery. Variation among research facility rates among institutions reflects real and legitimate differences among institutions -- universities and colleges vary in the utility, maintenance and labor costs on their location, the age, condition and type of their facilities, and the nature of research and education which they pursue.

Con

? Instead of these refinements to an already complex system, a cap on reimbursement rates or a standardized percentage cut of the reimbursement for all institutions could streamline the process and achieve cost savings for government. However these costs would be shifted to universities, thus continuing the increase in the university share of costs associated with federally funded research. The system could be made simpler by setting some fixed rate for all universities, although, as stated above this would reflect the differences among institutions.

2. Streamline the Grant Process

DRAFT

04/28/95 09:03

Differences in practice and policy across agencies oblige institutions of higher education to maintain separate internal operating procedures for each agency with which they do business. This increases the time spent on paperwork and correspondingly reduces the return on the taxpayers' investment in scientific research.

The Federal Demonstration Project (FDP), a cooperative effort among more than fifty universities or research institutes and nine federal agencies, is designed to improve management of federally-funded research. The FDP has developed and tested the following recommendations concerning the grants process:

? Direct all agencies to adopt the FDP General Terms and Conditions and the expanded authorities included in OMB Circular A-110 for all research and research-related project grants as a matter of agency policy. Where not inconsistent with statute, all federal agencies shall prescribe the General Terms and Conditions tested by the FDP as the default for all research and research-related project grants.

? These defaults may be overridden in rare and exceptional circumstances, only when there are compelling reasons to do so.

Pros

? Uniform policies and procedures for the administration of federal research project grants free faculty from paperwork and allow them to spend more time on research. Between 1988 and 1990, the FDP evaluated the impact of the "expanded authorities" at over 28 universities. Responses from over 2500 principal investigators indicated that these streamlined procedures saved more than 5 days annually per investigator, permitting over 50 additional person-years of scholarly activity in this sampling. No cases of mismanagement have been attributable to the implementation of the FDP terms and conditions at 50 institutions by 9 federal agencies since the inception of FDP in 1988.

? Grants officers from the six major funding agencies (NIH, DOE, DOD, NSF, USDA, NASA) concur with these recommendations.

Cons

? Agencies without major research activity may resist the effort necessary to implement the changes in terms and conditions necessary to achieve uniformity. The major research-sponsoring agencies, including the NIH and the NSF, are largely in compliance with these procedures now.

DRAFT

04/28/95 09:03

3. Use Electronic Communication to Make the Grants Process More Efficient

A number of federal agencies are experimenting with various forms of electronic grants applications and reporting to speed communications, lessen the paperwork burden and significantly lessen the amount of paper used in the process. These demonstration approaches show great promise in significantly changing the grants process. Agencies need to establish common data requirements for their grants submissions and reporting. Also, agencies will need to commit adequate resources and effort to develop, pilot, and adopt a common electronic standard in order that institutions not have to deal with plethora of agency requirements. Finally they will need to ensure that whatever standard or means they adopt, that sufficient technological options are available to institutions allow them some flexibility in selecting the approaches that are most useful and cost effective to them.

Current grant applications repetitively require basic information about applicant organizations on every hard copy submitted. This includes routine, descriptive information about the organization (e.g., name, address and type of organization, entity number, and information about organization officials), as well as other information including organizational certifications and representations (e.g., civil rights, drug-free workplace non-delinquency on Federal debt, etc.). For example, NSF estimates that they annually receive approximately 7,500 feet of stacked proposals (about 15 Washington Monument high) and that 2.4 Washington Monuments worth of paper could be eliminated by electronic submission of just the repetitive data.

Recommendations

? Direct agencies to develop and adopt a common set of data elements for use in proposal submission as an initial step in the development of standards and means for electronic submission and processing of proposals and awards.

? Direct agencies to develop and demonstrate electronic commerce systems for the administration of federal financial assistance, including assessments of the efficacy of electronic data interchange public standards such as ANSI X12 for computer-to-computer exchange of information. Assessments of the approach most suitable to the greatest number of proposals and recipient institutions should be made under the auspices of the OMB, in coordination with the Federal Business Practices Working Group and the Federal Demonstration Project. Agencies should permit technological options to allow institutions some flexibility in how they submit their proposals and interact.

DRAFT

04/28/95 09:03

with agencies so as not to require institutions to make costly modifications wh they may be unable to afford.

? Direct OMB, working with the FDP and the Federal Business Practices Working Group, to determine, test and implement the best means of establishing electronic access to profiles of recipients receiving federal financial assistance. These pr would include routine descriptive organizational information as well as Federal certification and assurances.

A dual system of electronic and hard copy submissions would have to be maintained du a transition period to aid the institutions and small businesses which may have diffic using electronic submission and could not modify their existing technology to comply federal electronic submission protocols.

Pros

? These recommendations would greatly simplify the administration of grant Efforts are already beginning in certain agencies to increase electronic communication in this area.

? DOE has awarded a cooperative agreement for a two year effort to assess the generation, submission and processing of university research grant applications and other research administration processes using EDI X12 standards.

? NSF has begun a project to re-engineer and automate all processes relate to grant proposals, awards and related business practices. NSF and NIH have developed client/serve database systems to permit electronic communication with grantees and grantee organizations. Both of these systems utilize the Internet, enabling grantees using any computer type to access the database to enter or modify data.

Cons

? Protocols and standards for electronic submission, processing and reportin of proposals are in an early stage of development and have numerous "kinks that need to be resolved.

4. Easing the Burden of Laboratory Waste Disposal

Regulatory requirements unnecessarily drive up the costs incurred by government university, and industrial laboratories when handling hazardous wastes during research testing. That is because the applicable regulations, which focus on large volume indust processes such as chemical manufacturing, are unwieldy when applied to research-testin proce

DRAFT

04/28/95 09:03

dures, which characteristically involve only tiny volumes of chemicals. Dollars that otherwise would be used to advance science are spent meeting unproductive administrative requirements. Even worse, one-size-fits-all rules and inflexible interpretations preclude laboratory oriented innovations that could yield increased work-place safety and enhance environmental protection at lower cost, e.g., recovery and reuse of lab chemicals.

Expenditures associated with handling hazardous and low level radioactive laboratory waste run into the hundreds of millions of dollars each year. For research-intensive universities, these expenditures can account for a significant fraction (about 3%) of total project costs and, in many institutions, are the fastest growing component of overhead. Waste handling regulations developed specifically for the laboratory could do much to assure a better return on the research investment.

Recommendations

Short Term. Simplify the process for obtaining a RCRA permit for on-site storage and treatment of hazardous laboratory waste.

To achieve effective waste handling, laboratories need only a small fraction of authorities normally included in a Treatment, Storage, Disposal (TSD) permit under RCRA. If a simplified TSD and streamlined application and review procedure were introduced, qualifying universities and other organizations that operate research facilities would be able to store small quantities of hazardous wastes on site for up to one year (currently 90 days) and to treat certain classes of wastes on the bench top or in other specified location. Simple reforms would reduce the volumes of waste handled within and shipped from the organizations with commensurate gains in work-place safety, pollution prevention, and savings.

Long Term. Establish a continuing national forum to address and promote other innovations with respect to reduction, management, and treatment of hazardous laboratory wastes.

This forum would involve all stakeholder groups, e.g., government, university, or industry labs; national and state regulators; environmental protection advocates; work-place safety advocates; and community representatives. It would be modeled on the series of national laboratory waste workshops conducted last year under the auspices of the Government/University/Industry Research Roundtable of the National Academy of Sciences. In addition to encouraging reforms within existing statutes and regulations (such as permit streamlining described above), the forum would seek to foster increased reliance on alternative methods of waste management and treatment.

DRAFT

04/28/95 09:03

mance standards when regulating laboratory waste management and accelerated development of environmentally benign laboratory procedures.

Pros

- ? Reduces administrative costs and non-productive time requirements for bench scale researchers permitting more resources to be applied to R&D.
- ? Would facilitate waste solvent recovery and waste "neutralization" that would reduce the waste burden on the environment.
- ? Essentially no down-side risks.

Cons

- ? Would require the EPA to develop an additional set of rules and forms for small volume facilities.

5. A System for Continuous Quality Improvement

The Federal Demonstration Project has been, and continues to be, an excellent vehicle for identifying and testing time and cost saving suggestions related to academic research. To facilitate the translation of these improvements into practice, an established group of senior Federal officials should be responsible for reviewing FDP results and making recommendations for implementation.

Recommendation

- ? Direct the Committee on Fundamental Science of the NSTC to review FDP demonstration project results and to make recommendations regarding those demonstrations to the Office of Management and Budget, the Office of Science and Technology Policy, and to the heads of all Federal research-sponsoring agencies.

Pro

- ? Anchoring the FDP into the Federal Government through the NSTC will insure the rapid adoption of the results of continuing FDP demonstrations and other streamlining initiatives.

DRAFT

04/28/95 09:03

B. Streamline the Private Sector Research Funding Process**CRADAs**

Much research with industry partners is accomplished through the use of Cooperative Research and Development Agreements (CRADAs), which allow government laboratories to conduct cost-shared R&D projects with industry in areas consistent with laboratory missions. These CRADAs are used extensively by the federal labs and by many different agencies.

Currently, agencies use a variety of different forms of agreements, include a variety of provisions in their CRADAs. CRADAs often do not have a constant format even within the same agency. In addition, projects involving several agencies often must require that the industry partner deal with all the agencies' various procedures and agreements.

While certain differences are required by statute, many are simply a function of custom and can be streamlined or eliminated. For example, the Department of Energy has developed a general-use modular CRADA and a short-form, fill-in-the-blanks CRADA. These changes have permitted DOE to cut its CRADA processing time in half -- from about 32 weeks to about 16 weeks. It appears likely that other agencies could achieve similar results.

Recommendations

The following recommendations were developed in consultation with NASA, DOE, DOC, and ARPA, which support these recommendations. Other agencies are not affected. The recommendations do not involve legislative change.

The affected agencies should be directed to begin efforts to ensure, to the extent consistent with statute and mission requirements, that all agencies develop standard form, general use, CRADAs that are consistent across agency lines. The inherent tensions between standardization and flexibility in use will dictate innovative solutions as modular CRADA agreements. The Partnership for a New Generation of Vehicles (PNGV) can be cited as a demonstration project that has been completed in this area. Participating agencies in that project have reviewed and conformed their CRADA documents to the extent possible for use in that project. The managers of the PNGV project can be the point of contact for agencies in organizing the interagency work of the larger universe of CRADAs.

If, as is likely, it is not possible to completely standardize agency practice, consideration should be given by the interagency group to the possibility in multi-agency projects to

DRAFT

04/28/95 09:03

assigning a lead agency to manage the agreement. This would provide a basis for a si approach to negotiation and processing. Statutory considerations that are agency spec can be noted in the multi-party agreements without the elements common to all the agencies having to be negotiated afresh for each agency. The lead agency will act as single point of contact for dealing with the industry partner. This will minimize th multiplicity of effort required of industry.

Other Research Agreements

With respect to other research agreements, there is a similar problem of inconsistency across agency lines, as well as substantive requirements that pose unnece barriers to research with the private sector. (See infra at section LA with respect university research). No pilot work has been done to determine the extent to which th inconsistencies or barriers can be eliminated within current statutory requirements.

Should the agencies be given expanded "other transactions" authority (see infra section LD), all such barriers should be eliminated, although work may remain to be do to make the form of agreements more uniform across agency lines. Prior to enactment such legislation the agencies should begin the process of identifying any such barrier are not required by statute and working toward their removal.

Recommendations

The PNGV, an existing, interagency R&D effort with the private sector, should be designated as a reinvention laboratory. Agencies involved in PNGV should be dir to (1) review their existing statutory authority to determine the degree of flexib available to them in negotiating research agreements, particularly in the areas of accounting, intellectual property, and multi-party "partnership" arrangements; (2) recommend any necessary changes in policy or statute in order to allow them to at the negotiation of R&D agreements; and (3) identify inconsistencies in current pract requirements among those agencies and the basis for those differences.

The PNGV reinvention laboratory should be directed to report its findings to al agencies involved in research agreements with recommendations for improvement in agen practices.

Pros

DRAFT

04/28/95 09:03

The inefficiencies in the current process affect the federal agencies' ability to work with industry and to effectively utilize the taxpayers' considerable capital investment in research facilities. These changes will improve the agencies' ability to effectively work with industry and leverage that investment for U.S. economic and social benefit.

Cons

Agencies currently control their own procedures and have different statutory constraints. Changes that move toward uniformity are difficult to implement without strong inter-agency consensus (which has to date been hard to achieve).

In addition, any effort to give one agency the lead in multi-agency projects must be careful to maintain agencies' compliance with the requirements of the Economy Act.

DRAFT

04/28/95 09:03

C. Improved Treatment of Intellectual Property

The inability of the federal government to obtain adequate intellectual property protection for computer software that may ultimately be a basis for private sector technology is currently a barrier to federal labs' work with the private sector in this and to the effective leveraging of the federal research effort to strengthen the general economy. Currently, federal laboratories may patent, but not copyright, computer programs written by their employees. Because of this limitation on intellectual property rights, the private sectors' willingness to enter into CRADAs is reduced.

In addition, in particular cases the requirement of the Bayh-Dole Act that the government always retain a government purpose license is viewed by industry as a bar to government-industry research agreements. While amendment of the Bayh-Dole act is warranted, expansion of "other transaction" authority (see, infra, at 1.D) would give agencies the ability to waive that requirement in the few cases in which that would be appropriate.

Recommendations

Allowing employees of Federal agencies to copyright computer software developed by them as part of their official duties under, or related to, a CRADA will promote the commercial application of software developed with federal funds and thereby strengthen the economy. Legislation providing this intellectual property protection is included in the "Federal Acquisition Improvement" legislation recently forwarded to the Hill by the Administration (see sections 6101-3). That legislative change should be actively pursued.

The flexibility with respect to intellectual property protection provided to a contractor through "other transactions" authority should be pursued legislatively. See, infra, section 1.D.

Pros

The recommended changes for the federal labs will improve the leverage the federal R&D investment provides to the private sector.

Improvements in the efficiency of commercial spin-off of federal research through CRADAs and licensing have traditionally received bipartisan support.

Cons

DRAFT

04/28/95 09:03

Federal licensing of intellectual property is currently insignificant in dollar and economic impact. Improvements are possible, but many problems are inevitable consequences of the agencies' focus on mission research as their first priority and limited funding for patent counsel, filings, etc. Thus, the resulting benefits of any statutory in this area may be relatively small, although significant to particular industry parts.

Regarding intellectual property protection for Federal software, previous attempts to modify the statutes were not strongly supported by industry. There are varying opinions whether it is better to keep government software in the public domain, or to protect and license it.

D. Expand "Other Transactions" Authority for Certain Types of Procurement

The National Performance Review recommended that heads of civilian agencies be granted authority similar to that provided the Department of Defense in 10 U.S.C. 2371, so-called "other transactions" authority. This expansion of "other transactions" authority would be limited to agreements for research and development, and would not extend to procurement of goods and services.

"Other transactions" authority is currently available to DOD, NASA, and DOT in funding certain research and development work, and it replaces standard procurement requirements with considerable flexibility to the project managers to craft a contract that contains only those provisions necessary to the particular project, and to revise the arrangement as research projects evolve. It would eliminate, for example, rigid mandatory intellectual property requirements and use of government accounting principles. In some cases, it also would allow R&D contracts to be let without the use of competitive bid practices, although DOD's experience with this authority has resulted in their voluntary use of competitive bidding practices in over 90% of their agreements.

Without this authority, firms which have not been government contractors and are accustomed to flexible, unencumbered negotiations and accounting procedures for research projects, are deterred from engaging in government research programs because of the inflexible accounting requirements and agreement provisions. DOE, for example, has experienced specific problems negotiating with commercial firms for conducting joint, cost-shared, research projects to demonstrate environmental remediation solutions. In one case, DOE had to go through ARPA at DOD to fund a cost-shared demonstration project with six major chemical companies. This project could lead to significant savings in up-front costs, but without "other transactions" authority DOE was unable to negotiate a workable agreement with multiple parties.

DRAFT

04/28/95 09:03

This statutory change would greatly increase government flexibility in negotiating updating agreements with private sector partners for technology R&D. It would allow agencies to make agreements with commercial organizations for applied and basic research projects based on best commercial practices, but with a minimum of administrative bur

Recommendations

The statutory change recommended by the National Performance Review, to extend "other transactions authority" to civilian research agencies for use in negotiating research and development agreements, should be pursued. Any legislative change would be drafted to allow, but not require, use of this authority by agencies entering into research agreements and would include a statement of principles to ensure public understanding and appropriate oversight of the increased discretion to be provided agency managers.

Pros

Other transactions authority is appropriate for research and development work, where the project evolves significantly over its lifetime, and in contrast to standard procurement goods and services. It will greatly improve the government's ability to enter into effective research projects with the private sector unencumbered by unnecessary regulations. Any legislative change would be drafted to allow, but not require, use of this authority by agencies entering into research agreements.

Cons

Eliminating the requirements for compliance with standard procurement regulations on these projects opens these projects to particular scrutiny by those who may not be supporters of the federal R&D effort, and the potential for criticism about mismanagement. Because of the wide discretion provided to agencies under this authority, these projects must be able to demonstrate that they are administered fairly and in a cost-effective manner and that the flexibility provided is not abused.

Expansion of this authority will likely require additional employee training and oversight to ensure that the agencies use this authority only for R&D work, and do not extend its use to procurement of goods and services in an attempt to avoid procurement requirements generally.

The SBA is concerned that the interests of small business would not be fully protected without existing set-asides and competitive bidding practices. Currently, about 7% of federal R&D spending outside the SBIR program goes to small business. This "other transactions"

DRAFT

04/28/95 09:03

authority would NOT alter the SBIR program. In addition, the experience of ARPA in its use of "other transactions" authority has been that all but one of such projects have competitively bid and the project that was not subject to competition went to a small business. In addition, the flexibility available in negotiating agreements simplifies the process for small business, and makes participation more likely for businesses that are currently able to deal with the procedural requirements of typical government cost-reimbursed contracts and the required accounting procedures.

E. Extend Non-Disclosure Protection to All DOE Federal Technology Partnerships

There are several statutes that provide for the protection from disclosure, including disclosure under the FOIA, for a period of up to 5 years, of information produced under DOE's collaborative agreements for research, development and demonstration with industrial partners (e.g., the Energy Policy Act of 1992 [12 U.S.C. 1320], the National Competitiveness Technology Transfer Act of 1989 [5 U.S.C. 3701], the Department of Interior Appropriations [P.L. 102-381], and the Metals Initiative legislation [P.L. 100-680 and 5 U.S.C. 5101]). The language in these statutes is not uniform, the date from which information can be protected varies depending on which statute applies, and the statute does not apply to the entire spectrum of agreements in which DOE enters with industrial partners (particularly in most of the agreements under DOE's defense programs). This protection from disclosure is important to industrial partners who ultimately plan to commercialize products resulting from the research with federal agencies. This inconsistency of statutory authority does not appear to be a problem for agencies other than DOE.

Recommendation

This barrier to research with industry partners could be most effectively addressed by a statutory change that brings uniformity to DOE's authority in this area and extends the protection of information produced under all federal research, development and demonstration agreements in all agencies from disclosure for a period of five years, in order to unify the ad hoc approach that has been taken to date.

Pros

Would provide consistent treatment of all DOE's Federal partners for all research, development and demonstration agreements and address a significant concern of industry about their ability to protect commercially valuable information developed as partner with the government.

DRAFT

04/28/95 09:03

Since the protection under the Energy Policy Act is limited to 5 years, federal efforts would afterwards be made public allowing others to benefit by taking those re (obtained in part with taxpayer dollars) and build on them.

Cons

The Atomic Energy Act of 1954, section 31d states that DOE's research agreements shall not prevent the dissemination of scientific or technical information except as o provided by law. This reflects the policy judgment of some that, absent exceptional circumstances, research funded with taxpayer dollars should be publicly available. The extension of current non-disclosure provisions to additional research may be criticized those grounds, with the claim that a few preferred contractors are allowed to tie up funded with taxpayer support for a period of time long enough to obtain all reasonabl commercial potential from that research.

There may be some increased administrative burden involved in protecting additional information from disclosure.

DRAFT

04/28/95 09:03

F. Specific Example of Targeted Regulatory Reform: Galvin Commission Recommendations

As part of the regulatory review, we have identified one additional specific area which administrative reform would be well-received by the affected communities.

DOE issues its own orders to laboratories relating to environment, safety and health. These orders are often far more restrictive than those imposed by regulatory agencies as EPA, FDA, and OSHA. In addition DOE laboratories are subject to a multitude of audits and reviews, some imposed by organizations outside the control of DOE management (e.g. the Congress), but many are inspired by DOE.

An extensive review of the DOE laboratories has just been completed, chaired by Robert Galvin, Chairman of the Executive Committee of Motorola clearly documents the excessive burden on DOE laboratories resulting from DOE orders, directives, and audits (see Appendix A of the report). The Secretary of Energy concurs that the existing system is costly, bureaucratic, and inefficient. Activities now ongoing within the Department are addressing some of the issues raised in the Galvin Committee Report. Given the intense budget pressures DOE will be under, we recommend that attention be directed toward achieving the large savings and increased efficiency that could be achieved by reducing excesses identified in the Galvin Report.

Recommendation

Department of Energy recognizes the seriousness of the situation and has steps underway to correct the deficiencies including revising their Directive system. Since 1994, the Department has eliminated about 25 percent of its orders (312 to 236). An accelerated order reduction effort is currently underway to reduce 103 of the remaining orders to 42 including 24 orders considered to be the most burdensome by our field offices and contractors. This accelerated effort will be completed by July 31, 1995. This will lead to a reduction in contractor requirements and overhead dollars. Orders that merely repeat external regulatory requirements are planned to be eliminated with the understanding that these external requirements must be followed. Any new orders that are developed (revisions to existing orders) are to include statements of resource impact and justification for issuance. DOE should be directed to complete this process with timelines and deliverables. At a minimum, DOE Orders should be done away with in cases where other federal agency regulations apply. In otherwise unregulated areas, the process should be that permits only those new orders

DRAFT

04/28/95 09:03

deemed essential to be promulgated. This should lead to a significant reduction in the Federal work force and allow the labs to reduce overhead and devote more of their resources to R&D.

Pros

- ? Removes what is generally recognized as excessive and costly oversight
- ? Responsive to findings of a prestigious review committee
- ? The DOE Lab Directors are unanimous in their belief that the Orders represent a seriously misguided oversight effort

Cons

- ? Some Orders are required to fulfill Congressional requirements of DOE's oversight responsibility
- ? The labs are more interested in carrying out their missions than adhering to regulations hence strenuous oversight is required
- ? This level of control is necessary to protect the public interest

DRAFT

04/28/95 09:03

II. FEDERAL LEADERSHIP IN COORDINATING FEDERAL, STATE, AND LOCAL REGULATORY ACTIVITIES

The burden of making regulatory activity operate more effectively rests at least much on state and local regulators as it does on the federal government. The federal government is in a unique position to provide leadership. Federal opportunities to work with states to establish linked electronic systems were discussed in an earlier section. Communication technologies will permit citizens to have a single point of entry, perhaps specialized to their unique interests, with links to all levels of government.

There are, however, many other areas where federal leadership could work to streamline complex, and occasionally contradictory regulatory actions at all levels of government. The actions needed will vary with each sector. Major actions are already underway in several areas including wage and tax reporting and efforts to coordinate product approval and building codes for the construction industry. We should take care for those actions, which are well underway.

Specific examples of projects could include:

? Coordinating of state, and federal wage and tax reporting. The interagency Government Information Technology Services group is developing coordinated electronic reporting systems for wages and taxes that will greatly simplify reporting requirements for individuals and businesses.

? Coordinating building codes and inspections. NIST and the Department of Energy are facilitating work by state and local building code organizations to provide a system that will simplify regulatory approvals for builders that must be in several jurisdictions and create reciprocity in approvals.

? Developing national standards for building products. NIST and DOE are also facilitating a process by which producers of building components can have their technologies inspected and certified in a way that will satisfy state, regional, national criteria and avoid redundant and expensive inspection and certification. The certifications and standards are unlikely to involve federal regulation but non-federal consortia or private inspection labs.

? Coordination of state, local, and federal environmental and zoning requirements. Builders and developers face a maze of requirements, paperwork, and inspections from

DRAFT

04/28/95 09:03

many different levels of government. Experiments which could combine all requirements in an integrated system would be of enormous value to the industr

Recommendation

The State and Federal Task Force should be asked to propose areas where Federal State, and local regulatory activities could be brought together in a way that simpli compliance and reporting for specific groups. Agencies with a prime responsibility in area should be assigned to take the leadership in convening state and local regulator authorities. A planning meeting involving the lead agency representatives and representatives of non-federal regulatory bodies should be convened to plan specific a

Pros

- ? The regulatory burdens faced by citizens and businesses can be reduced dramatically only if all levels of government cooperate in a streamlining effort.
- ? Progress in this area is eagerly solicited by the business community affected.

Cons

- ? May be difficult to deliver on schedule given the complexity of working with many different jurisdictions
- ? Without care, it may appear that the federal government is trying to us local functions

DRAFT

04/28/95 09:03

III. BIOTECHNOLOGY

Part of the impetus behind the effort to streamline and revamp Federal regulatory programs is the need to provide a system that encourages rather than stifles innovation and diffusion of newer, more efficient and cleaner technologies. Modern molecular biology offers several examples of how technological advances and increased understanding of biological processes are changing research, development and manufacturing in a variety of industrial sectors. Regulations that were intended to manage risks associated with new chemical entities or physical processes may not provide the optimal framework for new products and processes based on biological materials. Two examples of areas of difficulty are the Food and Drug Administration and the Environmental Protection Agency.

A. Simplify Approval of Biotechnology Drugs and Biologics

The majority of biotechnology products are reviewed by the Center for Biologics Evaluation and Review (CBER), although some are referred to the Center for Drug Development Evaluation and Review (CDER). The two centers operate under different authorizing legislation reflecting their individual historical mandates. This has led to inconsistencies in review and approval procedures that penalized drug manufacturers in certain cases. FDA has recognized this and has proposed a number of suggestions to remove the regulatory burden on CBER applicants and bring their reviews closer to procedures followed by CDER. This is very important in order to offer drug developers and manufacturers the flexibility to capitalize on technological progress as it occurs.

Changes in procedures to encourage the adoption of new methods without sacrificing public health or safety include:

- ? waiving the need for premarket approval of certain changes in manufacturing processes for biotechnology and traditional drugs,
- ? allowing the use of pilot facilities to produce drugs for development work, e.g., clinical trials,
- ? relaxing restrictions on the selection of subcontractors (originally intended to control variability of products made by living systems), and
- ? eliminating lot certification for insulin and antibiotics and updating quality control procedures for these products.

DRAFT

04/28/95 09:03

However, we believe more can be done along similar lines to speed up the approval process, reduce the regulatory burden, and focus agency resources without any decrease product safety or efficacy.

Specifically, we would recommend as a guiding principle that premarket approval manufacturing changes be required only in those cases in which the safety and efficacy of the product may be changed as a result of the process change. When the product can be fully documented as safe, effective, and unchanged, such approvals should not be required. The manufacturer would be held responsible for assuring a product that maintains the safety and efficacy as that produced using the original process.

In addition, manufacturing changes that do require FDA oversight should be allowed to go into effect in a timely fashion unless FDA has reason to object.

Pro

? The FDA and the Biotechnology Industry Organization support these recommendations.

Con

? The recommendations cannot be fully accomplished with administrative action alone. Implementation requires changes in the regulations issued under the Food, Drug and Cosmetic Act and the Public Health Service Act.

B. Facilitate Bioremediation Field Trials and Commercialization

There presently exists a reluctance to employ bioremediation in the U.S., largely because it is perceived as unproved technology, regulatory hurdles discourage application and the purveyors of conventional technology control the market. This reluctance will diminish substantially if large scale trials can be easily established to demonstrate efficacy. This proposal recommends a plan that would facilitate a scientifically objective evaluation of bioremediation as a predictable, safe, and cost effective clean-up option.

Recommendations

- (1) Dedicate one or more secure Federal field sites to coordinated, long-term research to underpin effective bioremediation of contaminated surface and subsurface environments.
- (2) Develop minimal state and Federal regulations to govern such restricted site field trials.

DRAFT

04/28/95 09:03

There are currently two primary regulatory constraints on the development and application of bioremediation as a clean-up option. The first constraint comes from the Resource Conservation and Recovery Act (RCRA) and its regulation of hazardous wastes administered by the EPA. Although EPA issued new rules for treatability studies in 1991 they are still not conducive to long-term research. There needs to be a mechanism for expediting RCRA rules when they apply to research applications on secure government land. The second constraint involves the use of recombinant (genetically altered) microorganisms in open field clean-up. This application of recombinant organisms come under the purview of the Toxic Substances Control Act (TSCA) also administered by the EPA. There needs to be a mechanism for expediting TSCA clearances when they apply to research applications on secure federal land.

In order for bioremediation to be successful, additional fundamental information must be obtained through field experimentation. Lacking progress at the field scale, extensive laboratory knowledge base that now exists cannot be exploited, and successful bioremediation will be largely serendipitous. Major knowledge gaps exist in the areas of delivery and transport of bioremediative agents (both native and genetically-engineered) within a contaminated site; biological fate (i.e., ecology, physiology, genetics) of the bioremediative agents, once they are introduced; availability of waste chemicals (including mixed wastes) to microbial attack, interactions between multiple chemical compounds and bioremediative agents in mixed-waste sites; and process monitoring and validation. The field knowledge gaps - which are bottlenecks to increased use of bioremediation - can be removed or minimized through coordinated iterative field research in the critical disciplines of microbial ecology, physiology, and genetics; geohydrology and geochemistry; and ecotoxicology. As field experimental data are verified, new discoveries can be transferred through engineering to the private sector for commercialization and application. Accordingly, dedicated federal field sites that include both contaminated and clean areas need to be made available to academic, government and private sector scientists and engineers. Specific examples of secure sites that also have access to appropriate analytical instrumentation include Oak Ridge National Laboratory, Pacific Northwest Laboratory, and selected National Environmental Research Parks.

Pros

- ? Will accelerate the development of new technology to clean up the environment
- ? Will stimulate the biotechnology industry and academics to devote more attention and creative thought to the subject.

Cons

- ? Will require EPA to develop a new, less stringent clearance for these test sites

DRAFT

04/28/95 09:03

? Will create some controversy among environmental public interest groups if not handled properly.

COURT-ORDERED DEADLINES MEETING
July 28, 1995

I. Background

A. Scope of Problem/ Proportion of Affected Resources

1. Many proscriptive statutory deadlines, in part imposed due to failure to meet (Tragedy of Distrust)
2. EPA review suggests moderate court-ordered program commitments ('94 Base Budget Review; OGC 11/94 Deadlines Project)

II. Current Approach to Managing Problem

- A. Strategic Implementation -- prioritize statutory deadlines (CAA Implementation Strategy)
- B. Vigorous negotiation -- take matters off the table when sued
- C. Build our preferred time outcome into Consent Decrees
- D. Build flexibility/relief valves into Consent Decrees & protect discretion (Effluent Guidelines Lamberth Consent Decree)
- E. Use minor relief valves -- frequent extensions
- F. Use major relief valves -- overall reprioritization -- attempt to achieve more rational system (SDWA)

III. Consent Decrees v. Litigation Results

- A. Litigation frequently results in shorter time frames, excised scientific or OMB review time (Litigation study)
- B. Debunking myths on constraining discretion (response to Abraham article)

TABLE 1**Significant EPA Rulemakings with Court Deadlines**

REQUIRED ACTION	JUDICIAL DEADLINE	REGULATORY EFFECT or ANNUAL COST (Source of Estimate)
Propose land disposal restrictions for Phase III (newly-identified wastes (wastewaters), any listed Category I carbamate wastes, and any listed organo-bromine wastes); promulgate revisions to "Third-Third" land disposal restrictions to respond to remand in CWM v. EPA	1/24/95 new - 2/23/95	\$100's of millions (OIRA/Other)
Propose to revise or not revise regulations concerning the testing of motor vehicles and motor vehicle engines.	1/31/95	\$175 - \$225 million (EPA)
Determine whether cement kiln dust should be regulated as hazardous wastes under Subtitle C of RCRA.	1/31/95	\$10's of millions (OIRA/Other)
Promulgate final hazardous waste listing determination for carbamates.	1/31/95	\$10 million (EPA)
Propose coastal oil and gas effluent guideline.	1/31/95	\$41 million (EPA)
Propose standards for medical waste incinerators under CAA §129.	2/1/95	\$425 million (EPA)
Promulgate final Ozone, CO FIPs for Los Angeles area, Ventura, and Sacramento. (Requirement to promulgate reversed by Congress)	2/22/95	\$1.8 - \$2.6 billion (EPA)
Propose pharmaceutical manufacturing effluent guideline.	2/28/95	\$80 million (EPA)
Supplemental Proposal for Risk Management Plans under CAA §112(r)	2/28/95	\$60 - \$200 million (EPA)

REQUIRED ACTION	JUDICIAL DEADLINE	REGULATORY EFFECT or ANNUAL COST (Source of Estimate)
Propose standards for one sources category - printing and publishing - under CAA §112d.	3/1/95	\$10's of millions (EPA)
Issue final Great Lakes Water Quality Initiative.	3/13/95	\$60 to 380 million (EPA)
Propose standards for 3-source categories (polymers and resins IV) under CAA §112d.	3/30/95	\$10's of millions (EPA)
Propose hazardous waste listing determination for category II and III solvents.	3/31/95 new - 3/31/96	unknown
Propose metal products and machinery - Phase I effluent guideline.	3/31/95	\$195 million (EPA)
Promulgate final hazardous waste listing determination for organobromine wastes.	4/30/95 new - 4/30/96	unknown
Propose criteria for RCRA Subtitle D facilities receiving waste from small quantity generators.	5/15/95	\$10's of millions (EPA)
Promulgate Phase I standards under CAA §213(a)(3) for small gasoline engines.	5/30/95	Over \$100 million? (RIA never submitted) (OIRA/Other)
Final MACT standards for secondary lead smelters.	5/31/95	Minor (EPA)
Response to National Food Processors Assn. petition due.	6/9/95	\$100's of millions (EPA?)
Final MACT standards for marine vessels.	6/29/95 new - 7/29/95	\$85 - \$150 million (EPA)
Issue final enhanced monitoring rules under CAA §114(a)(3). [Expect further extension of one year.]	6/30/95	unknown

REQUIRED ACTION	JUDICIAL DEADLINE	REGULATORY EFFECT or ANNUAL COST (Source of Estimate)
Final MACT standards for petroleum refineries.	6/30/95 new - 7/30/95	\$80 million (EPA)
Set Final standards for gasoline detergents under CAA §211(1) . (Interim program begun 10/14, deadline for final rule noe 6/95 extended to 3/96).	3/6	\$100+ million (EPA)
Propose land disposal restrictions for Phase IV (wood preserving wastes, aluminum potliners, TC metal wastes (D004-D017), characteristic mineral processing wastes, any listed dye and pigment production wastes, and remanded mineral processing wastes (K064-K066, K090-91) unless no longer generated).	7/30/95	\$100 Million to Greater Than \$1.2 Billion (EPA)
Final MACT standards for aerospace industries.	7/31/95	\$21 million (EPA)
Promulgate NPDWR for six radionuclides under SDWA.	*	\$100's of millions (EPA)
Propose NPDWRs for 13 contaminants under SDWA (Phase 6-B).	*	\$10's of millions to billions (EPA?)
Decision on whether to propose revocations of selected pesticide tolerances.	8/9/95	\$10's of millions (EPA?)
Propose standards for UIC Class 5	8/15/95	< \$10 million (EPA)
Propose hazardous waste identification rule (HWIR).	8/16/95	\$10's of millions - could be billions (EPA)
Propose NPDWR's for groundwater disinfection.	*	\$100's of millions (EPA)
Promulgate pesticides formulating and packaging effluent guideline.	(8/31/95) new - 5/31/96	\$10's of millions (EPA)

REQUIRED ACTION	JUDICIAL DEADLINE	REGULATORY EFFECT or ANNUAL COST (Source of Estimate)
Propose hazardous waste listing determination for petroleum refining wastes.	8/31/95	\$400 million (OIRA/Other)
Issue final standards for MWCs pursuant to CAA §129. (EPA expected to seek extension of deadline.)	9/1/95	\$445 million (EPA)
Propose standards (under either RCRA or CAA) for PM and metal emissions from facilities burning haz. waste solely for material recovery.	9/30/95	\$100 million (OIRA/Other)
Decide whether to propose revised emission standards (under either RCRA or CAA) for PM & CDDs for facilities burning haz. waste, & whether to propose revised stds. for small quantity burners.	9/30/95	\$100 million (OIRA/Other)
Decide whether to propose modification of NAAQs for NO ₂	10/2/95	unknown
Decision on whether to propose revocations of selected pesticide tolerances.	10/9/95	\$10's of millions
Propose regs regarding when munitions become hazardous wastes and providing for the safe transportation and storage of such waste.	10/31/95	\$10's to \$100's of millions (OIRA/Other)
Issue proposed revisions to NO _x NSPS for boilers under CAA.	10/31/95	unknown
Issue final revision to regulations concerning the testing of motor vehicles and motor vehicles engine.	10/31/95	\$175 - \$225 million (EPA)

REQUIRED ACTION	JUDICIAL DEADLINE	REGULATORY EFFECT or ANNUAL COST (Source of Estimate)
Final regs for marine vessel engines under CAA §112(d) printing & publishing; polymers & resins IV).	11/15/95	\$10's of millions (EPA)
Final regs for marine vessel engines under CAA §213(a)(3).	11/22/95	\$300 million (EPA)
Promulgate final hazardous waste listing determination for wastes from the production of azo/benzindine, anthraquinone and triarylemethane dyes and pigments.	11/30/95	\$10 million (EPA)
Propose NPDWR for arsenic under SDWA.	Report to Court by 10/17/95	\$10's of millions to \$1 billion (EPA)
Propose hazardous waste listing determination for chlorinated aliphatic wastes.	11/30/95	unknown
Promulgate rules under CAA §176(c) imposing conformity procedures in attainment areas.	12/31/95	unknown
Propose groundwater disinfection under SAWA.	*	\$100's of millions (EPA)

* - drinking water rulemaking schedules being revised based on Agency assessment and stakeholder input. EPA to tell court by 12/15/95 when rulemaking schedules will be ready.

TABLE 2

Incomplete EPA Rulemakings Submitted to OMB

RULE	JUDICIAL DEADLINE	SUBMITTED TO OMB	MISSING DOCUMENT AND DATE RECEIVED
HWIR	8/16/95	6/14/95	RIA, preamble, risk assessment missing
Phase IV LDR	7/28/95	5/3/95	Complete RCRA - Equivalency RIA - 6/15 Partial Mineral Processing Cost/Benefits Analysis 6/15
CA FIP	2/10/95	12/94/94	Completed Preamble - early February Completed RIA - early February
New Source Review Reforms	N/A	12/15/94	RIA received after 4/19/95
Marine Vessel	7/28/95	6/9/96	Still no complete preamble or background document Complete preamble received 7/27/95
Refinery MACT	6/30/95	6/14/95	RIA received 6/22/95

EPA's COURT-ORDERED AND SETTLEMENT-AGREEMENT DEADLINES

Updated: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
06/30/95	Oregon Natural Res. Council v. Browner, D.Ore, #93-79-AS.	Dubey, Air	Final rule setting standards for gasoline detergents under CAA §211(1). Parties have filed joint motion for extension of deadline to 3/29/96.
07/24/95	EDF v. EPA, E.D.N.C., #91-467 CIV	Winer, Water	Make CWA §404 wetland determination for Parker Tract in No. Carolina.
07/28/95	Sierra Club v. Browner, 93-0124	Averback, Air	Final MACT standards for petroleum refineries.
07/28/95	Sierra Club v. Browner, 93-0124	Horowitz, Air	Final MACT standards for marine vessels.
07/31/95	EDF v. Browner DDC #89-0598	Silverman, Waste	Propose land disposal restrictions for wood preserving wastes, aluminum potliners, TC metal wastes (D004-D017), characteristic mineral processing wastes, any listed dye and pigment production wastes, and remanded mineral processing wastes (K064-K066, K090-91) unless no longer generated (Phase IV).
07/31/95	Sierra Club v. Browner, DDC, #93-0124	Schwartz, Air	Final MACT standards for aerospace industries.

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
08/01/95	Miller v. Browner, D.Ore, #89-6328-JO	K. Clark, Water	Promulgate NPDWR for six radionuclides under SDWA.
08/01/95	Frohwerk v. Browner, D.Ore. #90-6363-JO	Sweeney, Water	Propose NPDWRs for 13 contaminants under SDWA (Phase 6-B).
08/15/95	Sierra Club v. Browner, DDC #93-2644	Curtin, Water	Propose standards for UIC Class 5.
08/16/95	Environmental Technology Council v EPA, DDC, #94-2119	Kaneen, Waste	Propose hazardous waste identification rule (HWIR).
08/30/95	Waxman & SCLDF v. Reilly, DDC, ##92- 1320 & 92-1749	Hannon, Air	Issue list of global warming potentials.
08/30/95	Donison v. Browner, D. Ore. 92-6280	K. Clark, Water	Propose NPDWR's for groundwater disinfection.
08/31/95	EDF v. Browner DDC, #89-0598	Openchowski, Waste	Propose hazardous waste listing determination for petroleum refining wastes.
09/01/95	NRDC v. EPA CV-92-2093	Fraser, Air	Issue final standards for MWCs pursuant to CAA §129.
09/15/95	California v. Browner, 89-0752	Fleuchaus, P&T	Decision on whether to propose revocations of selected pesticide tolerances.

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
09/30/95	Hazardous Waste Treatment Council v. EPA, DC Cir #91-1221	Silverman, Waste	Propose standards (under either RCRA or CAA) for PM and metal emissions from facilities burning haz. waste solely for materials recovery.
09/30/95	Alaska Center for the Environment v. EPA, WD Wash., #C90-595R	Siciliano, Water	Promulgate 4 TMDLs for Lemon Creek & Vanderbilt Creek in Alaska.
09/30/95	Hazardous Waste Treatment Council v. EPA, DC Cir #91-1221	Silverman, Waste	Decide whether to propose revised emission standards (under either RCRA or CAA) for PM & CDDs for facilities burning haz. waste, & whether to propose revised stds. for small quantity burners.
10/02/95	Oregon Natural Resources Council v. Browner, D.Ore #91-6529-HO	Backstrom, Air	Decide whether to propose modification of NAAQS for NO ₂
10/15/95	Sierra Club v. Browner, DDC 94-0553 & 94-0954	Embrey, Air	Rpt to Congress on acid rain deposition standard - CAA § 404
10/31/95	Tidewater Foundation v. EPA, DDC, #94 CV 02663	Michaud, Waste	Propose regs regarding when munitions become hazardous wastes and providing for the safe transportation and storage of such waste.

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
10/31/95	Waxman and SCLDF v. Reilly, DDC, ##92-1320 & 92-1749	Hannon, Air	Issue final revision to regulations concerning the testing of motor vehicles and motor vehicles engines (if 1/31/95 decision is to revise regs).
10/31/95	Sierra Club v. Browner, #93-0124 & Consolidated Cases	Fraser, Air	Issue proposed revisions to NOx NSPS for boilers under CAA.
11/15/95	Sierra Club v. Browner, #93-0124 (DDC)	Embrey, Horowitz, Air	Issue final standards for 4 source categories under CAA §112(d) printing & publishing; polymers & resins IV).
11/18/95	Alaska Center for the Environment v. EPA, WD Wash., #C90-595R	Siciliano, Water	Submit report assessing Alaska's monitoring program.
11/22/95	Sierra Club v. Browner, #93-0124 & Consolidated Cases	Marrella, Air	Final regs for marine vessel engines under CAA §213(a)(3).
11/30/95	EDF v. Browner DDC, #89-0598	Carpier, Waste	Propose hazardous waste listing determination for chlorinated aliphatic wastes.
11/30/95	Gearhart v. Browner, D. Ore., #89-6266	Witt, Water	List contaminants to be addressed in CWA Sludge Round II Rulemaking.
11/30/95	Miller v. Browner, D.Ore, #89-6328-JO	Bangser, Water	Propose NPDWR for arsenic under SDWA.

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
11/30/95	Northwest Environmental Advocates v. Browner, #C94-1666R	Siciliano, Water	If Oregon submits a CWA § 303(d) list to EPA by 9/30/95, EPA has until 11/30 to approve or disapprove the list.
11/30/95	EDF v. Browner DDC, #89-0598	Igoe, Waste	Promulgate final hazardous waste listing determination for wastes from the production of azo/benzidine, anthraquinone and triarylmethane dyes and pigments.
12/18/95	Alaska Center for the Environment v. EPA, WD Wash., #C90-595R	Siciliano, Water	Submit schedule to implement recommendations in monitoring report submitted on 11/18/95.
12/31/95	NRDC v. EPA, DDC, #89-2980	Wehling, Water	Complete steam electric industry study.
12/31/95	California v. Browner, #89-0752	Fleuchaus, P&T	Final action on proposed revocation of various pesticide tolerances.
12/31/95	NRDC v. EPA, DDC, #89-2980	Siciliano, Water	Complete iron and steel industry study.
12/31/95	California v. Browner, #89-0752	Fleuchaus, P&T	Decision on whether to propose revocations of selected pesticide tolerances.

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
01/16/96	CWM v. EPA, DC Cir.; EDF v. Browner, DDC #89-0598	Silverman, Waste	Promulgate land disposal restrictions for newly-identified wastes (wastewaters), any listed Category I carbamate wastes, & any listed organo-bromine wastes (Phase III); promulgate revisions to "Third-Third" land disposal restrictions to respond to remand in CWM v. EPA.
01/31/96	Environmental Technology Council v EPA, DC Cir.	Silverman, Waste	Promulgate rules for use of K061 wastes (encapsulated) which constitute disposal.
02/21/96	EDF v. Browner N.D. Calif, #92-1636.	Schneeberg, Air	Promulgate rules under CAA §176(c) imposing conformity procedures in attainment areas.
03/01/96	Sierra Club v. Browner, DDC 94-0553 & 94-0954	Fraser, Air	Administrator sign NPRM for emissions stnds for solid waste incinerators, CAA § 129(a)(1)(D).
03/15/96	Sierra Club v. Browner, 93-0124 (ADC)	Averback, Fraser, Air	Issue final standards for 4 source categories under CAA §112(d)
03/29/96	Sierra Club v. Browner, D. DC 94- 0553	Averback, Air	Issue final rule on RMP's under CAA§112(r) and related guidance.
03/31/96	EDF v. Browner DDC, #89-0598	Openchowski, Waste	Propose hazardous waste listing determination for category II & III solvents.

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
03/31/96	California v. Browner, 89-0752	Fleuchaus, P&T	Decision on whether to propose revocations of selected pesticide tolerances.
03/31/96	NRDC v EPA, DDC, #89-2980	Gordon, Water	Promulgate pesticides formulating and packaging effluent guideline.
04/01/96	Alaska Center for the Environment v. EPA, WD Wash., #C90-595R	Siciliano, Water	Develop problem assessments of certain waters on Alaska's 1992 CWA § 303(d) list to determine whether TMDLs are necessary.
04/14/96	ALA v. Browner EDNY, #92-CIV-5316	Gleason, Air	Final action on whether to revise primary NAAQS for SOx.
04/15/96	NRDC v. EPA, #CV-92-2093	Chang, Air	Issue final standards for medical waste incinerators, CAA §129
04/30/96	Sierra Club v. Browner, #93-0124 & Consolidated Cases	Thrift, Air	Propose Phase II standards for small gasoline engines under CAA § 213(a)(3).
04/30/96	EDF v. Browner DDC, #89-0598	Carprien, Waste	Promulgate final hazardous waste listing determination for organobromine wastes.
05/01/96	Alaska Center for the Environment v. EPA, WD Wash., #C90-595R	Siciliano, Water	Modify or reissue EPA-issued NPDES permits for seafood processors affected by Unalaska Bay and Akutan TMDLs promulgated by EPA for Alaska on 2/15/95.

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
05/19/96	Idaho Sportsmens Coalition v. Browner, WD Wash., #C93-943WD	Siciliano, Water	Submit, in conjunction with State of Idaho, reasonable schedule for developing TMDLs for waters on Idaho's CWA § 303(d) list.
05/31/96	Frohwerk v. Browner, D.Ore. #91-6549-TC	Clark, Water	Publish final findings of triennial review of technologies for TTHMs under SDWA.
05/31/96	Miller v. Browner, D.Ore, #89-6328-JO	Bangser, Water	Promulgate final NPDWR for sulfate under SDWA.
05/31/96	EDF v. Browner DDC, #89-0598	Openchowski, Waste	Issue the final report on toxicity and management of certain spent solvents.
06/03/96	LEAF v. Browner, # 92-40252-WS	Winer, Water	Promulgate water quality std. for Florida unless EPA approves state std.
06/07/96	Citizens Interested in Bull Run v. EPA, D.Ore. #92-1587-MA	Clark, Water	Promulgate final NPDWRs for 12 disinfection by-products (Phase 6-A) under SDWA.
06/18/96	California v. Browner, 89-0752	Fleuchaus, P&T	Final action on proposed revocation of various pesticide tolerances.

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
06/30/96	EDF v. Browner DDC, #89-0598	Badalamente Silverman, Waste	Promulgate final land disposal restrictions for wood preserving wastes, aluminum potliners, TC metal wastes (D004-D017), characteristic mineral processing wastes, any listed dye and pigment production wastes, and remanded mineral processing wastes (K064-K066, K090, K091) unless no longer generated (Phase IV).
06/30/96	EDF v. Browner DDC, #89-0598	Witt, Waste	Issue the final report on toxicity and management of certain petroleum refining wastes.
06/30/96	ALA v. Browner, D. Ariz., CIV-93-643-TUC-ACM	Gleason, Air	Propose any appropriate revision to NAAQS for particulate matter.
06/30/96	Sierra Club v. Browner, #93-0124	Martineau, Air	CAA §901 study on international air pollution control technology.
07/01/96	Sierra Club v. EPA, DDC, #93-2167	Gordon, Waste	Promulgate criteria for Subtitle D facilities receiving small quantity generator hazardous waste.
07/01/96	Sierra Club v. Browner, #93-0124 & Consolidated Cases	Tierney, Foote, Air	Issue final enhanced monitoring rules under CAA §114(a)(3).
07/31/96	NRDC v EPA, DDC #89-2980	Levine, Water	Promulgate coastal oil and gas effluent guideline.

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
08/28/96	NRDC v. EPA, DDC, #89-2980	Levine, Water	Publish 304(m) plan.
08/31/96	NRDC v EPA, DDC #89-2980	Siciliano, Water	Promulgate pharmaceutical manufacturing effluent guideline.
09/15/96	NRDC v EPA, DDC #89-2980	Witt, Water	Promulgate centralized waste treatment effluent guideline.
09/30/96	NRDC v EPA, DDC #89-2980	Clark, Water	Promulgate machinery manufacturing & rebuilding, Phase I effluent guideline.
09/30/96	Alaska Center for the Environment v. EPA, WD Wash., #C90-595R	Siciliano, Water	Develop TMDLs for two more unspecified waterbodies in Alaska.
10/01/96	Oregon Natural Resources Council v. Browner, D.Or. #91-6529-HO	Backstrom, Air	Make final decision whether to modify NAAQS for NO ₂
10/31/96	Tidewater Foundation v. EPA, DDC, #94 CV 02663	Michaud, Waste	Promulgate regulation regarding when munitions become hazardous wastes and providing for the safe transportation and storage of such waste.
10/31/96	EDF v Browner, DDC, #89-0598	Carpin, Waste	Promulgate final hazardous waste listing determination for chlorinated aliphatic wastes.

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
10/31/96	EDF v Browner, DDC, #89-0598	Openchowski, Waste	Promulgate final hazardous waste listing determination for petroleum refining wastes.
11/15/96	Sierra Club v. Browner, DDC #93-2644	Wehling, Water	Final action on proposed UIC Class 5 standards.
11/30/96	Sierra Club v. Browner, #93-0124 & Consolidated Cases	Martineau, Air	Make final determination under CAA §213(a)(2) that large gasoline engines or small diesel engines cause or contribute to air pollution or submit further schedule to Sierra Club.
11/30/96	EDF v Browner, DDC, #89-0598	Silverman, Waste	Promulgate final land disposal restrictions for Category II and Category III solvent wastes.
12/15/96	Hazardous Waste Treatment Council v. EPA, DC Cir., #91-1221	Silverman, Waste	Decide whether to issue final revised standards (under either RCRA or CAA) for emissions of PM & DCCs for facilities burning hazardous waste; decide whether to issue final revised standards for small quantity burners.
12/15/96	Hazardous Waste Treatment Council v. EPA, DC Cir #91-1221	Silverman, Waste	Promulgate standards (under either RCRA or CAA) for emissions of PM & metal emissions for facilities burning hazardous waste solely for materials recovery.
12/31/96	Environmental Technology Council v EPA, DDC, #94-2119	Kaneen, Waste	Promulgate final hazardous waste identification rule (HWIR).

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
12/31/96	NRDC v EPA, DDC #89-2980	Wehling, Water	Complete industry study # 8.
12/31/96	NRDC v EPA, DDC #89-2980	Levine, Water	Propose transportation equipment cleaning effluent guideline
12/31/96	NRDC v EPA, DDC #89-2980	Wehling, Water	Propose industrial laundries effluent guideline.
12/31/96	NRDC v EPA, DDC #89-2980	Levine, Water	Complete onshore oil & gas industry study.
12/31/96	EDF v Browner, DDC, #89-0598	Openchoswki, Waste	Propose hazardous waste listing determination for paint production wastes.
12/31/96	Sierra Club v. Browner, #93-0124 & Consolidated Cases	Fraser, Air	Issue final revisions to NOx NSPS for boilers under CAA.
01/31/97	ALA v. Browner, D. Ariz, CIV-93-643-TUC- ACM	Gleason, Air	Promulgate any appropriate revisions of NAAQS to particulate matter.
02/28/97	Citizens Interested in Bull Run v. EPA, D.Ore, #92-1587-MA	Sweeney, Water	Promulgate final NPDWRs for 13 contaminants (Phase 6-B) under SDWA.
03/20/97	California v. Browner, 89-0752	Fleuchaus, P&T	Final action on proposed revocation of various pesticide tolerances.

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
03/31/97	EDF v. Browner DDC, #89-0598	Kaneen, Badalamente, Waste	Propose hazardous waste listing determination for inorganic chemical industry wastes.
03/31/97	NRDC v EPA, DDC #89-2980	Witt, Water	Propose incinerators/ landfills effluent guideline.
03/31/97	EDF v. Browner DDC, #89-0598	Openchowski, Waste	Promulgate final hazardous waste listing determination for Category II and Category III solvent wastes.
03/31/97	California v. Browner, 89-0752	Fleuchaus, P&T	Decision on whether to propose revocations of selected pesticide tolerances.
04/30/97	Sierra Club v. Browner, #93-0124 & Consolidated Cases	Thrift, Air	Issue final Phase II standards for small gasoline engines under CAA §213(a)(3).
04/30/97	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Promulgate final land disposal restrictions for any listed petroleum refining wastes.
07/31/97	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Propose hazardous waste listing determination Category II carbamates (if still produced).
08/30/97	Donison v. Browner, D. Ore. 92-6280	K. Clark, Water	Promulgate final NPDWRs for groundwater disinfection.
09/01/97	NRDC v. Browner, DDC, #95-634 PLF	S. Sweeney, Water	Propose storm water regs under CWA § 402(p)(6). ["Storm Water Phase II"]

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
09/30/97	Alaska Center for the Environment v. EPA, WD Wash., #C90-595R	Siciliano, Water	Develop TMDLs for two more waterbodies in Alaska.
11/30/97	Miller v. Browner, D.Ore, #89-6328-JO	Bangser, Water	Promulgate final NPDWR for arsenic under SDWA.
12/31/97	NRDC v EPA, DDC #89-2980	Wehling, Water	Complete industry study #9.
12/31/97	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Issue report on a screening study of production wastes from all chemicals for which tests under TSCA have indicated the presence of dioxins or dibenzofurans.
12/31/97	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Promulgate final hazardous waste listing determination for paint production wastes.
12/31/97	NRDC v EPA, DDC #89-2980	Clark, Water	Propose machinery manufacturing and rebuilding, Phase II effluent guideline
12/31/97	NRDC v EPA, DDC #89-2980	Wehling, Water	Complete industry study #10.
12/31/97	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Promulgate final waste listing determination for triarylmethane dye and pigment production wastes.

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
12/31/97	NRDC v EPA, DDC #89-2980	Wehling, Water	Complete industry study # 11.
03/31/98	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Promulgate final hazardous waste listing determination for inorganic chemical industry wastes.
04/01/98	Gearhart v. Reilly, DDC, #91-2435	Messier, Waste	Determine whether to regulate wastes from the combustion of fossil fuels as hazardous wastes (Phase II).
06/30/98	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Promulgate final land disposal restrictions for any listed paint production wastes.
07/31/98	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Promulgate final hazardous waste listing determination for linuron wastes (if still generated).
07/31/98	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Promulgate final hazardous waste listing determination for dimethyl hydrazine wastes (if still generated).
07/31/98	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Promulgate final hazardous waste listing determination for Category II carbamate wastes (if still produced).
08/28/98	NRDC v. EPA, DDC, #89-2980	Wehling, Waste	Publish 304(m) plan.

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
09/30/98	Hazardous Waste Treatment Council v. EPA, DC Cir	Silverman, Waste	Propose stds. (under either RCRA or CAA) for emissions of PM and metals for boilers burning haz. waste.
09/30/98	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Promulgate final land disposal restrictions for any inorganic chemical industry wastes.
12/31/98	NRDC v EPA, DDC #89-2980	Levine, Water	Promulgate transportation equipment cleaning effluent guideline.
12/31/98	NRDC v EPA, DDC #89-2980	Wehling, Water	Promulgate industrial laundries effluent guideline.
12/31/98	NRDC v EPA, DDC #89-2980	Wehling, Water	Propose two effluent guidelines to be selected.
01/31/99	EDF v. Browner DDC, #89-0598	Badalamente, Waste	Promulgate final land disposal restrictions for any listed dimethyl hydrazine and linuron wastes.
01/31/99	EDF v. Browner DDC, #89-0598	Kaneen, Badalamente, Waste	Promulgate final land disposal restrictions for any listed Category II carbamate wastes.
03/01/99	NRDC v. Browner, DDC, #95-634 PLF	S. Sweeney, Water	Final storm water regs under §402(p)(6) of CWA. ["Storm Water Phase II"]
03/31/99	NRDC v EPA, DDC #89-2980	Witt, Water	Promulgate landfills/ incinerators effluent guideline.

Deadline Calendar: Compiled: July 15, 1995

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
07/02/99	Cronin v. Browner, SDNY #93-0314	Gravellese, Water	Propose CWA § 316(b) standards (cooling water intakes).
12/15/99	Gearhart v. Browner, D.Ore. #89-6266	Witt, Water	Propose sewage sludge, Phase 2 regulations.
12/15/99	Hazardous Waste Treatment Council v. EPA, DC Cir	Silverman, Waste	Promulgate final stds. (under either RCRA or CAA) for emissions of PM and metals from boilers burning hazardous waste.
12/31/99	NRDC v EPA, DDC #29-2980	Wehling, Water	Propose two effluent guidelines to be selected.
12/31/99	NRDC v EPA, DDC #29-2980	Clark, Water	Promulgate machinery manufacturing and rebuilding effluent guideline.

**EPA's COURT-ORDERED AND SETTLEMENT-AGREEMENT DEADLINES
AFTER JANUARY 1, 2000**

DATE DUE	CASE NAME & DOCKET NUMBER	OGC ATTORNEYS	REQUIRED ACTION
02/09/2000	California v. Browner, 89-0752	Fleuchaus, P&T	Final action on proposed revocation of various pesticide tolerances.
08/28/2000	NRDC V. EPA, DDC, #29-2980	Wehling, Water	Propose 304(m) Plan
12/31/2000	NRDC V. EPA, DDC, #29-2980	Wehling, Water	Promulgate 2 effluent guidelines proposed by 12/31/98.
12/31/2000	NRDC V. EPA, DDC, #29-2980	Wehling, Water	Propose 2 effluent guidelines, to be selected.
08/03/2001	Cronin v. Browner, SDNY, #93-0314	Gravellese, Water	Take final action on CWA § 316(b) proposal.
12/15/2001	Gearhart v. Browner, D.Ore, #89-6266	Dubois, Water	Promulgate sewage sludge, Phase 2, regulations.
12/31/2001	NRDC V. EPA, DDC, #29-2980	Wehling, Water	Propose 2 effluent guidelines, to be selected.
12/31/2001	NRDC V. EPA, DDC, #29-2980	Wehling, Water	Promulgate 2 effluent guidelines proposed by 12/31/99.
08/28/2002	NRDC V. EPA, DDC, #29-2980	Wehling, Water	Publish 304(m) Plan
12/31/2002	NRDC V. EPA, DDC, #29-2980	Wehling, Water	Promulgate 2 effluent guidelines proposed by 12/31/2000.
12/31/2003	NRDC V. EPA, DDC, #29-2980	Wehling, Water	Promulgate 2 effluent guidelines proposed by 12/31/2001.

Gary - FYI

in
CASE

you
hadn't
yet
seen
this
M.L.G.

A. The Breeding of Regulatory Failure

Congress responded to the perception of a national consensus in environmental protection by passing a series of laws in the 1970s that set the stage for institutional conflict and agency failure. Congress lacked the incentive to address or emphasize the pitfalls and chose instead to join the chorus in favor of immediate and fundamental change.⁴⁶ The congressional votes in favor of the new laws were accordingly overwhelmingly favorable. The average vote in favor of major federal environmental legislation during the 1970s was seventy-six to five in the Senate and 331 to thirty in the House.⁴⁷ As one legislator put it in describing his reluctant vote in favor of safe drinking water legislation in 1974, "[a]fter all, if one votes against safe drinking water, it is like voting against home and mother."⁴⁸

1. *From Public Aspiration to Statutory Mandate.* The federal environmental statutes of the early 1970s were dramatic, sweeping, and uncompromising, consistent with the nation's spiritual and moral resolution of the issue. The laws also reflected skepticism and distrust of agency implementation of statutory mandates, consistent with agency capture theory and the general political ill will then existing between the executive and legislative branches. The statutes imposed hundreds of stringent deadlines on the agency and removed much of the agency's substantive discretion in accomplishing them. One-third of the deadlines were for six months or less.⁴⁹ Sixty percent were for one year or less.⁵⁰ According to EPA's current administrator, William Reilly, Congress and the courts had imposed 800 deadlines on the agency through 1989.⁵¹ Congress made no effort to bridge the gap between the nation's aspirations for environmental protection and its understanding of the underlying issues and its own capacity for change.

The result was a seemingly never-ending onslaught of impossible agency tasks. Eighty-six percent of the statutory deadlines applied specifically to

46. John P. Dwyer, *The Pathology of Symbolic Legislation*, 17 *Ecol L Q* 233 (1990).

47. These numbers are based on the last recorded roll call vote taken in each chamber for each of the major bills ultimately passed by Congress in the 1970s. In most cases, the final votes were voice votes. The statutes covered include the Clean Air Act of 1970 ("CAA"), the Federal Water Pollution Control Act ("FWPCA"), the 1977 Clean Air Act, the 1977 Clean Water Act ("CWA"), the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), the Resource Conservation and Recovery Act ("RCRA"), and the Toxic Substances Control Act ("TSCA"). The numbers do not reflect the votes in favor of the Safe Drinking Water Act ("SDWA") in 1974 because there does not appear ever to have been a recorded roll call vote in the Senate. The formal votes are not, of course, an accurate measure of congressional support for every aspect of the bills passed. Many parts of those bills were likely quite contentious and, if added by amendment during debate, might well have been adopted by the narrowest of margins. The final votes are more lopsided because each legislator is faced with an all or nothing choice.

48. 120 Cong Rec 37594 (Nov 26, 1974) (remarks of Sen. Cotton).

49. *Statutory Deadlines In Environmental Legislation: Necessary But Need Improvement* 13-14 (Envir & Energy Study Inst and Envir L Inst, 1985) ("EESI, *Statutory Deadlines*").

50. *Id.*

51. See William K. Reilly, *The Turning Point: An Environmental Vision for the 1990s* (Marshall Lecture at the Natural Resources Defense Council, Nov 27, 1989), reprinted in 20 *Envir Rptr Curr Dev (BNA)* 1386, 1389 (Dec 8, 1989).

EPA.⁵² EPA was "told to eliminate water pollution, and all risk from air pollution, prevent hazardous waste from reaching ground water, establish standards for all toxic drinking water contaminants, and register all pesticides."⁵³ To date, EPA has met only about 14 percent of the congressional deadlines imposed and has had 80 to 85 percent of its major regulations challenged in court.⁵⁴

a. *Air Pollution.* In the Clean Air Act Amendments of 1970,⁵⁵ Congress mandated the achievement by 1975 of national ambient air quality standards ("NAAQS") necessary for the protection of public health (primary standard) and public welfare (secondary standard).⁵⁶ Congress also instructed EPA to publish an initial listing of "hazardous" air pollutants within ninety days and then, within 180 days of its listing, to publish for each such pollutant a proposed "emission standard" for the protection of public health.⁵⁷ The deadline for final emission standard regulations was 180 days later.⁵⁸ Congress established a similarly rigid schedule for EPA's listing of categories of stationary sources that "may contribute significantly to air pollution which causes or contributes to the endangerment of public health or welfare" (ninety days), and an even tighter schedule for promulgation of regulations for new sources (120 days after inclusion as a secondary source for proposal; ninety days after proposal for final promulgation).⁵⁹ The Clean Air Act also mandated that the administrator achieve a 90 percent reduction in existing automotive pollutant levels by 1975 (hydrocarbons and carbon monoxide) and 1976 (nitrogen oxides), with a narrow provision for a possible one-year extension.⁶⁰

The administrative task was enormous. It required strict regulation of 20,000 to 40,000 major stationary sources of air pollution, millions of cars

52. EESI, *Statutory Deadlines* at 11 (cited in note 49). The remaining 14% was evenly divided between the regulated community (including public water supply companies) and the states. *Id.*

53. Council on Environmental Quality, *Sixteenth Annual Report* 14 (U.S. Govt Printing Office, 1985) ("CEQ, *Sixteenth Annual Report*").

54. EESI, *Statutory Deadlines* at ii, 12 (cited in note 49) (14% compliance refers to all environmental statutory deadlines, 86% of which apply to EPA); Bryner, *Bureaucratic Discretion* at 117 (cited in note 37) (80% of EPA's major regulations challenged in court). See CEQ, *Sixteenth Annual Report* at 2-3 (cited in note 53) ("Fully 85 percent of EPA's regulations result in litigation.").

55. Pub L No 91-604, 84 Stat 1676 (1970), then codified at 42 USC §§ 1857 et seq (1970). Apart from scattered minor revisions, Congress has amended the Clean Air Act twice: in 1977 (Pub L No 95-95, 91 Stat 685 (1977)) and 1990 (Pub L No 101-549, 104 Stat 2391 (1990)). The 1977 amendments also called for a recodification of the entire Act, now found at 42 USC §§ 7401-7642 (1988).

56. Congress authorized EPA to extend for up to two years the 1975 deadline for compliance with the primary standard. Congress also authorized EPA to extend the deadline for submission of the plans for compliance with the Act's secondary standards. See Clean Air Act Amendments of 1970, Pub L No 91-604, §§ 109, 110, 84 Stat 1679-83, then codified at 42 USC §§ 1857c-4, 1857c-5 (1970). See generally James E. Krier & Edmund Ursin, *Pollution and Policy* 200-08 (U Cal Press 1977).

57. Clean Air Act Amendments of 1970, Pub L No 91-604, §§ 112(b)(1)(A)-(B), 84 Stat 1685 then codified at 42 USC §§ 1857c-7(b)(1)(A)-(B) (1970).

58. 42 USC § 1857c-7(b)(1)(B) (1970).

59. *Id.* § 1857c-6(b)(1).

60. *Id.* § 1857f-1.

61.
62.
Comm
63.
of Clea
Institut
include
in the
deadlin
64.
Law &
65.
66.
Congres
on only
(Pub L 1
67.
(2), 86 S
Environm
68.
1972).

and trucks being driven by average citizens,⁶¹ and 275 toxic air pollutants (sixty of which are known or suspected carcinogens),⁶² many of which were emitted by industries vital to local economies. In short, the Act challenged not only "business as usual" but "life as usual" in the United States and demanded that EPA immediately seek dramatic change in both. The short time scale necessarily precluded prolonged attention to the tremendous scientific uncertainty associated with the complex mechanics of air pollution. It also did not allow for much serious agency consideration of the relative costs and benefits of air pollution reduction. Neither the NAAQS nor the toxic emission standards allowed for any significant consideration of their economic costs.

Not surprisingly, fewer than 15 percent of the Clean Air Act's deadlines were met. None of those met pertained to compliance with environmental quality standards.⁶³ Twenty years later, many areas of the nation still have not met the NAAQS. Both EPA and Congress have given the auto companies numerous extensions of the deadline for meeting 90 percent reduction in emissions of hydrocarbons, carbon monoxide, and nitrogen oxides, and, twenty years later, the companies have still not reduced nitrogen oxides by 90 percent.⁶⁴ EPA has acted on only seven of the 274 known hazardous substances emitted into the air.⁶⁵

b. *Water Pollution.* The Federal Water Pollution Control Act Amendments of 1972 took a similar approach.⁶⁶ The 1972 enactment sought fishable and swimmable waters everywhere by 1983 and zero discharge of pollutants by 1985,⁶⁷ and it made unlawful any discharge of pollutants into navigable waters absent a permit issued by EPA. The act instructed EPA to require through the permitting process that industry secure the "best practicable control technology currently available" ("BPT") by 1977 and "best available technology economically achievable" ("BAT") by 1984.⁶⁸

61. Melnick, *Regulation and the Courts* at 307 (cited in note 8).

62. Clean Air Act Amendments of 1990, Report of the House Committee on Energy and Commerce, HR Rep No 101-490, 101st Cong. 2d Sess 151-52 (1990).

63. See EESI, *Statutory Deadlines* at 11-16 (cited in note 49). The 15% figure reflects the number of Clean Air Act deadlines that EPA had met as of 1985 when the Environmental and Energy Study Institute released its report on statutory deadlines. Because, however, that study necessarily included the Clean Air Act Amendments of 1977, which extended some of the deadlines established in the original 1970 Act, the 15% figure is likely high with regard to EPA's meeting the earlier deadlines.

64. See Frederick R. Anderson, Daniel R. Mandelker & A. Dan Tarlock, *Environmental Protection: Law & Policy* 203-06 (Little, Brown, 1990).

65. HR Rep No 101-490 at 151 (cited in note 62).

66. Pub L No 92-500, 86 Stat 816-903, then codified at 33 USC §§ 1251-1376 (Supp II 1972). Congress has since enacted scattered revisions of the law but has passed comprehensive amendments on only two subsequent occasions: in 1977 when Congress renamed the law the Clean Water Act (Pub L No 95-217, 91 Stat 1566) and then again in 1987 (Pub L 100-4, 101 Stat 7).

67. Federal Water Pollution Control Act Amendments of 1972, Pub L No 92-500, §§ 101 (a)(1)-(2), 86 Stat 816, then codified at 33 USC §§ 1251(a)(1), (2) (Supp II 1972). See generally Rodgers, *Environmental Law* § 4.2, at 361-68 (cited in note 41).

68. Pub L No 92-500, 86 Stat 844, then codified at 33 USC §§ 1311(b)(1)(A), (2)(A) (Supp II 1972).

Section 306 of the Act compelled EPA to require new sources of water pollution to achieve effluent reduction "achievable through the application of the best available demonstrated control technology" ("BDT").⁶⁹ EPA was supposed to promulgate effluent guidelines by October 1973 and permit limitations by December 1974.⁷⁰

The required administrative undertaking was no less daunting than that posed by the Clean Air Act. There are at least 68,000 point sources of water pollution requiring federal permits and probably thousands more.⁷¹ As one commentator put it, to develop appropriate effluent limits for each of those sources based on BPT, BAT, and BDT technological standards demanded "omniscience."⁷² The zero discharge goal was plainly impossible and the fishable/swimmable mandate could not, in any event, be met by the strict technology-based effluent reduction requirements of the permit program; the large amount of nonpoint pollution not covered by the Act's permitting program was sufficient, by itself, to prevent EPA's success.⁷³ By 1985, only 18 percent of the deadlines established by federal water pollution legislation had been met.⁷⁴ As with the Clean Air Act, none of the deadlines for compliance with environmental quality standards was met.⁷⁵

c. *Pesticides, Toxic Substances, and Hazardous Waste*. In the 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"),⁷⁶ Congress gave EPA just four years to review approximately 50,000 pesticides that had previously been registered under far more permissive statutory requirements.⁷⁷ For registration, EPA had to determine that the pesticide's intended use would not cause "unreasonable adverse effects on the environment" when used "in accordance with widespread and commonly recognized practice."⁷⁸ The 1976 deadline, like others, proved

69. Pub L No 92-500, 86 Stat 854, then codified at 33 USC § 1316 (Supp II 1972).

70. Id § 1316(b)(1).

71. EPA had issued this number of permits under the act by October 1982. A. Myrick Freeman, III, *Water Pollution Policy*, in Portney, ed, *Public Policies for Environmental Protection* at 112 (cited in note 11). Thousands of facilities discharge into permitted, publicly owned treatment works. See *State of the Environment—A View Toward the Nineties* 102 (Conservation Foundation, 1987) ("A recent EPA study, for instance, identifies about 160,000 industrial and commercial facilities that discharged wastes containing hazardous constituents to publicly owned treatment works.").

72. Charles L. Schultze, *The Public Use of the Private Interest* 52 (Brookings Inst, 1977).

73. See John E. Bonine & Thomas O. McGarity, *The Law of Environmental Protection: Cases—Legislation—Policies* 436-37 (West, 1984). See generally *State of the Environment* at 104-06 (cited in note 71); Daniel R. Mandelker, *Controlling Non-Point Source Water Pollution: Can It Be Done*, 65 Chi-Kent L Rev 479, 480-82 (1989).

74. EESI, *Statutory Deadlines* at 12 (cited in note 49).

75. Id at 12, 15.

76. Pub L No 92-516, 86 Stat 973-999, then codified at 7 USC §§ 136-136y (Supp II 1972).

77. See Note, *Pesticide Safety Regulation Under the Federal Insecticide, Fungicide and Rodenticide Act: Debacle at the Environmental Protection Agency*, 1 Fordham Envir L J 47, 51 (1989) (authored by John P. Gasior). Unlike the congressional committees that fashioned the other major environmental protection laws of the early and mid-1970s, those who drafted the 1972 FIFRA amendments were not "strongly committed to environmental values." Rodgers, *Environmental Law* § 8.3, at 849 (cited in note 41). As a result, the law's "sometimes contradictory aims compound the usual problems of interpretation." Id at 850.

78. 7 USC § 136a(c)(5) (Supp II 1972).

I
i
r
a
th
E
th

19
in
to
the
ass

clea
Con
after
regt
treat
Com
("CE
clean
lawsu
the si
lawsui
Th
the me
hazard

79.
80. I
81. C
editorial
Washingt
has mana
82. W
83. P
84. Se
Qualified S
Environmen
21-22 (cite
85. Cf
Environmen
86. Pul
87. Id.
88. Pul
1980).
89. 42

impossible. EPA believed that it would take at least ten years to complete the re-registration process, and it has actually taken much longer.⁷⁹ EPA has issued relatively few final re-registrations each year.⁸⁰ By 1984, EPA had re-registered less than half of the 600 active pesticide ingredients and had not addressed any of the 900 inert ingredients, some of which may be more toxic than the active ingredients.⁸¹ Before recent changes in the pesticides law, EPA's rate of re-registration suggested that the agency would not complete the re-registration process until 2024.⁸²

The Toxic Substances Control Act ("TSCA"), which became law in 1976,⁸³ asked EPA to review approximately 50,000 to 55,000 chemicals then in commerce as well as each of the 1,000 new chemicals introduced each year to determine if they "may present an unreasonable risk of injury to health or the environment."⁸⁴ By 1985, EPA had performed the necessary health assessments on fewer than 100 of the chemicals in commerce.⁸⁵

Finally, congressional dictates to EPA regarding the regulation and cleanup of hazardous wastes were no less overwhelming. In the Resource Conservation and Recovery Act of 1976 ("RCRA"),⁸⁶ enacted just ten days after TSCA, Congress gave EPA only eighteen months to promulgate regulations regarding the identification, generation, transportation, treatment, storage, and disposal of hazardous wastes.⁸⁷ In the Comprehensive Environmental Response Compensation and Liability Act ("CERCLA"), enacted in 1980,⁸⁸ Congress authorized EPA to take action to clean up inactive and abandoned hazardous waste sites either by filing lawsuits against those who contributed to the sites to force them to clean up the sites themselves, or by arranging for government cleanup, followed by lawsuits for reimbursement from contributors.⁸⁹

These mandates on hazardous waste control and cleanup may have proved the most difficult to achieve. There are approximately 650,000 generators of hazardous wastes producing 250 million metric tons of such waste each

79. Anderson, Mandelker & Tarlock, *Environmental Protection* at 577 (cited in note 64).

80. *Id.*

81. CEQ, *Sixteenth Annual Report* at 14-15 (cited in note 53). A more recent Washington Post editorial found even less EPA progress in pesticide re-registration. See *More Minutes on Pesticides*, Washington Post A26 (Nov 2, 1989) ("Of more than 600 active ingredients in older pesticides, EPA has managed in 17 years to complete the reevaluation by modern techniques of fewer than 10.")

82. William H. Rodgers, 3 *Environmental Law: Pesticides and Toxic Substances XI* (West, 1988).

83. Pub L No 94-469, 90 Stat 2003-2051, codified at 15 USC §§ 2601-2629 (1988).

84. See 15 USC § 2603(a)(1)(A) (1988) (TSCA testing requirements); Steven Cohen, *EPA: A Qualified Success*, in Sheldon Kamieniecki, Robert O'Brien & Michael Clarke, eds, *Controversies in Environmental Policy* 191 (State U NY Press, 1986); Portney, *Public Policies for Environmental Protection* at 21-22 (cited in note 11).

85. CEQ, *Sixteenth Annual Report* at 15 (cited in note 53). See also Portney, *Public Policies for Environmental Protection* at 21-22 (cited in note 11).

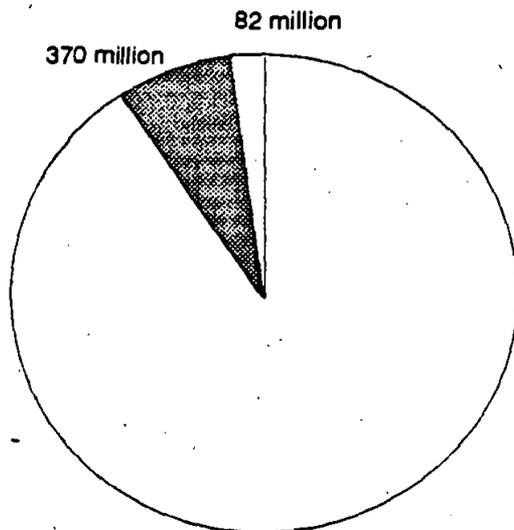
86. Pub L No 94-580, § 2, 90 Stat 2795-2841, then codified at 42 USC §§ 6901-6987 (1976).

87. *Id.*, 90 Stat 2806-2808, then codified at 42 USC §§ 6921-6925 (1976).

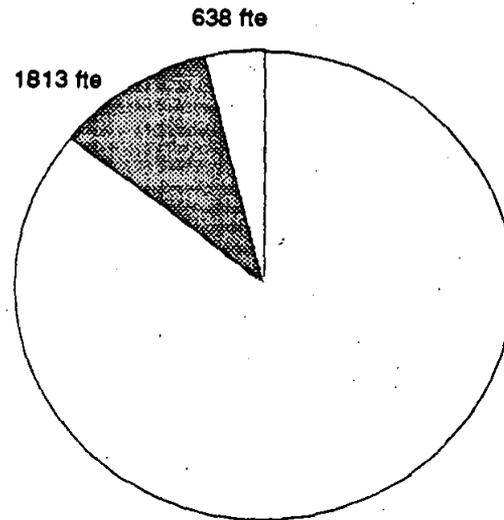
88. Pub L No 96-510, § 2, 94 Stat 2767-2811, then codified at 42 USC §§ 9601-9657 (Supp IV 1980).

89. 42 USC §§ 9604-9607 (1988).

**Agency-wide Resources
Core Program, Statutory Deadlines and Court-ordered Deadlines**



**Extramural Dollars
Total = 4.8 Billion**



**FTE
Total = 17.5 Thousand**

- Core Program
- Statutory Deadline
- Court-ordered Deadline

NOTE:

- "Court-ordered" deadlines include those resources required for a program to do something by a certain date as directed through the judicial process.
- "Statutory deadlines include one-time only deadlines for implementing various sections of a statute.
- All other resources are included as the "core program."

<u>Environmental Protection Agency</u>	
Extramural Dollars	4.83 billion
Ceiling and PRO	1.53
Total FY 1994	6.36
Total FTE	17,474



Implementation Strategy For The Clean Air Act Amendments Of 1990

Update, May 1994

INTRODUCTION

This is the fourth in a series of Implementation Strategy documents issued to inform Congress and the public on the status of activities implementing the Clean Air Act Amendments of 1990. The paragraphs immediately following present highlights of the past year's activities, as well as a summary of achievements to date. The remainder of the document consists of a cumulative list of significant actions already taken to carry out the 1990 Amendments, as well as a two-year projection of future activities.

An overarching Clean Air Act goal of this Administration is to restore the confidence of key constituencies—including Congress, business, state and local governments, and environmental and health advocates—in EPA's commitment and competence to carry out the mandates of the Act. To accomplish this, we are streamlining our internal processes and working with OMB to cut lag times and meet deadlines for regulations, reports, and State Implementation Plan (SIP) approvals. We recently announced a reform of EPA's rule development system which is expected to achieve substantial reductions in the time it takes to move a rule through EPA, and we have negotiated with OMB to obtain review exemptions for a substantial percentage of our rules—about 30 percent have been exempted to date, and we expect this to increase as we both become more comfortable with the exemption process. The combined effect of these reforms will greatly help us meet our deadlines.

HIGHLIGHTS OF THE PAST YEAR

The past year has been notable for EPA achievements in breaking the gridlock on proposing or finalizing a number of challenging and important Clean Air Act rules. Among the highlights of the year's activities are the following:

Attainment of Air Quality Standards

• The Clean Air Act is working to bring cleaner air to our nation's cities. Air quality data for 1992 show that 46 of the 98 ozone areas and 21 of 41 carbon monoxide areas originally designated as "non-attainment areas" after the

1990 Amendments were signed into law now have air quality in line with national health standards. Many are now going through the process of meeting the Act's requirements for being redesignated as meeting the standards. Of the ozone areas, 25 have formally submitted requests, and four areas already have been redesignated.

• Final rules were published requiring that Federally-approved development activities help to achieve air-quality goals by conforming to requirements of the Clean Air Act; consensus on these highly controversial rules was reached via an unprecedented consultation process among Federal agencies and air-quality officials.

Air Toxics Control

• A final rule was issued controlling toxic air emissions from chemical plants, reducing toxic emissions by one billion pounds annually. Final rules were also issued for steel industry coke ovens and dry cleaners.

• Rules were proposed for controlling toxic air emissions from seven more industry categories: commercial sterilizers, magnetic tape coating operations, gasoline marketing, chromium electroplating, pulp and paper production, industrial cooling towers, and degreasing operations.

• A comprehensive study of air toxics from automobiles was published, which will be used to assess the need for future controls.

Control of Emissions from Vehicles and Fuels

• Final rules were published on reformulated gasoline and emission standards for heavy-duty non-road engines.

• Final standards were published to reduce particulates from urban buses by over 90 percent.

• A final rule was published controlling emissions from automobile refueling via onboard vapor recovery, breaking years of gridlocked debate on this issue.

Protection of Stratospheric Ozone

• A number of final rules protecting stratospheric ozone were published, most notably the rule accelerating to 1995 the phaseout of the most harmful ozone-depleting sub-

stances, including CFCs. Other rules include a refrigerant recovery rule, a ban on nonessential products, a requirement to label products made with ozone-harming substances, and rules promoting safe substitutes for these substances and requiring Federal agencies to avoid procuring ozone-depleting substances.

- Late this spring, a joint EPA-National Weather Service project will begin producing daily forecasts of ultraviolet radiation for several U.S. cities. Television weather forecasters are expected begin advising the public each night if extra care should be taken the next day to limit exposure to the sun -- for example, by applying sunscreen or wearing sunglasses.

NOx Control to Prevent Acid Rain and Smog

- A final rule was published controlling powerplant NOx emissions as part of the acid rain program. Several alternative control technology documents for NOx control also were published.

Enforcement

- A proposed rule was published establishing an enhanced emissions monitoring program for all major sources covered by the Clean Air Act.

- EPA levied the largest penalty ever under the Clean Air Act (\$11.1 million) against the Louisiana-Pacific Corporation for failure to comply with permitting procedures under the Act. The settlement requires state-of-the-art control equipment which will reduce emissions of particulates, carbon monoxide and volatile organic compounds by more than 20,000 tons per year.

- Rules were proposed to provide monetary awards to citizens who uncover violations of the Clean Air Act, and to allow Federal inspectors to issue on-the-spot notices of violation for non-compliance with Federal rules.

Economic Incentives

- A final rule was published promoting and providing guidelines for the use of economic incentives in Clean Air Act programs.

- Two major elements of the market-based emissions trading system for the acid rain control program -- the allowance tracking system and the allowance allocations rule -- were put in place. The innovative system of marketable allowances is expected to cut cleanup cost by half compared to a comparable non-market program.

In addition to these rulemaking highlights, a large number of important supporting actions were taken, including publishing of several kinds of guidance documents for use by the States, and approving/disapproving submittals of State plans to achieve air quality standards. Many of these activities are listed in the cumulative schedule presented later in this report.

SUMMARY OF ACHIEVEMENTS SINCE ENACTMENT

Both in terms of emission reductions and number of rulemakings, EPA has now completed a large portion of the rulemaking actions set out by Congress in the 1990 Amendments. As of the end of March, over 200 actions have been published in the *Federal Register*—113 rules have been proposed, and 88 of these have been completed. The rules already completed will control emissions from the most important air pollution sources, and account for more than 90 percent of the 57 billion pounds of emissions reductions expected from the 1990 Amendments. The remainder of the rules already proposed and under development, when completed, will account for much of the remainder. A summary of the most important of these rulemakings follows.

Preventing Acid Rain

- We have nearly completed rules implementing the Acid Rain Program, an innovative market-based program to protect our lakes, streams and other resources from acid-rain-causing sulfur dioxide and nitrogen oxide emissions.

Protecting the Ozone Layer

- We have issued all of the major rules needed to implement the CAA's program for protecting the stratospheric ozone layer. The rules require a gradual phase-out of the production of ozone-depleting chemicals, the labeling of products containing or manufactured with ozone-depleting chemicals, and the recycling of ozone-depleting compounds.

- These rules, in combination with international restrictions, are expected to halt erosion of the ozone layer. International agreements to phase out ozone-depleting chemicals, in which the United States played a leading role, already have slowed the rate of increase of CFC concentrations in the stratosphere. Ozone concentrations are expected to recover eventually to levels observed prior to 1985 if these measures continue to be implemented.

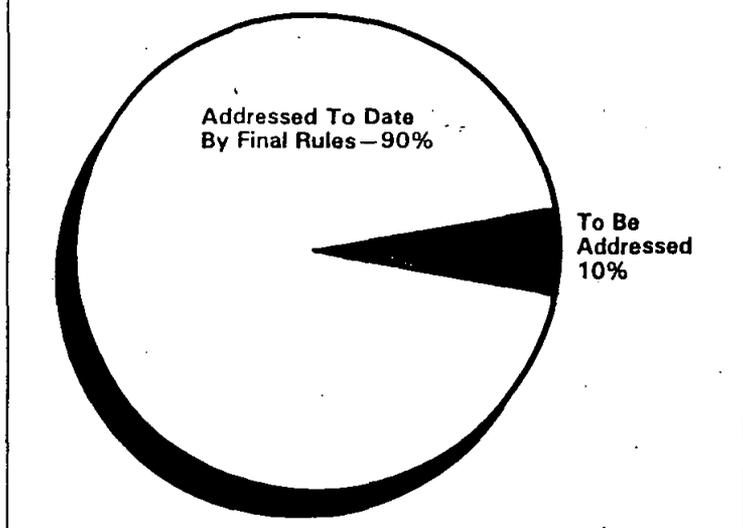
Cleaning up Fuels and Vehicles

- We have issued 15 major final or proposed rules that will cut motor vehicle emissions and help to bring clean air to our nation's cities. Among these are final rules on tier I tailpipe standards, on-board diagnostic devices, evaporative emissions controls, cold-start carbon monoxide standards, reformulated gasoline, heavy-duty non-road engine standards, clean fuel fleet programs, urban bus standards, and on-board vapor recovery.

Controlling Air Toxics

- We have laid the foundation for cutting toxic emissions from all major pollution sources by issuing several critical rules and beginning to move large numbers of additional rules through the regulatory pipeline. In addition to the aforementioned final rules for the chemical industry, coke

Emissions Reduction To Date



ovens, and dry cleaners, air-toxics rulemakings for about 40 source categories are now in progress. Most of these efforts have moved forward quickly since January 1993. Several rules have been proposed recently, and many more are to be proposed during the next two years.

- While moving forward with standards, EPA has also established the groundwork for the air toxics program by issuing essential program infrastructure rules -- for example, general provisions for monitoring and other "housekeeping" requirements that will apply to all regulated industries, and rules for delegating the air toxics program to the states.

Protecting Urban Air Quality

- We have published extensive guidance to help states develop and implement plans for bringing urban air quality into line with federal standards by deadlines established in the Act.
- We have issued guidance and regulations for state operating permit programs which will improve administration and enforcement of CAA requirements.

NEW DIRECTIONS IN IMPLEMENTATION

Although EPA has made great progress in carrying out the Clean Air Act, the success of the Act is far from guaranteed. Much remains to be done if the Act's health and environmental goals are to be achieved. EPA must issue over a hundred more regulations and guidance documents, as well as dozens of mandated studies and reports. The largest group of remaining rulemakings will be those controlling air-toxics emissions. Other significant future rulemakings will include emissions standards for non-road engines, standards for municipal and medical waste combustion, enhanced emissions monitoring, Federal

operating permits, and new-source review reform.

The Agency also must accelerate and expand a host of activities to ensure that EPA and states are implementing and enforcing the Act effectively. For example, EPA must assess hundreds of state implementation plan revisions, as well as 120 state and local permit programs, and provide technical assistance to states and sources. The list of significant actions following this section lists most of the significant actions expected within the next two years.

Because EPA has completed many key rules and guidance documents, the responsibility for implementation of the 1990 Amendments is shifting increasingly to state and local governments. Effective implementation at the state and local level is critical to the success of the Act. This Administration is aware of how important it is to get the Federal framework right, and to provide the right kind of guidance and support to state and local agencies. We also understand the importance of timeliness: the gridlock of the past has already delayed key Federal elements far too long. Over the past year, we have broken the regulatory gridlock in a number of areas critical to providing states the necessary support, and we intend to do an even better job in the future, so that states and industries will have the information they need, when they need it, to plan for compliance in the most effective way.

One key element the states need in crafting effective, efficient compliance program is the flexibility to use economic incentives in ways that reduce costs while assuring that the environmental goals are met. One of the principal themes of this Administration is that a healthy environment and a strong economy are not only compatible but essential to each other, and that the appropriate use of economic incentives can enhance this compatibility by providing flexibility and incentives for technological innovation. We recently took a large step in this direction by finalizing the economic incentives rule, which shows states and industries how to use incentive-based approaches that encourage advanced technologies that both save money and make it possible to get more environmental results. We also worked closely with the California South Coast Air Quality Management District to establish an innovative NO_x trading program for smog control; this program is being closely watched as a possible model for other areas. We intend to continue making the use of such approaches a centrally important tool in helping the states plan for meeting the ambitious goals of the Clean Air Act. We believe that the combination of flexibility and timeliness of Federal support will prove to be the twin keys to success as the implementation of the Clean Air Act enters this next, critical stage.

**The Clean Air Act Implementation Strategy
(Revised May 1994)**

Date	Title	Activity	Compl.	Stat. Deadline
May-95	Title II - Mobile Sources			
		Finalize non-road emission standards for <25 HP SI engines - Phase I		
	Title III - Air Toxics			
		Final MACT for secondary lead smelters		Nov-94
	Title IV - Acid Rain			
		Certify continuous emissions monitors for Phase II units		
Jun-95	Title III - Air Toxics			
		Finalize MACT for petroleum refineries		
	Title VII - Enforcement			
		Update enhanced monitoring referencing document		
Jul-95	Title I - Nonattainment			
		Finalize Part C & D new source review requirements		
	Title III - Air Toxics			
		Final MACT for aerospace industry		
	Title IV - Acid Rain			
		Propose NO _x emission limits for Group 2 utility boilers		Jan-95
Aug-95	Title I - Nonattainment			
		Finalize NSPS for cold cleaners		
		Finalize NSPS for SOCMII secondary wastewater		
		Finalize NSPS for starch manufacturing		
	Title III - Air Toxics			
		Develop inspection manual and training materials for Stage I vapor recovery systems		
		Develop inspection manual & training materials for industrial cooling towers		
Sep-95	Title I - Nonattainment			
		Publish web offset lithography CTG		Nov-93
		Publish SOCMII batch processes CTG		Nov-93
		Publish petroleum/industrial wastewater CTG		Nov-93
		Publish plastic parts coating CTG		Nov-93
		Publish storage tanks CTG		Nov-93

**The Clean Air Act Implementation Strategy
(Revised May 1994)**

Date	Title	Activity	Compl.	Stat. Deadline
Sep-95	Title I - Nonattainment	Publish auto body refinishing CTG		
		Publish aerospace CTG		
		Publish clean-up solvents CTG		
		Publish shipbuilding CTG		
	Title III - Air Toxics	Promulgate paper & pulp MACT		Nov-94
		Promulgate standards for large MWCs		Nov-92
		Promulgate standards for small MWCs		Nov-93
	Title V - Permits	Finalize Federal operating permit program		
Oct-95	Title I - Nonattainment	Publish air quality and emission trends report		
		Finalize rules for risk management plans and prevention		Nov-93
	Title IV - Acid Rain	Finalize opt-in regulations - process sources		
	Title VII - Enforcement	Finalize rule for contractor listing		
Nov-95	Title II - Mobile Sources	Finalize marine engine emission standards		
		Finalize locomotive emission standards		Nov-95
		Final MACT for solid waste TSDF		Nov-94
		Finalize MACT for wood furniture		
		Study of electric utilities generating units		Nov-93
	Title III - Air Toxics	Promulgate asbestos MACT		
		Final MACT for shipbuilding (surface coatings)		Nov-94
Jan-96	Title I - Nonattainment	Final NSR Simplification rule		

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FILED

JAN 31 1992

Clerk, U.S. District Court
District of Columbia

NATURAL RESOURCES DEFENSE COUNCIL,
INC.; PUBLIC CITIZEN, INC.,

Plaintiffs,

v.

WILLIAM K. REILLY, ADMINISTRATOR,
U.S. ENVIRONMENTAL PROTECTION AGENCY,

Defendant,

and

AMERICAN PAPER INSTITUTE; NATIONAL
FOREST PRODUCTS ASSOCIATION; et al.,

Intervenor-Defendants,

Civ. No. 89-2980
(RCL)
(Lamberth, J.)

CONSENT DECREE

WHEREAS, plaintiffs Natural Resources Defense Council, Inc., and Public Citizen, Inc. (collectively, "plaintiffs"), filed this action on October 30, 1989, against defendant William K. Reilly, Administrator, U.S. Environmental Protection Agency ("EPA" or "Agency");

WHEREAS, this action involves plaintiffs' allegations concerning (a) EPA's obligations under section 304(m) of the Clean Water Act, as amended, 33 U.S.C. § 1314(m) (the "First Claim for Relief"), and (b) EPA's obligations under section

3018(b) of the Resource Conservation and Recovery Act of 1976, as amended, 42 U.S.C. § 6939(b) (the "Second Claim for Relief");

WHEREAS, plaintiffs and EPA agree that this Court has jurisdiction over the First Claim for Relief;

WHEREAS, by Order filed April 23, 1991, this Court granted plaintiffs' motion for partial summary judgment as to the First Claim for Relief, and declared that EPA is in violation its statutory responsibilities under 33 U.S.C. § 1314(m);

WHEREAS, the parties enter into this Consent Decree in settlement of the First Claim for Relief;

WHEREAS, by Order filed April 23, 1991, this Court held that plaintiffs had filed the Second Claim for Relief in a court that lacked subject matter jurisdiction to hear the claim, and accordingly dismissed the Second Claim for Relief;

WHEREAS, plaintiffs have agreed not to appeal this Court's dismissal of the Second Claim for Relief, if this Consent Decree is entered by the Court;

WHEREAS, as of the date hereof, plaintiffs have agreed to seek the dismissal of their petitions for review in NRDC v. Reilly, No. 90-1228 (D.C. Cir.), and NRDC v. Reilly, No. 90-1497 (D.C. Cir.), if this Consent Decree is entered by the Court;

WHEREAS, EPA wishes to take advantage of the best opportunities for reducing risks to human health and the environment across all environmental media;

Effluent Guidelines Currently Under Development

2. (a) EPA shall propose and take final action with respect to effluent guidelines for the following point source categories according to the following schedules:

<u>Point Source Category</u>	<u>Proposal</u>	<u>Final Action</u>
1. Pesticide Manufacturing	March, 1992	July, 1993
2. Pesticide Formulating and Packaging	January, 1994	August, 1995
3. Centralized Waste Treatment-Phase I	April, 1994	January, 1996
4. Machinery Manufacturing and Rebuilding - Phase I	November, 1994	May, 1996
5. Pharmaceutical Manufacturing	August, 1994	February, 1996
6. Organic Chemicals, Plastics & Synthetic Fibers - Response to Remand in <u>CMA v. EPA</u> , 870 F.2d 177, rehearing granted in part, 885 F.2d 253 (5th Cir. 1989)	(published December, 1991)	May, 1993
7. Coastal Oil and Gas	January, 1995	July, 1996

(b) Revision of effluent guidelines for the Pulp, Paper and Paperboard point source category is the subject of litigation in EDF v. Thomas, Civ. No. 85-0973 (D.D.C.). Revision of effluent guidelines for the Offshore Oil and Gas point source category is the subject of litigation in NRDC v. EPA, Civ. No. 79-3442 (D.D.C.). The schedules for proposal and final action for those guidelines are the subject of those proceedings, and are not the subject of this Decree.

Studies

3. (a) EPA shall conduct studies according to the following schedules, which shall be reflected in the next 304(m) Plan:

<u>Point Source Category</u>	<u>Start</u>	<u>Complete</u>
1. Petroleum Refining	1992	1993
2. Metal Finishing	1992	1993
3. Iron and Steel	1993	1994
4. Inorganic Chemicals	1993	1994
5. Leather Tanning	1994	1995
6. Coal Mining	1994	1995
7. Onshore/Stripper Oil & Gas	1995	1996
8. Textiles	1995	1996
9. Study Category #9	1996	1997
10. Study Category #10	1996	1997
11. Study Category #11	1996	1997

(b) Notwithstanding the provisions of Paragraph 3(a), EPA may replace any or all of the eight (8) point source categories specifically identified in Paragraph 3(a) with other point source categories, provided EPA notifies plaintiffs within thirty (30) days following a decision to make such a replacement. EPA shall determine which point source categories shall be the subject of study categories Nos. 9 - 11 referenced in Paragraph 3(a).

period the task force remains in existence. In addition, EPA shall request recommendations from the task force with respect to:

(a) a process for deciding which additional point source categories to regulate by means of effluent guidelines, based on potential for risk reduction, the utility of regulation and the schedule for promulgation of such rules;

(b) a process and schedule for reviewing and determining whether to revise additional existing effluent guidelines;

(c) new technologies and control methods, including methods to achieve zero discharge;

(d) the minimum components of new and revised effluent guidelines to ensure that they are adequate in scope and coverage;

(e) minimum requirements for surveys under section 308 of the Clean Water Act, 33 U.S.C. § 1318; and

(f) a process for promoting effective co-regulation of point source categories to eliminate or minimize cross-media transfer of pollution.

Modification of this Decree

9. (a) The provisions of this Decree shall be modified for good cause shown.

(b) The provisions relating to dates established by this Decree shall be modified according to the procedures set forth in Paragraph 10. All other provisions of this Decree may be

modified by written consent of plaintiffs and EPA, or by the Court upon request of either party.

(c) In EPA's view, the schedules for effluent guidelines and studies incorporated into this Decree assume the following: (i) that Congress will appropriate funds for the effluent guideline program at the levels requested by the Administration, (ii) that sufficient qualified personnel will be available to staff the effluent guidelines program, (iii) that no rule subject to the schedules set forth in this Decree will require either (A) more than one Notice of Proposed Rulemaking, or (B) a Notice of Data Availability subsequent to publication of a Notice of Proposed Rulemaking. In EPA's view, the failure of any one of these assumptions to be true with respect to an effluent guideline or study which is the subject of this Decree would constitute "good cause" for modification of the schedule with respect to such effluent guideline or study. Plaintiffs do not necessarily agree that the above factors constitute good cause to modify the Decree.

10. Modification of the dates set forth in this Decree shall be by written consent of plaintiffs and EPA, or in accordance with the procedures specified below.

(a) If a party files a motion requesting modification of a date or dates established by this Decree and provides notice to the other party at least thirty (30) days prior to filing such motion, and files the motion at least sixty (60) days prior to the date for which modification is sought, then the filing of

= 90 days
total
prior
notice

such motion shall, upon request, stay the date for which modification is sought. Such stay shall remain in effect until the earlier to occur of (i) a dispositive ruling by this Court on such motion, (ii) the date sought in the modification, or (iii) the date which is one hundred eighty (180) days after the date such motion is filed. Only one such automatic stay shall be permitted for each deadline for which modification is sought.

(= 120
day
stay at
the
most)

(b) If a party files a motion requesting modification of a date or dates established by this Decree totalling thirty (30) days or less and provides notice to the other party at least thirty (30) days prior to the filing of such motion, and files the motion at least seven (7) days prior to the date for which modification is sought, then the filing of such motion shall, upon request, stay the date for which modification is sought. Such stay shall remain in effect until the earlier to occur of (i) a dispositive ruling by this court on such motion, or (ii) the date sought in the modification. Only one such automatic stay shall be permitted for each deadline for which modification is sought.

(c) If a party seeking modification does not provide notice pursuant to subparagraphs (a) or (b) above, that party may move the Court for a stay of the date for which modification is sought. The party seeking modification under this subparagraph (c) shall give notice to the other party as soon as possible of its intent to seek a modification and/or stay of the date sought to be modified. The notice provided under this Paragraph 10(c)

and any motion for stay shall demonstrate why the party could not have utilized the notification procedures set forth in subparagraphs (a) and (b) above.

(d) If the Court denies a motion by EPA to modify a date established by this Decree, then the date for which modification had been requested shall be such date as the Court may specify.

(e) Any motion to modify the schedule established in this Decree shall be accompanied by a motion for expedited consideration. All parties to this Decree shall join in any such motion for expedited consideration.

11. Nothing in this Decree, or in the parties' agreement to its terms, shall be construed to limit the equitable powers of the Court to modify those terms upon a showing of good cause by any party.

Termination of this Decree

12. The Court shall retain jurisdiction to determine and effectuate compliance with this Decree. When EPA's obligations under this Decree have been completed, this case shall be dismissed.

Savings provisions

13. Nothing in the terms of this Decree shall be construed to confer upon this Court jurisdiction to review any decision, either procedural or substantive, to be made by the Administrator

called by
12/21/78
at dismissal
w/ x time

Safe Drinking Water Act Rulemaking Schedules/Consent Decrees

EPA currently is subject to consent decrees with schedules for proposal and promulgation of six drinking water rules. EPA negotiated the consent decrees in settlement of citizen suits brought after EPA failed to issue rules pursuant to SDWA section 1412(b) which compels EPA to issue rules for 83 named contaminants by 1989 and for 25 additional contaminants every three years thereafter. Faced with an inability to meet the schedules in the decrees and growing concerns that EPA was not regulating the highest risk contaminants, in late 1994 EPA initiated a reassessment of the drinking water program. The reassessment has involved public meetings with stakeholders addressing all aspects of EPA's drinking water program. Agency management is now reviewing the results of the stakeholder meetings and considering changes to the drinking water program. One of the possible decisions will be to seek to renegotiate some of the decrees to either relieve EPA of obligations to do rules addressing low-risk contaminants or establish very long-term schedules for those rules.

To: Michael S. Winer
From: Leslye M. Fraser
Date: July 24, 1995
Re: Deadline Suits: Summary of Cases

Attached is a table summarizing a number of cases in which agencies were sued for missing statutory deadlines. My general observations from reviewing the cases are as follows:

- If an agency has missed a statutory deadline, the court will not award the agency more time than the statute specifies, and it may order the agency to complete the action in less time than the statute specifies.

See e.g., Sierra Club v. Thomas, 668 F. Supp. 165 (N.D. Cal. 1987) (although EPA claimed it could not promulgate PSD regulations in less than 50 months, the court stated the agency was not entitled to more than the 2 years specified in the statute, reasoning that Congress already had balanced the need for additional time to do a better rulemaking against the need for promulgated regulations; the court then imposed an 18 month deadline).

- Any time in an agency's proposed schedule that is related to activities which are not required by statute or otherwise essential will likely be eliminated by the court.

See e.g., Natural Resources Defense Council v. EPA, 797 F. Supp. 194 (E.D.N.Y. 1992) (since review by OMB serves no congressional purpose and is wholly discretionary, the schedule shall exclude such review);

American Lung Ass'n v. Browner, 884 F. Supp. 345 (D.Az. 1994) (in PM NAAQS case, the court reduced the comment period from the proposed 90 days to 60 days, specifically excluded time for interagency review, and effectively barred the Clean Air Scientific Advisory Committee and the public from reviewing more than one draft of fundamental supporting documents).

SUITS IN WHICH AGENCIES LITIGATED DEADLINES AND DEADLINE IMPOSED BY COURT

CASE NAME AND CITE	P TIME	D TIME	CT ORDER	COMMENTS
<u>American Lung Ass'n v. Browner</u> , 884 F. Supp. 345 (D. Az. 1994) (suit to compel EPA to review PM NAAQS; CAA requires review every 5 years)	12/31/95 (next 5 yr dead- line) or 18 mos	12/1/98	1/31/97	Court noted that EPA's proposed date effectively extends 5 year review interval to 11 years due to previous missed review date; date ordered by court shortened EPA's accelerated review schedule an additional 22 months, and eliminated time proposed for several activities not required by statute, such as OMB review.
<u>Sierra Club v. Thomas</u> , 658 F. Supp. 165 (N.D. Cal. 1987) (action to compel promulgation of regs for PSD program re: NOx 10 years after due date)	2 years per statute	50 months (claimed can't do it in less)	propose w/i 10 months; prom. w/i 18 mos; submit progress report at 16 mos.	Court stated that cases make it clear that if the statutory deadline has passed by the time the court issues decree, EPA remains obligated to issue regs w/i timeframe mandated by Congress.
<u>Public Citizen Health Research Group v. Aughter</u> , 702 F.2d 1150 (D.C.C. 1983) (appeal of district court order requiring OSHA to issue w/i 20 days emergency temporary standard regulating EtO)		end of 1984	issue NPRM w/i 30 days	No date set for final rule, but agency directed to issue permanent standard ASAP but well before its 1984 proposed date.
<u>Sierra Club v. Gorsuch</u> , 551 F. Supp. 785 (N.D. Cal. 1982) (suit to compel EPA to establish national emission standards for radionuclides; EPA listed on 11/8/79 and statute required EPA to issue proposed rule w/i 180 days after listing).	mand. inj.	issue by 1989	issue proposed rule w/i 180 days	Court noted that EPA's proposed date was more than 9 yrs after 180 day statutory deadline
<u>Sierra Club v. Ruckelshaus</u> , 602 F. Supp. 892 (N.D. Cal. 1984) (follow-up to prior case -- action to compel compliance with CAA w/r to radionuclides; statute reqd EPA to issue final standards 180 days after issuing proposed standards)	mand. inj.		90 days final standard	EPA missed deadline and held in contempt; court issued new order giving EPA 30 days to issue final standards

CASE NAME AND CITE	P TIME	D TIME	CT ORDER	COMMENTS
<u>NRDC v. EPA</u> , 797 F. Supp. 194 (E.D.N.Y. 1992) (action to compel EPA to issue I&M regs under CAA for states to adopt; statute required promulgation within one year of CAAA (11/15/91))	4 months	7 months	propose w/i 1 wk; publish final w/i 4 mos	Court determined that EPA was sufficiently along in the process to be able to meet P's schedule
<u>New York v. Ruckelshaus</u> , 21 ERC (BNA) 1721 (D.C.C. 1984) (action to compel EPA to issue timely ruling on the States' inability to meet NAAQS due to interstate pollution); statute reqd EPA to respond w/i 60 days.	w/i 60 days	until 4/85	60 days (case decided 10/5/84)	
<u>National Congress of Hispanic American Citizens v. Marshall</u> , 626 F.2d 882 (D.C.C. 1979) (action to compel promulgation of OSHA standard for field sanitation)				Court did not compel due date, just a proposed schedule for completion stating that agency may delay standard beyond a statutory timetable when in good faith it determines that other priorities demand adjustment
<u>NRDC v. Train</u> , 510 F.2d 692 (D.C.C. 1975) (action to compel compliance of effluent guidelines under FWPCA; statute reqd publishing by 4/1/74; district court ordered final by 10/1/74)			final by 12/31/74	Court states agency may petition for modification of the order if it determines that guidelines should not be promulgated for certain categories or deadline for certain categories cannot be met
<u>Environmental Defense Fund v. EPA</u> , 852 F.2d 1316 (D.C.C. 1988) (challenge to withdrawal of proposed reinterpretation of mining waste exclusion)			Propose by 10/15/88 (78 days)	Court ordered EPA to relist six smelting hazardous wastes and fulfill its statutory duty w/r to processing wastes; also ordered final determination by 2/15/89; complete studies and report to Congress by 7/31/89; and per statute, make regulatory determination w/i 6 mos of report to Congress

CONSENT DECREES ARE AN APPROPRIATE WAY
FOR AGENCIES TO ACHIEVE COMPLIANCE WITH THE LAW

What is a consent decree?

Regulatory agencies such as EPA are regularly sued by a variety of parties who claim that the Agency is acting, or failing to act, in violation of a statute or other legal requirement. Often, the agency's lawyers and the Department of Justice attorneys assigned to the case conclude that the best interests of the government would be served by compromising the matter rather than litigating.

Frequently, the only practicable means of resolving a lawsuit short of litigating it is through a consent decree. A consent decree is a binding agreement between the parties to a lawsuit, embodied in an order issued by the court for the enforcement of the agreement. At EPA, the most common sort of consent decree involves a case in which the plaintiff alleges that the agency has failed to comply with a statutory deadline to issue a rule mandated by Congress or to take some other final action according to a congressionally mandated schedule. Under the consent decree in such a case, the Agency is typically ordered to issue the rule according to a schedule that provides sufficient time for the development of the necessary supporting record, full public participation, evaluation of comments, and review by OMB and other agencies. In many cases, such as enforcement consent decrees and decrees under the Clean Air Act, the Agency solicits public comment on the consent decree itself before it is made final.

Why are consent decrees useful?

If the Agency could not enter into consent decrees, it and the Department of Justice would be forced to litigate each and every case brought against it. This would be an enormous waste of time and would actually result in much higher costs and less favorable results for the government. This is so because EPA and the Department of Justice counsel enter into consent decrees only when they are convinced that doing so is likely to yield a court order as favorable to the government as would have resulted from litigating the case, or more favorable. In practice, the government has had very poor results litigating deadline cases. For example, EPA filed affidavits in district court in support of a four-year schedule for issuing final rules for NO_x "increments" for new source permitting under the Clean Air Act. The court issued an order adopting the two-year schedule sought by the plaintiffs.

The courts have been especially inhospitable to attempts by the government to litigate to secure adequate time for interagency and OMB review of its rules. The courts that have addressed the question have generally concluded that Congress

002456

A24

decided the schedule on which rules are to be issued, and have excised any time for OMB and interagency review from the schedule.

By contrast, when the government negotiates a consent decree, it is able to incorporate many provisions favorable to it. These include provisions limiting the government's obligations to perform actions to those permitted by appropriated funds; provisions for routine or, in some cases, automatic time extensions when unforeseen obstacles arise; and a schedule providing adequate time for OMB review of proposed and final rules.

Are consent decrees being abused by EPA?

Under long-standing EPA practice, and guidance issued by the Attorney General during the Reagan administration, the use of consent decrees is restricted to those cases where they are necessary and are appropriately limited. Consent decrees may only be agreed to when the court has jurisdiction over the case, and when, if the case had been litigated, the court would have had the power to enter the substance of the consent decree as a contested order against the agency. Similarly, the government may not enter into a consent decree that:

- converts a discretionary duty into a mandatory one;
- commits the agency to expend funds that have not been appropriated or to seek additional appropriations; or
- strips the agency of its proper discretion over the content of any rules it may be directed to issue.

Conclusion

Consent decrees are now used by the government, but they are not abused. EPA is currently subject to deadlines in settlement agreements or court orders to issue over 100 regulations or to take other regulatory actions. Most of these schedules are based on statutory deadlines, and are embodied in consent decrees. Because the Agency has had the power to negotiate consent decrees with the plaintiffs in these cases, it has been able to secure schedules that allow for the orderly conduct of business. To be required to litigate each of these cases to a conclusion would be extraordinarily wasteful of time and litigation resources, and would very likely result in orders in many cases flatly incompatible with the government's budgetary resources and the need to attend to other matters, including regulatory reform efforts.

RESPONSE TO SENATOR ABRAHAM

In a recent editorial, Senator Abraham decries the use of consent decrees to:

- 1) "force regulatory agencies to impose restrictions not intended by Congress;"
- 2) make "a change in public policy without congressional action or public input;"
- 3) "substitut[e] [environmental] groups' own will for the procedures and scientific methodology prescribed by the agency's enabling legislation and administrative regulations."

Senator Abraham argues that federal legislation is needed to bar federal agencies from entering decrees that limit their discretion. We think the Senator is addressing a non-problem.

According to the Senator, the consent decree in California v. Browner provides an example of evils noted above. The Senator described that consent decree as requiring EPA "to institute proceedings to bar use of a number of pesticides (which its own research showed posed no health risks)." Further, the Senator cites the decree in California v. Browner and the settlement in Citizens for a Better Environment v. Gorsuch, as proof that the government is not following guidelines established by the Reagan Justice Department to prevent federal agencies from entering settlements that deprived them of their discretion.

Let's look at the facts. The California v. Browner consent decree does not in any way limit EPA's discretion. Rather, the decree establishes a schedule for EPA to make a decision on whether to retain a few uses of 36 pesticides. Under the decree, EPA could revoke all of the uses, none of the uses, or some percentage of them. EPA's agreement to a schedule for decisionmaking was appropriate because the statute has timeframes (much shorter ones than in the decree) for actions on petitions. More importantly, at every turn, the consent decree emphasizes that EPA retains its substantive policy discretion. A couple of examples:

- 1) The consent decree requires EPA to respond to an industry petition ("the NFPA petition") but also specifies that "[t]his Consent Decree in no way constrains EPA's judgment regarding the substance of EPA's response to the NFPA petition nor obligates EPA to reach a particular decision."
- 2) The consent decree requires decisions under various agency policies but also specifies that "[n]othing in this Paragraph or in the Consent Decree shall limit EPA's ability to modify its policies interpreting and implementing FFDCA

sections 402, 408, and 409 in the future where EPA has the authority or discretion to make such modifications."

The one place in which the decree includes a substantive standard, the decree expressly notes that EPA is free to change this standard so long as it gives 30 days notice to the plaintiffs in the case. Incidentally, the court that approved the decree found the substantive standard that was included to be fully consistent with past EPA and FDA practice.

Senator Abraham is right when he notes that the pesticide uses that may be affected have been found by EPA to pose little or no risk. However, if EPA eventually decides to revoke some of these uses it will not be because EPA or some environmental group thinks that is a good idea but because the congressionally-mandated Delaney clause in the Federal Food, Drug, and Cosmetic Act requires it.

In sum, the decree in California v. Browner does not impose restrictions not intended by Congress, does not change public policy, and is fully consistent the statute, EPA's regulations, and the scientific methodology followed by EPA. Accordingly, this decree does not violate the Reagan Justice Department's guidelines. The other allegedly violative decree the Senator cited was actually signed by the government and entered by the court in 1976, five years before Ronald Reagan became President. Senator Abraham needs to find some better "facts" to justify the proposed legislation limiting the ability of federal agencies to enter consent decrees.

The CBE case cited in the article by Sen. Abraham is, as you can probably tell by the reference to "judge wilkey", a very old one. The decree at issue was entered into almost 20 years ago (1976), after a series of lawsuits by environmental groups challenging EPA's failure to implement the effluent and pretreatment standards required by dates certain under the 1972 CWA Act. The decree is no longer effective.

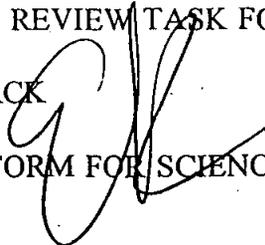
There were a variety of challenges to the decree, including challenges that the decree bound EPA's discretion beyond the terms of the statute. The provisions at issue did NOT dictate substantive outcomes but did provide criteria for EPA's development of effluent guidelines and pretreatment standards that were not in the statute (e.g. criteria for excluding industrial categories and pollutants from regulation). The district court, and ultimately, the D.C. Circuit upheld the decree against industry challenges that only provisions expressly mandated by statute could be in the decree.

The Court of Appeals found that the provisions in question did not dictate a substantive outcome and were largely ratified by the 1977 amendments to the CWA. Judge Wilkey dissented, finding that the decree improperly went beyond the statutory mandates. Cert. was denied in 1984.

It is important to note that we do NOT anymore enter into decrees that go beyond the statutory mandates in question to the same extent as this 1976 decree. Agency and DOJ lawyers are very careful to follow the Meese memo prescriptions on binding future administrations.... None of the current Agency decrees that I am aware of contain any provisions similar to the decree mentioned in the article.

July 28, 1995

MEMORANDUM FOR THE REGULATORY REVIEW TASK FORCE
FROM: ELAINE C. KAMARCK
SUBJECT: REGULATORY REFORM FOR SCIENCE AND
TECHNOLOGY



Attached is a draft Decision Memo outlining the OSTP Regulatory Reform initiatives. The availability of the Vice President is extremely limited this summer and there does not appear to be anything controversial in the packet. Therefore, rather than calling a meeting, we would like each of you to review the proposal and send any comments you may have to both Jack and me.

Please return your comments by Friday, August 4.

ATTACHMENT

DRAFT

MEMORANDUM FOR THE VICE PRESIDENT

FROM: JOHN H. GIBBONS,
ASSISTANT TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY

SUBJECT: Regulatory Reform for Science and Technology

Summary

This memo seeks your approval of a set of regulatory reforms designed to increase the productivity of the federal science and technology enterprise. The specific proposals are outlined in the attached report.

Background

Federal funding plays a central role in U.S. science and technology research and development. The reforms proposed will ensure that federal funds are used more efficiently in part by enabling recipients to spend more of their energy on research and less on paperwork. Streamlining and simplifying federal funding of research and development will also encourage a wider range of organizations to compete for federal R&D funds.

The majority of the recommendations contained in the report are non-controversial and have been reached through consensus with the affected agencies. However, I wish to call your attention to several of the report's recommendations which may generate some controversy:

1. Expand "Other Transactions" Authority. [See TAB A, page A.7] We recommend that this authority, which currently allows some agencies to avoid standard procurement requirements in making agreements for R&D in circumstances where competitive contracts, grants, and cooperative agreements are not appropriate, be extended to other civilian research agencies. Note that implementation of this authority will virtually guarantee increased scrutiny of agency practices, and success will depend on the skill and good faith of those who use the expanded authority.

2. Revise Non-Disclosure Protection for Technology Partnerships. [See TAB A, page A.9] We recommend that the Administration seek a statutory change that brings uniformity to DOE's authority in this area and extends the protection of information produced by industry partners under research development and demonstration agreements from disclosure for a period of five years, in order to unify the *ad hoc* approach that has been taken to date. This extension of the current provisions may be criticized by some on the grounds that research funded in part with taxpayer dollars should be publicly available. However, there is precedent in current DOE statutes for

non-disclosure protection, and this change would merely bring uniformity to DOE authority. We do not recommend expansion of other agencies' non-disclosure authority at this time. The current situation for other agencies has not been identified as a barrier to research and development, and an expansion of their authority could unnecessarily exacerbate the current debate over federal expenditures for R&D with commercial potential.

3. Export Commodity Jurisdiction. [See TAB A, page A.15] An Interagency Working Group (IWG) led by the NSC has been working to design an effective mechanism for managing export requests and for resolving jurisdictional disputes in a timely, predictable way. The issue, however, remains unresolved. We recommend that a deadline be set for the IWG to resolve the dispute as quickly as possible, but not later than August 15, 1995. Exporting firms, and many in Congress, want the administration to resolve this issue promptly.

Additionally, the report contains a set of recommendations on the use of information technology to streamline regulations and reduce paperwork which were recently announced in summary form in connection with the White House Conference on Small Business. We propose to follow up on the commitments made at the Conference through the actions indicated in Attachment 2 (TAB C).

This review was conducted in cooperation and consultation with businesses, universities, and other organizations which have participated in Federal research programs, as well as the agencies which fund most Federal research, including NSF, NIH, DOD, DOE, DOC, USDA, and NASA. SBA, State, and FDA have also participated. [The Regulatory Reform Task Force has reviewed the recommendations and supports them.]

If you approve of the report's recommendations, we will prepare a set of directives to the agencies to implement the reforms. If you require further discussion of any of these issues, we would be happy to brief you.

Approve: _____

Disapprove: _____

Let's Discuss: _____

Cleared: NPR/Kamarck

**REGULATORY REFORM
FOR
SCIENCE AND TECHNOLOGY**

July 24, 1995

REGULATORY REFORM FOR SCIENCE AND TECHNOLOGY

Scope

Federal regulations can have a profound impact on the efficiency and effectiveness of research and development conducted with Federal dollars, just as they can either spur or hinder private incentives to invest in R&D. Regulations that affect Federal R&D are especially critical since the Federal government supports 40% of all U.S. R&D and two-thirds of fundamental research.

The Administration has worked hard to develop collaborations with industry to increase commercial investment in science and technology. The skillful investment of Federal seed money is a key component of U.S. science and technology policy, particularly in the current fiscal environment. Too often, however, the seedbed is salted with unproductive regulation. This can frustrate potential investors and hamper the productivity of researchers. Reducing the onerous burden of unnecessary regulation is critical to encouraging private investment in R&D and to maintaining U.S. economic competitiveness.

Researchers must be given the time and the tools they need to be most productive. The Federal government must strive to create an environment that invites private investment in science and technology and does not discourage entrepreneurs from investing in high technology endeavors. The Administration must endeavor to:

- Lower the barriers that currently impede research and development
- Increase the productivity of Federal research dollars
- Attract increased private investment in science and technology
- Use information technology to increase the efficiency and effectiveness of government functions

These goals must be accomplished without lessening our commitment to the regulatory goals that protect the Nation's health, safety, and environment.

The close working relationships formed by the government with business and academia in R&D partnerships have disclosed a number of additional opportunities to get a "better bang for the buck" in science and technology. These opportunities, which generally involve multiple agencies rather than a single regulatory agency, are the focus of this report. They include regulations which affect how researchers apply for Federal dollars, how and under what restrictions research and development are conducted, how government-industry cooperation is structured, and how best the Federal government can make its resources available to the private sector to boost innovation and creativity.

This review has been conducted in cooperation and consultation with businesses, universities, and other organizations which have participated in Federal research programs, as well as the agencies providing most Federal research funding, including NSF, NIH, DOD, DOE, DOC, USDA, and NASA. SBA, State, and FDA have also participated.

REGULATORY REFORM FOR SCIENCE AND TECHNOLOGY

Recommendations (*TAB A*)

I. Raising the Productivity of R&D in Universities

- A. Standardize and Streamline the Grant Process
- B. Implement Electronic Communications in the Grants Process
- C. Ease the Burden of Laboratory Waste Disposal

II. Removing Barriers to and Raising Productivity of R&D in the Private Sector

- A. Streamline Government-Private Sector Research & Development Interactions
- B. Expand "Other Transactions" Authority
- C. Extend Non-Disclosure Protection to Additional Technology Partnerships
- D. Implement Galvin Commission Recommendations
- E. Facilitate Bioremediation Field Trials and Commercialization

III. Impose a Deadline for Creating an Effective Export Commodity Jurisdiction Dispute Resolution Procedure

Attachment 1: Research Reform Efforts Already Underway (*TAB B*)

- A. Reform the Treatment of Research Costs for Universities
- B. Implement a System for Continuous Quality Improvement for the Grant Process
- C. Improve Treatment of Intellectual Property
- D. Coordinate Federal, State, and Local Regulatory Activities
- E. Simplify Approval of Biotechnology Drugs and Biologics
- F. Relax FDA Export Controls on Advanced Drug and Medical Device Technology

Attachment 2: Information Technology Reforms Announced at the White House Conference on Small Business on June 14, 1995 (*TAB C*)

- A. Use Information Technology to Reduce Paperwork Burden
- B. Use Information Technology to Improve the Rulemaking Process
- C. Create a Digital Signature Infrastructure
- D. Implement Nationwide Electronic Benefits Transfer
- E. Implement a Simplified Tax and Wage Reporting System
- F. Integrate Telephone and Computer-Based Government Information Services
- G. Improve Cross-Agency Retrieval Tools for the Public

Summary descriptions are provided for proposals listed in **Sections I, II, and III (TAB A)**. Recommendations for action by the Vice President, with associated pros and cons, are presented as part of each proposal.

Attachment 1 (TAB B) contains summary descriptions of reforms that are already underway and require no decision by the Vice President. These reforms, however, have been greatly facilitated by the regulatory review process, and it is recommended that the Administration include these reforms in any briefing on the S&T review. **Attachment 2 (Tab C)** contains descriptions of and milestones for information technology-related reforms announced by the President and Vice President at the White House Conference on Small Business.

RECOMMENDATIONS

I. Removing the Barriers to Research and Development in Universities

A. Standardize and Streamline the Grant Process

Differences in practice and policy across Federal agencies oblige institutions of higher education to maintain separate internal operating procedures for each agency with which they do business. This increases the time spent on paperwork and correspondingly reduces the return on the taxpayers' investment in scientific research.

The Federal Demonstration Project (FDP), a cooperative effort among more than fifty universities or research institutes and nine Federal agencies, is designed to improve the management of Federally-funded research. The FDP has developed and tested the following recommendations concerning the grants process.

Recommendation

Direct all agencies to adopt the FDP General Terms and Conditions and the expanded authorities included in OMB Circular A-110 for all research and research-related project grants as a matter of agency policy. Where not inconsistent with statute, all Federal agencies shall prescribe the General Terms and Conditions tested by the FDP as the default for all research and research-related project grants.

These defaults may be overridden in rare and exceptional circumstances, only when there are compelling reasons to do so.

Pros

- Uniform policies and procedures for the administration of Federal research project grants free faculty from paperwork and allow them to spend more time on research. Between 1988 and 1990, the FDP evaluated the impact of the "expanded authorities" at over 28 universities. Responses from over 2500 principal investigators indicated that these **streamlined procedures saved more than 5 days annually per investigator, permitting over 50 additional person-years of scholarly activity** in this sampling. No cases of mismanagement have been attributable to the implementation of the FDP terms and conditions at 50 institutions by 9 Federal agencies since the inception of FDP in 1988. Grants officers from the six major funding agencies (NIH, DOE, DOD, NSF, USDA, NASA) concur with these recommendations.

Cons

- Agencies without major research activity may resist the effort necessary to implement the changes in terms and conditions necessary to achieve uniformity, although some, such as USDA, have actively participated in the FDP. The major research-sponsoring agencies, including the NIH and the NSF, as well as USDA, are largely in compliance with these procedures now.

B. Implement Electronic Communications in the Grants Process

A number of Federal agencies are experimenting with various forms of electronic grants applications and reporting to speed communications, lessen the paperwork burden and significantly lessen the amount of paper used in the process. Agencies will need to establish common data requirements for their grants submissions and reporting; commit adequate resources and effort to develop, pilot, and adopt a common electronic standard; and ensure that sufficient technological options are available to institutions to allow some flexibility in selecting the approaches that are most useful and cost effective to them.

NSF estimates that they annually receive approximately 7,500 feet of stacked proposals (about 15 Washington Monuments high) and that **2.4 Washington Monuments worth of paper could be eliminated by electronic submission of just the repetitive data** (i.e., civil rights, drug-free workplace, non-delinquency on Federal debt, etc.).

Recommendations

Direct agencies to develop and adopt a common set of data elements for use in proposal submission as an initial step in the development of standards and means for electronic submission and processing of proposals and awards.

Direct agencies to develop and demonstrate electronic commerce systems for the administration of Federal financial assistance, including assessments of the efficacy of electronic data interchange public standards such as ANSI X12 for computer-to-computer exchange of information.

Direct OMB to develop and implement for use an electronic communication system that provides organizational profiles that would include certifications of compliance with Federal regulations and other information required from recipients of Federal funds.

Pros

- These recommendations would greatly simplify the administration of grants.
- NSF has begun a project to re-engineer and automate all processes related to grant proposals, awards and related business practices. NSF and NIH have independently developed client/server database systems to permit electronic communication with grantees and grantee organizations. Both of these systems utilize the Internet, enabling grantees using any computer type to access the database to enter or modify data. DOE also has a system under review using ANSI-X12 standards for computer to computer exchange of information.

Cons

- Protocols and standards for electronic submission, processing and reporting of proposals are in an early stage of development and have numerous "kinks" that need to be resolved.

C. Ease the Burden of Laboratory Waste Disposal

Regulatory requirements unnecessarily drive up the costs incurred by government, university, and industrial laboratories when handling hazardous wastes during research and testing. That is because the applicable regulations, which focus on large volume industrial processes such as chemical manufacturing, are unwieldy when applied to research-testing procedures, which characteristically involve only tiny volumes of chemicals. One-size-fits-all rules and inflexible interpretations preclude laboratory oriented innovations that could yield increased work-place safety and enhanced environmental protection at lower cost, e.g., recovery and reuse of lab chemicals.

For research-intensive universities, expenditures associated with handling hazardous and low level radioactive laboratory waste can account for a significant fraction (about 5%) of total project costs and, in many institutions, are the fastest growing component of overhead.

Recommendations

Short Term. Simplify the process for obtaining a RCRA permit for on-site storage and treatment of hazardous laboratory waste. To achieve effective waste handling, laboratories need only a small fraction of the authorities normally included in a Treatment, Storage, Disposal (TSD) permit under RCRA. If a simplified TSD and streamlined application and review procedure were introduced, qualifying universities and other organizations that operate research facilities would be able to store small quantities of hazardous wastes on site for up to one year (currently 90 days) and to treat certain classes of wastes on the bench top or in other specified locations. This could be accomplished without the need for new legislation by either of two methods:

Option 1

The preferred route would be to use a "permit-by-rule" approach. EPA would set enforceable performance standards for on-site storage and treatment of small quantities of waste by research-testing laboratories (and possibly other small volume generators). Universities and other institutions involved in research and/or testing could then certify to their state EPA that they have met the standards and were proceeding with the new rules. No approval process would be needed. The states would have inspection and enforcement powers, as they do now.

Option 2

A somewhat more laborious, but perhaps less controversial, procedure for the regulated community would be to develop and issue a modified TS (but not D) permit for small volume users. The "D" (disposal) is not a need for most research-testing institutions. They would then apply for the modified permit as they do now.

Long Term. Establish a continuing national forum to address and promote other innovations with respect to reduction, management, and treatment of hazardous laboratory wastes. In addition to encouraging reforms within existing statutes and regulations, the forum would seek to foster increased reliance on performance standards when regulating laboratory waste management and accelerated development of environmentally benign laboratory procedures.

Pros

- Reduces administrative costs and non-productive time requirements for bench scale researchers permitting more resources to be applied to R&D.
- Would facilitate waste solvent recovery and waste "neutralization" that would reduce the waste burden on the environment.
- Essentially no down-side risks.

Cons

- Could entail greater transaction costs for the rule-making.

II. Removing Barriers to and Raising Productivity of R&D in the Private Sector

A. Streamline Government-Private Sector Research & Development Interactions

Much research with industry partners is accomplished either through the use of Cooperative Research and Development Agreements (CRADAs), which allow government laboratories to conduct cost-shared R&D projects with industry, or more general research agreements that do not involve work at the labs. For each type of agreement there is unnecessary inconsistency in the form of the agreement within agencies and across agency lines, as well as some substantive requirements imposed by agencies that pose unnecessary barriers to research with the private sector. (See Section I.A with respect to university research.)

While certain differences are required by statute, many are simply a function of custom and could be streamlined or eliminated, which would improve the efficiency and effectiveness of these agreements and would simplify interaction with the private sector. For example, the Department of Energy has developed a general-use modular CRADA and a short-form, fill-in-the-blanks CRADA. These changes have permitted DOE to cut its CRADA processing time in half -- from about 32 weeks to about 16 weeks. It appears likely that other agencies could achieve similar results.

Recommendations

The following recommendations were developed in consultation with NASA, DOE, DOC and ARPA, the agencies that have the vast majority of involvement with the private sector in R&D. Other agencies are not affected. These recommendations do not involve legislative change.

The affected agencies should be directed to begin efforts to ensure, to the extent possible and consistent with statute and mission requirements, that all agencies develop standard form, general use, CRADAs and other research agreements that are consistent across agency lines; and to identify barriers to private sector involvement in R&D that are unnecessary and can be dealt with in more creative and flexible ways. If, as is likely, it is not possible to completely standardize agency practice, consideration should be given to the possibility in multi-agency projects to assigning a lead agency to manage the agreement and to act as a single point of contact for dealing with the industry partners. The agencies should be directed to report their progress to OMB and OSTP within 45 days of the directive.

The Partnership for a New Generation of Vehicles (PNGV), an existing, interagency R&D effort with the private sector that has begun streamlining the interagency process involved, should be designated as a demonstration project for CRADAs and other research agreements.

Agencies involved in PNGV should be directed to (1) review their existing statutory authority to determine the degree of flexibility available to them in negotiating research agreements, particularly in the areas of cost accounting, intellectual property, and multi-party "partnership arrangements," and to use available flexibility to negotiate effective and efficient agreements; (2) recommend any necessary changes in policy or statute in order to allow them to streamline the negotiation of R&D agreements; and (3) identify inconsistencies in current practices or requirements among those agencies and the basis for those differences. The PNGV reinvention lab also should be directed to report its findings to OMB, OSTP, and to the research procurement offices of all agencies involved in this effort to streamline R&D agreement practices within 30 days of the directive.

Pros

- The inefficiencies in the current process affect the agencies' ability to work with industry and to effectively utilize the taxpayers' considerable capital investment in research facilities. These changes will improve the agencies' ability to work with industry and leverage that investment for U.S. economic and social benefit.

Cons

- Agencies currently control their own procedures and have different statutory constraints. Changes in established practice may be resisted by the agencies unless they are convinced that such changes are in the best interest of the agency and its research partners.
- If consistency is emphasized above all other goals it can lead to acceptance of the "lowest common denominator." Care must be taken to preserve agencies' abilities to seek creative solutions. One size does not necessarily fit all.

B. Expand "Other Transactions" Authority

"Other transactions" authority is currently available to DOD, NASA, and DOT in funding certain research and development work. It is limited to agreements for research and development, and does not extend to procurement of goods and services. It is available only in circumstances in which contracts, grants, and cooperative agreements are not appropriate. It eliminates standard procurement requirements. Thus it gives considerable flexibility to the project managers to craft an agreement that contains only those provisions necessary to the particular project, and to revise the working arrangement as research projects evolve. As used by DOD, NASA, and DOT, these transactions are typically cost-shared with industry (which demonstrates the private sectors' commitment to success), and are awarded competitively so long as practicable.

Without this authority, firms which have not been government contractors and are accustomed to flexible, unencumbered negotiations and accounting procedures for research projects are deterred from engaging in government research programs. DOE, for example, has experienced specific problems negotiating with commercial firms for conducting joint, cost-shared, research projects to demonstrate environmental remediation solutions. "Other transactions" authority permits technology partnerships to utilize arrangements that reflect commercial practice as well as the terms and conditions specifically tailored to best achieve project success.

Recommendation

A statutory change to extend "other transactions authority" to additional civilian research agencies for use in negotiating research and development agreements should be pursued. Any legislative change should be drafted to allow, but not require, use of this authority by agencies entering into research agreements and would include a statement of principles to ensure agency and public understanding of its scope and appropriate oversight of the increased discretion to be provided to agency managers. As with the other transactions authority currently available, it would apply only to R&D and not to procurement of goods and services.

Pros

- Such authority is appropriate for R&D work, where the project evolves significantly over its lifetime, in contrast to standard procurement of goods and services.
- It will greatly improve the government's ability to enter into effective research projects with the private sector unencumbered by unnecessary regulations.

Cons

- This authority provides maximum discretion to project officers, who are guided only by general mission goals and equitable principles as opposed to detailed procurement requirements. Its implementation will virtually guarantee increased scrutiny, and its success will depend on the skill and good faith of those who use it. It provides some

potential for misuse and will require careful employee training and oversight. If misused, the expanded authority could poison the well for those who are currently using it successfully.

C. Revise Non-Disclosure Protection for Technology Partnerships

There are several statutes that provide for the protection from disclosure (including disclosure under the FOIA) of information produced under DOE's and other agencies' collaborative agreements for research, development and demonstration with industrial partners (e.g., for DOE, the Energy Policy Act of 1992 [42 U.S.C. 1320], the National Competitiveness Technology Transfer Act of 1989 [15 U.S.C. 3701], and the Metals Initiative legislation [15 U.S.C. 5101]). The language in these statutes is not uniform, the date from which information can be protected varies depending on which statute applies, and the statutes do not apply to the entire spectrum of agreements into which DOE enters with industrial partners (particularly in most of the agreements under DOE's defense programs). This protection from disclosure is important to industrial partners who ultimately plan to commercialize products resulting from the research with Federal agencies. Other research agencies have a variety of types of authority to protect information developed under collaborative agreements from disclosure.

This situation could be addressed in two ways:

Option 1

Seek a statutory change that brings uniformity to DOE's authority in this area and extends the protection of information produced under research development and demonstration agreements from disclosure for a period of five years, in order to unify the ad hoc approach that has been taken to date. However, it should be made clear that (1) protection from disclosure does not apply to the research agreement itself, (2) that absent extraordinary circumstances information on the nature of the agreement will be publicly available, and (3) such protection applies only to research which is cost-shared with industry.

Option 2

Develop legislation to provide all agencies at least a five year exemption from disclosure.

Recommendation

We recommend Option 1 at this time. Consistency within DOE will address the primary problems industry and the agencies have identified. To attempt to address all the research agencies at this time could provide an opening for those who want to debate the issues of Federal research expenditures benefiting private business in the budget context. Since no other agencies identified this as a major barrier to their activities, it seems unwise to open the broader debate at this time.

Pros

- Either option would improve consistency of treatment of all Federal partners for all research, development and demonstration agreements and address a concern of industry about their ability to protect commercially valuable information developed as partners with the government.
- Since the protection under either option would be limited to 5 years unless the current authority provides a longer time period, Federal R&D efforts would afterwards be made public allowing others to benefit by taking those results (obtained in part with taxpayer dollars) and build on them.

Cons

- The Atomic Energy Act of 1954 states that DOE's research agreements shall not prevent the dissemination of scientific or technical information except as otherwise provided by law. This reflects the policy judgment of some that, absent exceptional circumstances, research funded with taxpayer dollars should be publicly available. In addition, the scientific community generally supports the widest possible dissemination of research results. The extension of current non-disclosure provisions to additional research may be criticized on those grounds. Option 2 particularly could unnecessarily raise this issue as part of the ongoing debate over Federal expenditures for applied research.

D. Implement Galvin Commission Recommendations

As part of the regulatory review, we have identified one additional specific area in which administrative reform would be well-received by the affected communities. DOE issues its own orders to its laboratories relating to environment, safety and health. These orders are often far more restrictive than those imposed by regulatory agencies such as EPA, FDA, and OSHA. In addition DOE laboratories are subject to a multitude of audits and reviews, some imposed by organizations outside the control of DOE management (e.g. the Congress), but many are inspired by DOE. The Galvin Commission report clearly documents the excessive burden on DOE laboratories resulting from DOE orders, directives, and audits (see Appendix A of the report). The Secretary of Energy concurs that the existing system is costly, bureaucratic, and inefficient. Activities now ongoing within the Department are addressing some of the issues raised in the Galvin Report. Given the intense budget pressures DOE is under, we recommend that attention be directed toward achieving the large savings and increased efficiency achievable by reducing the excesses identified in the Galvin Report.

The Department of Energy recognizes the seriousness of the situation and has steps underway to correct the deficiencies including revising its Directives system. Since March 1994, the Department has eliminated about 25 percent of its orders (312 to 236). An accelerated order reduction effort is currently underway to reduce 92 orders -- including 26 orders considered to be the most burdensome by DOE field offices and contractors -- to 22 orders and 3 rules. This accelerated effort will be completed by July 31, 1995, and an interim report submitted to the President at this time will indicate improvements made and anticipated cost savings or cost avoidance. This will lead to a reduction of requirements placed on our contractors including reduction of their overhead dollars. At the same time, DOE is being assisted by its Advisory Committee on External Regulation of Nuclear Safety in evaluating activities to which the regulatory jurisdiction of other Federal agencies might be applied by legislative extension of the appropriate statutory authorities. In otherwise unregulated areas, the internal DOE process is fashioned with evaluation criteria, to permit only those new orders deemed essential to be promulgated. This effort to reduce the burden on DOE contractors will result in increased productivity and output for its R&D programs.

Recommendation

DOE should submit an interim report upon completion of the accelerated effort to reduce DOE orders (as detailed above) to the President by July 31, 1995.

DOE should include final data regarding the number of orders, directives, and audits which are eliminated, and the personnel reductions at headquarters, field offices, and laboratories which result from this elimination, in a report to the President no later than February 15, 1996 [as part of the report required by Presidential Decision Directive/NSTC-5].

Pros

- Removes what is generally recognized as excessive and costly oversight
- Responsive to findings of a prestigious review committee
- The DOE Lab Directors are unanimous in their belief that the Orders represent a seriously misguided oversight effort

Cons

- Some orders are required to fulfill Congressional requirements of DOE's oversight responsibility
- In the interest of expeditiously and efficiently carrying out DOE missions, the labs require more strenuous and expert oversight
- Because of the unique aspects of DOE nuclear operations, the level of control that could be exerted by other Federal agencies may be inadequate to fully protect the public interest

E. Facilitate Bioremediation Field Trials and Commercialization

Modern biotechnology has greatly improved our ability to solve some of the world's major, long range problems. Genetically improved agricultural crops and fish species offer great hope of a sufficient and stable future food supply. Microbial degradation of spills and toxins, or concentration of these pollutants by plants, could solve many of our current environmental problems. The early impact of biotechnology on the treatment of a wide range of previously incurable diseases is evident at this point.

The Administration has recognized the importance of this technology and is working to remove barriers to further its development. Some of the actions already underway include:

- strengthening intellectual property rights by clarification of the biotech drug "utility" requirements and by a strong international enforcement policy on patents;
- elimination of the favorable pricing clause in NIH CRADAs;
- extensive biotechnology funding through the Advanced Technology Program at NIST; and
- the proposal to extend the R&D tax credit.

Two additional recommendations presented here are meant to promote the development of biotechnology and to help maintain our world leadership position in this crucial field. Action on one of these recommendations, to simplify the approval of biotechnology drugs and biologics, is already underway within the FDA and is included in the Attachment. The second recommendation follows below.

The scope of the contaminated site cleanup problem in the United States indicates the need for more effective, less costly remediation technologies. One such cleanup technology is bioremediation. However, due to the limited availability of adequate cost and performance data on bioremediation remedies, as well as regulatory barriers, it has been difficult to implement this technology nationally. A more expeditious and efficient plan to allow full scale field studies is warranted. This proposal recommends a plan that would facilitate a scientifically objective evaluation of bioremediation as a predictable, safe, and cost effective cleanup option.

There are currently two primary regulatory constraints on the development and application of bioremediation as a clean-up option. The first constraint comes from the Resource Conservation and Recovery Act (RCRA) and its regulation of hazardous wastes administered by the EPA. Although EPA issued new rules for treatability studies in 1994, they are still not conducive to long-term research. There needs to be a mechanism for expediting RCRA rules when they apply to research applications on secure government land. The second constraint involves the use of recombinant (genetically altered) microorganisms in open field clean-up. This application of recombinant organisms comes under the purview of the Toxic Substances Control Act (TSCA) also administered by the EPA. There needs to be a mechanism for expediting TSCA clearances when they apply to research applications on secure

Federal land. Accordingly, dedicated Federal field sites that include both contaminated and clean areas need to be made available to academic, government and private sector scientists and engineers. Specific examples of secure sites that also have access to appropriate analytical instrumentation include Oak Ridge National Laboratory, Pacific Northwest Laboratory, and selected National Environmental Research Parks.

The use of Federal field sites for long-term research in bioremediation would respond, in part, to the Galvin Task Force observation that the advanced technologies necessary to enable DOE to conduct an effective clean up of its sites are not currently available, and would respond to the Task Force's suggestion that the National Laboratories be employed to innovate in this area.

Recommendations

Direct the Bioremediation Working Group of the Biotechnology Research Subcommittee to develop, in consultation with the private sector and appropriate agencies, (1) a plan for the selection of sites and (2) a mechanism for selecting, obtaining regulatory approvals, and funding proposals of interest.

Pros

- Will accelerate the development of new technology to clean up the environment
- Will stimulate the biotechnology industry and academics to devote more attention and creative thought to the subject.

Cons

- Will require EPA to develop a new, less stringent clearance for these test sites
- Will create some controversy among environmental public interest groups and individuals that are unalterably opposed to any demonstrations using recombinant DNA subjects (materials) in an extra-laboratory environment.

III. Impose a Deadline for Creating an Effective Export Commodity Jurisdiction Dispute Resolution Procedure

The Department of Commerce processes export license applications for items on the Commodity Control List. The Department of State processes export license applications for items on the U.S. Munitions List. For certain items (e.g., communications satellites, hot sections of jet engines, encryption), it is unclear whether they should be controlled by Commerce or State. (Commerce tends to favor economic interests; State tends to favor national security interests.) In some cases, the process of resolving these "commodity jurisdiction" disputes has languished for years.

At issue is the process, timetable, and definition to be used in resolving these "CJ" disputes. The NSC has convened an interagency working group (IWG) to resolve this issue, but agreement has been difficult. In the past, Congress has threatened to legislate a process, as well as decide itself where key items (e.g., satellites, hot sections) should be controlled. This year, the Hill staff is willing to defer to the Administration, provided it ultimately resolves this issue.

An efficient commodity jurisdiction process can be created without new legislation.

Recommendation

We recommend that the NSC-led IWG be asked to resolve the commodity jurisdiction dispute within 90 days of the date of this report.

Pros

- Resolving this management issue in a way that creates a transparent, predictable process of decision making would be warmly welcomed by U.S. exporters.
- If the administration does not resolve the issue, Congress is likely to intervene with its own proposal introducing a potential source of controversy in the EAA. Members of both parties are likely to be relieved that the administration has resolved the issue.

Cons

- Forcing the issue to conclusion will require putting strong pressure on either State or Commerce -- or possibly both.

ATTACHMENT 1

RESEARCH REFORM EFFORTS ALREADY UNDERWAY

ATTACHMENT I: RESEARCH REFORM EFFORTS ALREADY UNDERWAY

Many of the recommendations in the following section are already underway at the agencies. The S&T working group has found that the Regulatory Review process provided the additional incentive to get these reforms implemented.

A. Reform the Treatment of Research Costs for Universities

The cost reimbursement system for overhead or "indirect costs" for research grants has been harshly criticized for its complexity and allegedly provides Federal reimbursement that is widely variant. There are proposals in Congress to cap the rates used by universities to calculate Federal reimbursement and use the resulting "savings" for other Federal needs. A legislated cap setting an arbitrary limit on rates would repudiate the cost principles stated in OMB Circular A-21, under which the government has negotiated reimbursement rates with individual universities for decades. Such a cap could deny millions of dollars of legitimate reimbursement to universities for research facilities built to undertake Federally funded research based on long-standing principles and agreements.

We propose to implement a number of revisions to OMB Circular A-21, which were published in the Federal Register on February 6. OMB and OSTP, working in collaboration with Federal agencies and universities, and building on prior work, have completed their study of the system and the following changes have been recommended.

Develop uniform methods and procedures. Discard past notions of "direct and indirect" costs which were needlessly complicated and poorly understood. Instead, three new categories of costs, all necessary to the conduct of fundamental research, will be used: research activities, research facilities, and research administration. Standardize methods for determining utility costs and eliminate special studies to reduce the variation in the utility portion of overhead rates across universities. Develop a methodology to determine uniform treatment of special services (such as hazardous waste facilities), to ensure that similar activities are treated consistently by universities. Include other new policies for areas such as: useful life for research equipment, consistent Federal agency transition policies for university changes from use-allowance to depreciation, appropriate Federal policies for interest costs, uniform accounting methodology, make total costs part of competitive award process.

Make use of cost efficiencies. Tough Federal review of facility construction costs, utilization, and operations and maintenance will be imposed to ensure that Federal science agencies are paying only for efficient and reasonable use of university research space. Benchmarks would be established by research and construction experts for different classes of facilities -- which could apply to new construction and existing facilities

Pros

- These changes would reinvent the system of cost reimbursement in the spirit of the National Performance Review. They would achieve greater uniformity and

cost efficiencies while retaining the core principles of negotiated cost reimbursement based on the government-university sharing of actual costs. The necessary stability would be retained to stimulate universities and their governing boards to invest in world class research and education facilities.

- The chief alternatives to these revisions, a cap on reimbursement rates (or an across the board cut of reimbursement), would have serious consequences to the excellence and future vitality of U.S. academic science. Universities presently receiving Federal reimbursement for their substantial investments in research facilities would suffer immediate and significant decreases in their Federal recovery. Variation among research facility rates of institutions reflects real and legitimate differences among institutions -- universities and colleges vary in the utility, maintenance and labor costs based on their location, the age, condition and type of their facilities, and the nature of research and education which they pursue.

Con

- Instead of these refinements to an already complex system, a cap on reimbursement rates or a standardized percentage cut of the reimbursement to all institutions could streamline the process and achieve cost savings for the government. However these costs would be shifted to universities, thus continuing the increase in the university share of costs associated with Federally funded research. The system could be made simpler by setting some fixed rate for all universities, although, as stated above this would not reflect the differences among institutions.

B. Implement a System for Continuous Quality Improvement for the Grant Process

The Federal Demonstration Project has been, and continues to be, an excellent vehicle for identifying and testing time and cost saving suggestions related to academic research. To facilitate the translation of these improvements into practice, an established group of senior Federal officials should be responsible for reviewing FDP results and making recommendations for implementation.

Recommendation

Direct the Committee on Fundamental Science of the NSTC to review FDP demonstration project results and to make recommendations regarding those demonstrations to the Office of Management and Budget, the Office of Science and Technology Policy, and to the heads of all Federal research-sponsoring agencies.

Pro

- Anchoring the FDP into the Federal Government through the NSTC will insure the rapid adoption of the results of continuing FDP demonstrations and other streamlining initiatives.

C. Improve Treatment of Intellectual Property

The inability of the Federal government to obtain adequate intellectual property protection for computer software that may ultimately be a basis for private sector technology is currently a barrier to Federal labs' work with the private sector in this area, and to the effective leveraging of the Federal research effort to strengthen the general economy. Currently, Federal laboratories may patent, but not copyright, computer programs written by their employees. Because of this limitation on intellectual property rights, the private sectors' willingness to enter into CRADAs is reduced.

In addition, in particular cases the requirement of the Bayh-Dole Act that the government always retain a government purpose license is viewed by industry as a barrier to government-industry research agreements. While amendment of the Bayh-Dole act is not warranted, expansion of "other transaction" authority (See Section II.B) would give agencies the ability to waive that requirement in the few cases in which that would be appropriate.

Recommendations

Allowing employees of Federal agencies to copyright computer software developed by them as part of their official duties under, or related to, a CRADA will promote the commercial application of software developed with Federal funds and thereby strengthen the economy. *Legislation providing this intellectual property protection is included in the "Federal Acquisition Improvement" legislation recently forwarded to the Hill by the Administration (see sections 6101-3). That legislative change should be actively pursued.*

The flexibility with respect to intellectual property protection provided to agencies through "other transactions" authority should be pursued legislatively. See section II.B.

Pros

- The recommended changes for the Federal labs will improve the leverage the Federal R&D investment provides to the private sector.
- Improvements in the efficiency of commercial spin-off of Federal research through CRADAs and licensing have traditionally received bipartisan support.

Cons

- Federal licensing of intellectual property is currently insignificant in dollar amounts and economic impact. Improvements are possible, but many problems are inevitable consequences of the agencies' focus on mission research as their first priority and

limited funding for patent counsel, filings, etc. Thus, the resulting benefits of any statutory change in this area may be relatively small, although significant to particular industry partners.

- Regarding intellectual property protection for Federal software, previous attempts to modify the statutes were not strongly supported by industry. There are varying opinions on whether it is better to keep government software in the public domain, or to protect and license it.

D. Coordinate Federal, State, and Local Regulatory Activities

The burden of making regulatory activity operate more effectively rests at least as much on state and local regulators as it does on the Federal government. The Federal government is in a unique position to provide leadership. New communication technologies will permit citizens to have a single point of entry, perhaps specialized to their unique interests, with links to all levels of government.

There are, however, many other areas where Federal leadership could work to streamline complex, and occasionally contradictory regulatory actions at all levels of government. The actions needed will vary with each sector. Major actions are already underway in several areas including wage and tax reporting and efforts to coordinate product approval and building codes for the construction industry. We should take credit for those actions, which are well underway.

Specific examples of projects could include:

- *Coordinating of state, and Federal wage and tax reporting.* The interagency Government Information Technology Services group is developing coordinated electronic reporting systems for wages and taxes that will greatly simplify reporting requirements for individuals and businesses
- *Coordinating building codes and inspections.* NIST and the Department of Energy are facilitating work by state and local building code organizations to provide a system that will simplify regulatory approvals for builders that must work in several jurisdictions and create reciprocity in approvals.
- *Developing national standards for building products.* NIST and DOE are also facilitating a process by which producers of building components can have technologies inspected and certified in a way that will satisfy state, regional, or national criteria and avoid redundant and expensive inspection and certification. The certifications and standards are unlikely to involve Federal regulation but involve non-Federal consortia or private inspection labs.

- *Coordination of state, local, and Federal environmental and zoning requirements.* Builders and developers face a maze of requirements, paperwork, and inspections from many different levels of government. Experiments which could combine all requirements in an integrated system would be of enormous value to the industry.

Recommendation

The State and Federal Task Force should be asked to propose areas where Federal, State, and local regulatory activities could be brought together in a way that simplifies compliance and reporting for specific groups. Agencies with a prime responsibility in the area should be assigned to take the leadership in convening state and local regulatory authorities. A planning meeting involving the lead agency representatives and representatives of non-Federal regulatory bodies should be convened to plan specific actions.

Pros

- The regulatory burdens faced by citizens and businesses can be reduced dramatically only if all levels of government cooperate in a streamlining effort.
- Progress in this area is eagerly solicited by the business community affected.

Cons

- May be difficult to deliver on schedule given the complexity of working with many different jurisdictions
- Without care, it may appear that the Federal government is trying to usurp local functions

E. Simplify Approval of Biotechnology Drugs and Biologics

The majority of biotechnology products are reviewed by the Center for Biologics Evaluation and Research (CBER), although some are referred to the Center for Drug Development Evaluation and Review (CDER). The two centers operate under different authorizing legislation reflecting their individual historical mandates. This has led to inconsistencies in review and approval procedures. FDA has recognized this and has proposed a number of suggestions to reduce the regulatory burden on CBER applicants, bring their reviews closer to procedures followed by CDER, and, in some instances, increase the regulatory flexibilities by expanding options commensurate with the type of product being regulated.

The scope of the products regulated by CBER spans the range from the relatively simple to the increasingly complex, i.e., from regulation of blood for transfusion to the newer somatic cell and gene therapy products.

CBER has discovered that regulatory flexibility can be built into the current statutory framework to recognize the scientific complexities while reducing the regulatory burden on industry. This is very important in order to offer the drug developers and manufacturers the flexibility to capitalize on technological progress as it occurs.

Changes in procedures to encourage the adoption of new methods without sacrificing public health or safety include:

- waiving the need for premarket approval of certain changes in manufacturing processes for biotechnology and traditional drugs,
- allowing the use of pilot facilities to produce drugs for development work, e.g., clinical trials,
- relaxing restrictions on the selection of subcontractors (originally intended to control variability of products made by living systems), and
- eliminating lot certification for insulin and antibiotics and updating quality control procedures for these products.

However, we believe more can be done along similar lines to speed up the approval process, reduce the regulatory burden, and focus agency resources without any decrease in product safety or efficacy.

Specifically, we would recommend as a guiding principle that premarket approval of manufacturing changes be required only in those cases in which the safety and efficacy of the product may be changed as a result of the process change. When the product can be fully documented as safe, effective, and unchanged, such approvals should not be required. The manufacturer would be held responsible for assuring a product that maintains the same safety and efficacy as that produced using the original process.

In addition, manufacturing changes that do require FDA oversight should be allowed to go into effect in a timely fashion unless FDA has reason to object.

Pro

- The FDA and the Biotechnology Industry Organization support these recommendations.

Con

- The recommendations cannot be fully accomplished with administrative action alone. Implementation requires changes in the regulations issued under the Food, Drug and Cosmetic Act and the Public Health Service Act.

F. Relax FDA Export Controls on Advanced Drug and Medical Device Technology

The Food, Drug, and Cosmetic Act currently requires pre-approval of medical devices and drugs in the U.S. before they can be exported, even if they have been approved in the importing country. This practice increases our response time to business opportunities and reduces our international competitiveness. It is redundant to have FDA conduct an approval process that has already been completed by a competent foreign agency. The FDA has recently recognized this duplication of effort (Reinventing Drug & Medical Device

Regulations, April 1995) and proposed removal of restrictions on exports to a list of 21 qualified countries. They have expressed willingness to work with Congress to amend the list as appropriate.

The Senate and House have also introduced bills (HR 1300 and S 593) to accomplish the same thing.

Recommendation

We recommend support of the FDA proposal as contained in the above reference. This would allow export of drugs and devices to the countries on the list of 21 without prior U.S. approval as long as local authorities have done so. Also, devices could be exported to any nation as long as an Investigational Device Exemption for testing on humans was granted here and the importing nation approved the device.

Pros

- Will make U.S. manufacturers more competitive internationally.
- Will eliminate the need to move manufacturing overseas to get a fast start.
- Moves toward regulatory "harmonization."

Cons

- None to U.S. citizens. May be slight risk to countries with less rigorous product reviews.

ATTACHMENT 2

INFORMATION TECHNOLOGY REFORMS

**ANNOUNCED AT
THE WHITE HOUSE CONFERENCE ON SMALL BUSINESS
JUNE 14, 1995**

**ATTACHMENT 2: INFORMATION TECHNOLOGY REFORMS ANNOUNCED AT THE WHITE HOUSE
CONFERENCE ON SMALL BUSINESS ON JUNE 14, 1995**

A. Use information technology to reduce paperwork burden.

President Clinton stated at the signing of the Paperwork Reduction Act Amendments of 1995 on May 22nd, that agencies shall ensure in the future that government forms can be filed electronically. For example, IRS tax forms are already available electronically through the Commerce Department's FedWorld system, and the Electronic Filing (ELF) initiative has been expanding, with efficiency benefits to both the public and the IRS.

Milestones:

- By June 1996, most commonly used forms should be made available through direct dial "bulletin board" services and over the Internet.
- By the end of 1996, all agency regulations prescribing the collection of information through the use of forms or otherwise, shall be amended to permit the filing of the required information in electronic formats and also, in the case of forms, with forms that are computer generated by the public.
- Filing of information in electronic formats shall use the least burdensome medium for the affected respondent population, e.g. magnetic media ("diskettes"), direct dial-up, or Internet.

B. Use information technology to improve the rulemaking process.

The National Electronic Open Meeting on "People and their Governments in an Information Age," held May 1 - 14, demonstrated the practical feasibility of using a mix of technologies to facilitate broad public participation in a notice and comment process. Utilizing the World Wide Web, basic Internet connectivity, dial-in bulletin board technology, and public access sites nationwide, over 100,000 observers and 10,000 active participants filed nearly 3000 individual comments in response to an OMB Notice published both in the Federal Register and over the Internet. This level of participation is significantly in excess of any typical rulemaking proceeding. Similar strategies for increasing public participation should be adopted for all significant agency rulemakings.

Milestones:

- By the end of 1995, all significant rulemaking documents should be made available electronically via bulletin board and over the Internet.

- By the end of 1995, the software suite used in the National Electronic Open Meeting shall be refined and made available to Federal agencies and others at no more than the cost of distribution.
- By the end of 1996, all significant rulemaking proceedings shall use either the National Electronic Open Meeting software suite, or similar technologies, to ensure the widest possible participation in rulemaking.

C. Create a digital signature infrastructure.

A digital signature performs more functions than a written signature in that it is used to verify both the origin and the contents of a message. Digital signatures are based on public key cryptography. Presently, there are three major cryptographic systems that support digital signatures. One of these, the Digital Signature Standard, was developed by the government. The other two are proprietary. In order to function effectively, however, an infrastructure of support services must be developed. The government may have a role in assisting in the development of a public key infrastructure for the general public.

Under the auspices of the NII Security Issues Forum, the General Services Administration has established a Security Infrastructure Program Management Office. This office is coordinating the development of a public key infrastructure to meet the Federal government's needs for digital signature and confidentiality purposes. The U.S. Postal Service is pursuing complementary efforts.

Milestones:

- By December of 1995, begin work with industry and the private sector to foster development of a public key infrastructure.
- By June of 1996, develop a public key infrastructure for government use and demonstrate interoperability with multiple agencies and with industry.

D. Implement nationwide electronic benefits transfer (EBT).

The NPR called for the creation of a national electronic benefit transfer (EBT) system and created a Federal EBT Task Force to accomplish this goal. The task force is committed to delivering all federal benefits electronically by March, 1999. There are several milestones that need to be reached in order to meet this goal.

Milestones:

- By the end of 1995, change the Food Stamp regulations to lift the "cost neutrality" requirements on the program.
- By mid-1996, reexamine the applicability of Regulation E to EBT where the benefits are not in depository accounts, and develop alternative consumer protection procedures by developing administrative controls to limit risks.
- By mid-1996, modify Treasury regulations to require recipients of direct federal payments who have bank accounts to use direct deposit/electronic funds transfer.

E. Implement a simplified tax and wage reporting system.

The GITS Action Plan says that a Pilot Office has been established and is producing a timeline for pilots and that another meeting with stakeholders was scheduled for February 1995. The Treasury is scheduled to announce action on STAWRS on Friday, June 9, 1995, at the Department's Reinventing Government event.

Milestones:

- Accomplish milestones announced on June 9, 1995.

F. Integrate telephone and computer-based government information services.

There is currently little connection between the Federal Information Center and the work agencies do to get information online. The FIC should be given a distinct assignment or role to play in the auditing of publicly-accessible government information.

Milestone:

- The FIC should provide a report to the NPR by September 1, 1995, which discusses their ability to answer citizen's inquiries with online rescues and makes concrete suggestions for improvement. This report should be updated semi-annually.

G. Improve cross-agency information retrieval tools for the public.

Citizens should be able to place a plain language query and retrieve an accurate online response to the most frequently asked questions of the Federal government (which is known from the FIC experience). Finding the answers to queries should not require the average citizen to have detailed knowledge of agency names and executive branch structure. Providing

