



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET


WASHINGTON, D.C. 20503

October 12, 1993

THE DIRECTOR

M-94-3

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, AND
INDEPENDENT REGULATORY AGENCIES

FROM: Leon E. Panetta 
Director

SUBJECT: Guidance for Implementing E.O. 12866

The President issued Executive Order No. 12866, "Regulatory Planning and Review," on September 30, 1993. This Order directs the Office of Management and Budget (OMB) to carry out the centralized review of significant regulatory actions under development at regulatory agencies.

Within OMB, the Office of Information and Regulatory Affairs (OIRA) has the primary responsibility under the Executive Order for a number of the specific regulatory review and planning functions. Sally Katzen, the OIRA Administrator, has prepared a memorandum setting forth initial steps to implement the Order. Among other things, each agency must promptly designate a Regulatory Policy Officer and begin discussions with OIRA concerning those regulations that warrant centralized review.

I urge you to send Administrator Katzen's memorandum (attached) to the appropriate officials for their immediate attention.

Attachment



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MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, AND
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FROM: Sally Katzen *S.Katzen*
Administrator, Office of
Information and Regulatory Affairs

SUBJECT: Guidance for Implementing E.O. 12866

The President issued Executive Order No. 12866, "Regulatory Planning and Review," on September 30, 1993 (58 Fed.Reg. 51735 (October 4, 1993)).¹ It calls upon Federal agencies and the Office of Information and Regulatory Affairs (OIRA) to carry out specific actions designed to streamline and make more efficient the regulatory process. This memorandum provides guidance on a number of the provisions of the new Order. Undoubtedly, with experience, additional questions will be raised, and we will attempt to respond promptly as they arise.

1. Coverage

The Order as a whole applies to all Federal agencies, with the exception of the independent regulatory agencies (Sec. 3(b)). The independent regulatory agencies are included in provisions concerning the "Unified Regulatory Agenda" (Sec. 4(b)) and "The Regulatory Plan" (Sec. 4(c)). However, while the President's "Statement of Regulatory Philosophy and Principles" (Sec. 1) applies by its terms only to those agencies that are not independent, the independent regulatory agencies are requested on a voluntary basis to adhere to the provisions that may be pertinent to their activities.

In addition, the Order states that the OIRA Administrator may exempt agencies otherwise covered by the Order. Appendix A is a first cut of those agencies that have few, if any, significant rulemaking proceedings each year; effective immediately, these agencies are exempt from the scope of the

¹ This Order replaces E.O. 12291 and E.O. 12498.

Order.² Like the independent agencies, those agencies listed in Appendix A are requested to adhere voluntarily to the relevant provisions of the Order, particularly the President's "Statement of Regulatory Philosophy and Principles" (Sec. 1).

2. Designation of Regulatory Policy Officer.

The Order directs each agency head to designate a Regulatory Policy Officer "who shall report to the agency head" (Sec. 6(a)(2)). This Regulatory Policy Officer is to be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations. Because the Regulatory Policy Officer will in most circumstances serve as the agency representative to the Regulatory Working Group (see below), please provide us with the name, mailing address, and telephone and fax numbers of your designee as soon as possible.

3. Regulatory Working Group.

The Order directs the OIRA Administrator to convene a Regulatory Working Group consisting, in part, of the representatives of the heads of each agency having significant domestic regulatory responsibility (Sec. 4(d)).

Again, we have made a first cut of a list of those agencies which should be members of the Regulatory Working Group, which is attached as Appendix B. Some of the Departments that have separate regulatory components may qualify for multiple representatives. Please notify us if you believe that your Department should have more than one representative. In suggesting additional representatives, please identify these persons and provide us with their mailing addresses, and telephone and fax numbers.

The Administrator is to convene the first meeting of the Regulatory Working Group within 30 days. It is therefore essential that we have your response as soon as possible.

4. Regulatory Planning Mechanism.

The Order emphasizes planning as a way of identifying significant issues early in the process so that whatever coordination or collaboration is appropriate can be achieved at

² To assure that the purposes of the Executive Order are carried out, we may ask these agencies to review particular significant regulatory actions of which we become aware. These Agencies should advise OIRA if they believe that a particular rule warrants centralized review.

the beginning of the regulatory development process rather than at the end (Sec. 4).

There are two specific planning documents discussed in the Order. The first, the semiannual Unified Regulatory Agenda (Sec. 4(b)), is on schedule and will be published before the end of October. Traditionally, all agencies participate, describing briefly the regulations under development. The Order does not call for any change in either the scope or format of this document.

The second planning document is the annual Regulatory Plan (Sec. 4(c)), which is to be published in October as part of the Unified Regulatory Agenda. The Regulatory Plan seeks to capture the most important significant regulations. In advance of agencies drafting their Regulatory Plans, the Vice President will meet with agency heads to seek a common understanding of regulatory priorities and to coordinate regulatory efforts to be accomplished in the upcoming year (Sec. 4(a)). The Vice President will convene the first meeting in early 1994. Following that meeting, we will provide appropriate guidance on the scope and structure of the submissions for the 1994 Regulatory Plan.

As you may recall, OMB had asked in OMB Bulletin No. 93-13 (May 13, 1993) that certain agencies prepare a draft 1993 Regulatory Program under the then applicable Executive Order No. 12498. Many agencies sent in some or all of their proposed programs. Other agencies informed us that they wanted to wait for the confirmation of political appointees or the issuance of the new Executive Order. While there is now insufficient time for all of the steps necessary to prepare a formal regulatory plan for this year, the materials we have received will be useful in preparing for the meeting with the Vice President and our other coordination efforts. Those agencies that have already drafted but not submitted materials, as well as those who wish to augment what we have already received, are encouraged to send these materials to OIRA.

5. Review of Existing Regulations.

The Order directs each agency to create a program under which it will periodically review its existing significant regulations to determine whether any should be modified or eliminated to make the agency's regulatory program more effective, less burdensome, and in greater alignment with the President's priorities and regulatory principles (Sec. 5). Specifically, within 90 days, agencies are to submit to the OIRA Administrator a program establishing, consistent with the agency's resources and regulatory priorities, the procedures for carrying out a periodic review of existing significant

regulations and identifying any legislative mandates that may merit enactment, amendment, or rescission (Sec. 5(a)).

We are aware that past Administrations have required agencies to undertake similar review efforts. Some of these have been so broad in scope that necessary analytic focus has been diffused, or needed follow-up has not occurred. This current effort should be more productive because it focuses only on significant regulations and the legislation that mandates them, and because we will be looking at groups of regulations across agencies with the help of the Vice President and the White House Regulatory Advisers, as well as the public.

Pursuant to the Order, we are asking each agency to send to the OIRA Administrator within 90 days a work-plan which identifies who and which office within the agency will be responsible for assuring that periodic reviews take place; the criteria to be used for selecting targets of review; the kinds of public involvement, data collection, economic and other analysis, and follow-up evaluation that are planned; the timetables to be applied; and, to the extent then known, the targets selected. As the program is implemented and an agency selects specific targets for review, please identify the specific programs, regulations, and legislation involved. To the extent they are relevant, we will share with you the review efforts of other agencies.

6. Centralized Review of Regulations.

One of the themes in the Order is greater selectivity in the regulations reviewed by OIRA, so that we can free up our resources to focus on the important regulatory actions and expedite the issuance of those that are less important. Another theme is that we are to determine early in the process which regulations are important (the term in the Order is - "significant"). Among other things, this will permit agencies to conduct the needed analyses for these regulations as part of the development process, not as an after-the-fact exercise (Sec. 6(a)(3)(B)).

The Order defines "significant" regulatory actions as those likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impact of entitlements, grants, user fees, or loan programs; or

(4) raising novel legal or policy issues (Sec. 3(f)).³ This definition is not wholly susceptible to mechanical application; rather, in many instances, it will require the exercise of judgment. We will work with the agencies to come to a consensus on the meaning of this term in the context of the specific programs and characteristics of each agency.

To begin, we ask the appropriate personnel at each agency to work with the OIRA desk officer(s) to develop an appropriate list of rulemakings that are under development for submission to OIRA. For each rulemaking, please use the format below:

DEPARTMENT/REGULATORY COMPONENT. Title ([Indicate significance⁴]; Upcoming Action: [Identify]⁵) Planned Submission/Publication: [date]; RIN: [number⁶]. Statutory/Judicial Deadline: [date, if any].

[Describe briefly what the agency is intending to do and why, including whether the program is new or

³ The Order is intended to cover any policy document of general applicability and future effect, which the agency intends to have the force and effect of law, such as guidances, funding notices, manuals, implementation strategies, or other public announcements, designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. Such documents are normally published in the Federal Register, but can also be made available to the affected public directly.

⁴ State one of the following: "Not Significant", "Significant", or "Economically Significant". A designation as "Economically Significant" means that the regulatory action is likely to result in the effects listed in the first subsection -- namely, i.e., "have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." A regulatory action that is considered "Economically Significant" must ultimately be supported by the analyses set forth in Section 6(a)(3)(C).

⁵ Indicate whether the upcoming regulatory action is a "Notice of Inquiry", "Funding Notice", "ANPRM", "NPRM", "Interim Final Rule", "Final Rule", or what other action it may be.

⁶ "RIN" is the Regulation Identifier Number published in the Unified Regulatory Agenda. If a RIN has not been assigned, the agency should obtain one through the normal process by contacting the Regulatory Information Service Center.

continuing and, if continuing, the significant changes in program operations or award criteria. Briefly describe issues associated with the rulemaking, as appropriate, e.g., impacts (both benefits and costs), interagency and intergovernmental (State and local) effects, budgetary effects (e.g., outlays, number of years and awards, administrative overhead), time pressures, and why the regulatory action is important, sensitive, controversial or precedential. For final regulatory actions, include a brief statement of the nature and extent of public comment, and the nature and extent of changes made in response to the public comments.] ([Name and telephone number of program official who can answer detailed questions])

We are not looking for a lengthy or detailed description of the issues listed above. All we need is information sufficient to confirm the characterization of "significant" or "not significant". Similarly, for final regulatory actions, the description of the public comments and changes is simply to enable us to decide whether we can expedite or waive our review of the final rule where, for example, there are few or no public comments and little or no substantive change from the previously reviewed NPRM.

Under the Executive Order, within 10 working days after OIRA receives this list, we will meet with or call your office to discuss whether or not listed regulatory actions should be submitted for centralized review (Sec. 6(a)(3)(A)). The purpose of this meeting is to confirm the characterization of the proposal as "significant" or "not significant", the characterization is important because, absent a material change in the development of the rule, those characterized as "not significant" need not be submitted for OIRA review before publication.

OIRA will also want to discuss the timing for updates that would identify any new regulatory actions under development. OIRA implemented this procedure with several agencies on a pilot basis while the Order was being drafted. We are most pleased by the results. It has in some instances taken one or two tries to develop a process that works for a particular agency. In most instances, submission of a list once a month has proven sufficient for our purposes.

Once it is clear that a rulemaking warrants review by OIRA, the process will be facilitated by your advising the OIRA staff as soon as possible on the basic concept, direction, and scope of the rulemaking. This will enable us to identify early the issues that we are concerned about and to inform agency personnel of the type of analyses that OIRA will look for when it reviews the

regulatory action. All of this is designed to make the review process more efficient and avoid last minute problems.

When an agency submits a significant regulatory action for review, the Order sets forth certain information that each agency should provide a description of the need for the regulatory action, how the regulation will meet that need, and an assessment of the potential costs and benefits of the regulatory action, together with an explanation of how it is consistent with a statutory mandate, promotes the President's priorities, and avoids undue interference with State, local, and tribal governments. This should not impose additional burden on the agency. All of the information should have been prepared as part of the agency's deliberative process; and much, if not all, of this information should already be set forth in the preamble of the proposal so as to allow more informed public comment.

If the regulatory action is economically significant (as defined in Sec. 3(f)(1)),⁷ the Order sets forth additional information that an agency must provide -- an assessment of benefits, costs, and of potentially effective and reasonably feasible alternatives to the planned regulatory action (Sec. 6(a)(3(C))). We recognize that this material may take different forms for different agencies. We are reviewing our current guidance to see what changes, if any, are appropriate. Pending the conclusion of this review, agencies should continue to adhere to the existing OMB guidance on how to estimate benefits and costs.

In order to assure that the public is aware of our review under the Order and the possible effects that this review may have had, agencies should indicate in the preamble to the regulatory action whether or not the regulatory action was subject to review under E.O. 12866. On the other hand, there is no requirement that an agency document (in the preamble or in its submissions to OIRA) compliance with each principle of regulation set forth in the beginning of the Executive Order (Sec. 1(b)); we do, however, expect agencies to adhere to these principles and to respond to any questions that may be raised about how a regulatory action is consistent with these provisions of the Order.

The OIRA Administrator was given the authority to exempt any category of agency regulations from centralized review (Sec. 3(d)(4)). To begin with, we have decided that the previously granted exemptions should be kept in effect, except as the Order

⁷ See footnote 4.

specifically includes them.⁸ Several additional exemptions have been added as a result of our ongoing discussions with agencies. A list of current exemptions is set forth in Appendix C. We will add to this list as experience warrants. We urge you to contact the Administrator, or have your staff contact your OIRA desk officer, to discuss those categories you believe may be suitable for exemption.

7. Openness and Public Accountability.

To assure greater openness and accountability in the regulatory review process, the Order sets forth certain responsibilities for OIRA (Sec. 6(b)(4)). Among other things, OIRA is placing in its public reading room a list of all agency regulatory actions currently undergoing review. This list is updated daily, and identifies each regulatory action by agency, title, date received, and date review is completed.

The reading room also contains a list of all meetings and telephone conversations with the public and Congress to discuss the substance of draft regulations that OIRA is reviewing. Within OIRA, only the Administrator (or an individual specifically designated by the Administrator -- generally the Deputy Administrator) may receive such oral communications.

When these meetings are scheduled, we are asking those outside the Executive branch to have communicated their concerns and supporting facts to the issuing agency before the meeting with OIRA. To assure that the matters discussed are known to the agency, we are inviting policy-level officials from the issuing agency to each such meeting.

In addition, written materials received from those outside the Executive branch will be logged in the reading room and forwarded to the issuing agency within 10 working days. It will be up to each agency to put these in its rulemaking docket.

After the regulation is published, OIRA is making available to the public the documents exchanged between OIRA and the issuing agency. These materials will also be made public even if the agency decides not to publish the regulatory action in the Federal Register. In addition, the Order directs that, after a

⁸ Section 3(d)(2) includes within the definition of "regulation" or "rule" those pertaining to "procurement" and the "import or export of non-defense articles and services." The OIRA Administrator interprets the latter to include within the scope of the Order the regulations of the Bureau of Export Administration, and to exclude State Department regulations involving the Munitions List.

regulatory action has been published in the Federal Register or otherwise released, each agency is to make available to the public the text submitted for review, and the required assessments and analyses (Sec. 6(a)(3)(E)). In addition, after the regulatory action has been published in the Federal Register or otherwise issued to the public, each agency is to identify for the public, in a complete, clear, and simple manner, the substantive changes that it made to the regulatory action between the time the draft was submitted to OIRA for review and the action was subsequently publicly announced, indicating those changes that were made at the suggestion or recommendation of OIRA (Sec. 6(a)(3)(E)(ii) & (iii)). Should you have any questions about these matters, please call the Administrator or one of your OIRA Desk Officers.

8. Time Limits for OIRA Review.

The Order sets forth strict time limits for OIRA review of regulatory actions. For any notices of inquiry, advance notice of proposed rulemaking, or other preliminary regulatory action, OIRA is to complete review within 10 working days (Sec. 6(b)(2)(A)). For all other regulatory actions, OIRA has 90 calendar days, unless OIRA has previously reviewed it and there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case there is a limit of 45 days (Sec. 6(b)(2)(B)). Because of these tight time limits, we must work closely together to ensure that requests for clarification or information are responded to promptly. Upon receipt of a regulatory action, we plan to take a quick look and make certain that whatever analyses should be included are included, and to get back promptly to the agency to ask for whatever is missing.

In some instances, a reason for OIRA review will be the potential effect of a regulation on other agencies. In these circumstances, OIRA will attempt to provide the affected agencies with copies of the draft regulatory action as soon as possible. If you are aware that another agency has an interest in the draft regulatory action, please let us know quickly.

We also want to stress the provision in the Order that calls upon each agency, in emergency situations or when the agency is obligated by law to act more quickly than normal review procedures allow, to notify OIRA as soon as possible and to schedule the rulemaking proceedings so as to permit sufficient time for OIRA to conduct an adequate review (Sec. 6(a)(3)(D)).

9. Regulation Identifier Number (RIN).

We ask that each agency include a Regulation Identifier Number in the heading of each regulatory action published in the

Federal Register.⁹ This will make it easier for the public and agency officials to track the publication history of regulatory actions throughout their life cycles and to link documents in the Federal Register with corresponding entries in the Unified Agenda of Federal Regulations (Sec. 4(b)) and the Regulatory Plan (Sec. 4(c)).

* * * * *

We look forward to working with you to implement this Executive Order. If you have any questions, please let us know. We will, of course, provide additional guidance as experience and need dictate.

⁹ The Office of the Federal Register has issued guidance to agencies on the placement of the RIN number in their documents. See Document Drafting Handbook, 1991 ed., p. 9.

APPENDIX A

AGENCIES EXEMPT FROM E.O. 12866

Advisory Council on Historic Preservation
African Development Foundation
Alaska Natural Gas Transportation System,
Office of the Federal Inspector
American Battle Monuments Commission
Arms Control and Disarmament Agency
Board for International Broadcasting
Central Intelligence Agency
Commission of Fine Arts
Committee for Purchase from the Blind
and Severely Handicapped
Export-Import Bank of the United States
Farm Credit System Assistance Board
Federal Financial Institutions Examination Council
Federal Mediation and Conciliation Service
Harry S. Truman Scholarship Foundation
Institute of Museum Services
Inter-American Foundation
International Development Corporation Agency
James Madison Memorial Fellowship Foundation
Merit Systems Protection Board
Navajo Hopi Indian Relocation Commission
National Capital Planning Commission
Office of Special Counsel
Overseas Private Investment Corporation
Panama Canal Commission
Pennsylvania Avenue Development Corporation
Peace Corps
Selective Service System
Tennessee Valley Authority
United States Metric Board
United States Information Agency
United States International Development Cooperation Agency

APPENDIX B

MEMBERS OF THE REGULATORY WORKING GROUP

Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Housing and Urban Development
Department of the Interior
Department of Justice
Department of Labor
Department of Transportation
Department of the Treasury
Department of Veterans Affairs
Environmental Protection Agency
Small Business Administration
General Services Administration
Equal Employment Opportunity Commission

APPENDIX C

REGULATORY ACTIONS EXEMPTED FROM CENTRALIZED REGULATORY REVIEW

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service--Special Nutrition program notices that revise reimbursement rates and eligibility criteria for the School Lunch, Child Care Food, and other nutrition programs.

Food and Nutrition Service--Food Stamp program notices that set eligibility criteria and deduction policies.

Agricultural Marketing Service--Regulations that establish voluntary standards for grading the quality of food.

Animal and Plant Health Inspection Service--Rules and notices concerning quarantine actions and related measures to prevent the spread of animal and plant pests and diseases.

Animal and Plant Health Inspection Service--Rules affirming actions taken on an emergency basis if no adverse comments were received.

Rural Electrification Administration--Rules concerning standards and specifications for construction and materials.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration--Certain time-sensitive pre-season and in season Fishery Management Plan regulatory actions that set restrictions on fishing seasons, catch size, and fishing gear.

DEPARTMENT OF EDUCATION

Certain Final Rules Based on Proposed Rules--Final regulations based on proposed regulations that OMB previously reviewed where: (1) OMB had not previously identified issues for review in at final regulation stage; (2) Education received no substantive public comment; and (3) the proposed regulation is not substantively revised in the final regulation.

Rules Directly Implementing Statute--Final regulations that only incorporate statutory language with no interpretation.

Notices of Final Funding Priorities--Notices of final funding priorities for which OMB has previously reviewed the proposed priority.

DEPARTMENT OF ENERGY

Power Marketing Administrations--Regulations issued by various power administrations relating to the sale of electrical power that they produce or market.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration--Agency notices of funds availability.

Food and Drug Administration--Medical device reclassifications to less stringent categories.

Food and Drug Administration--OTC monographs, unless they may be precedent-setting or have large adverse impacts on consumers.

Food and Drug Administration--Final rules for which no comments were received and which do not differ from the NPRM.

DEPARTMENT OF THE INTERIOR

Office of Surface Mining--Actions to approve, or conditionally approve, State regulatory mining actions or amendments to such actions.

Office of Surface Mining--Approval of State mining reclamation plans or amendments.

Office of Surface Mining--Cooperative agreements between OSM and States.

United States Fish and Wildlife Service--Certain parts of the annual migratory bird hunting regulations.

DEPARTMENT OF TRANSPORTATION

All Office of DOT--Amendments that postpone the compliance dates of regulations already in effect.

Coast Guard--Regatta regulations, safety zone regulations, and security zone regulations.

Coast Guard--Anchorage, drawbridge operations, and inland waterways navigation regulations.

Coast Guard--Regulations specifying amount of separation required between cargoes containing incompatible chemicals.

Federal Aviation Administration--Standard instrument approach procedure regulations, en route altitude regulations, routine air space actions, and airworthiness directives.

National Highway Traffic Safety Administration--Federal Motor Vehicle Safety Standard 109 table of tire sizes.

DEPARTMENT OF THE TREASURY

Internal Revenue Service, Bureau of Alcohol, Tobacco, and Firearms, and Customs Service--Revenue rulings and procedures, Customs decisions, legal determinations, and other similar ruling documents. Major legislative regulations are covered fully.

ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticides and Toxic Substances--Actions regarding pesticide tolerances, temporary tolerances, tolerance exemptions, and food additives regulations, except those that make an existing tolerance more stringent.

Office of Pesticides and Toxic Substances--Unconditional approvals of TSCA section 5 test marketing exemptions, and of experimental use permits under FIFRA.

Office of Pesticides and Toxic Substances--Decision documents defining and establishing registration standards; decision documents and termination decisions for the RPAR process; and data call-in requests made under section 3(c)(2)(B) of FIFRA.

Office of Air, Noise, and Radiation--Rules that unconditionally approve revisions to State Implementation Plans.

Office of Air, Noise, and Radiation--Unconditional approvals of equivalent methods for ambient air quality monitoring and of NSPS, NESHAPS, and PSD delegations to States; approvals of carbon monoxide and nitrogen oxide waivers; area designations of air quality planning purposes; and deletions from the NSPS source categories list.

Office of Water--Unconditional approvals of State Water Standards.

Office of Water--Unconditional approval of State underground injection control programs, delegations of NPDES authority to States; deletions from the 307(a) list of toxic pollutants; and suspension of Toxic Testing Requirements under NPDES.

Office of Solid Water and Emergency Response--Unconditional approvals of State authorization under RCRA of State solid waste management plans and of hazardous waste delisting petitions under RCRA.

PENSION BENEFIT GUARANTY CORPORATION

Interest Rates--Changes in interest rates on later premium payments and delinquent employer liability payments under sections 6601 and 6621 of the Internal Revenue Code as amended by the Tax Equity and Fiscal Responsibility Act of 1982.