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Series: Bromley, D. Allan, Files
Subseries: Correspondence Files

OA/ID Number: 62002
Folder ID Number: 62002-006

Folder Title:
D. Allan Bromley Correspondence - J-S [2 of 4] [1992]

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THE WHITE HOUSE

WASHINGTON

May 7, 1992

Dear Saunders:

I am sorry that we did not have an opportunity to chat during the Academy meetings but the registration this year was so high that it was almost impossible to find anyone.

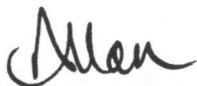
A great many of your colleagues, however, did get to me concerning the matter of mathematics support at the National Science Foundation.

While I understand their concern and yours I have to say that I think, in part at least, that the concern reflects an unfortunate presentation in the NSF budget more than the actual fact. I have talked at length with Walter Massey and Fred Bernthal about this issue and, first of all, it is clear that in a year when we are operating under a budget authority freeze--that is with no provision for inflation adjustment--mathematics support at NSF was increased in our request by eight percent. Unfortunately, the NSF staff chose to show this as all being concentrated in initiatives like high performance computing and communications, advanced materials and processing, mathematics and science education, and so on, leaving the specific line item for core mathematics support unchanged from last year. Were they doing it over again obviously they would not do this but I am assured by both Massey and Bernthal that proposals that would fall in the core areas certainly can be considered for funding through the allocations to any of the special Presidential initiatives. I am equally assured that excellent proposals, even in the most esoteric mathematics, will not remain unfunded simply because no increase has been shown in the area of core mathematics.

I can assure you that all of us recognize the importance of mathematics as underlying all that we do in science and technology and I regret that this NSF budget was prepared in the way it was because it has caused unnecessary concern and worry throughout the mathematics community.

With all best wishes,

Sincerely yours,



D. Allan Bromley
The Assistant to the President
for
Science and Technology

**Professor Saunders MacLane
Department of Mathematics
University of Chicago
5734 University Avenue
Chicago, Illinois 60637**

"Document Control"

TYPE: INFORMATION

ORIGINATOR: 02

STATUS C

DOCUMENT NUMBER: 9201442

DIRECTORATE STATUS

FROM: MACLANE, SAUNDERS: THE UNIVERSITY OF CHICAGO

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 04/16/92

SUBJECT: HOPEFUL TO TALK TO DR. BROMLEY AT THE UPCOMING
ACADEMY MEETING.

DIRECTORATE STAFF
ASSIGNED: ASSIGNED:

ACTION STAFF
REQUIRED: ACTION:

SENDER'S DUE DATE:
OSTP DUE DATE: STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT:

COPIES TO: INTERNATIONAL/POLICY
D. Allan Bromley
PHYSICAL SCIENCES

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:

REMARKS: Allan - Some observations about NSF math FY93
1) David Sanchez - a mathematician - helped set the priorities
2) Overall, math is up by 80%
3) The controversy arises because of a shift in emphasis toward
applied math* - especially that associated with ECSET initiative

OSTP RECEIVED: 04/16/92 DEPT RECEIVED:
FILE: INTERNATIONAL-POLICY

CENTRAL FILES:

* applied math, computational math, and probability & statistics

Maybe the shift in emphasis will help us, as a nation, get
a better handle on risk analysis!

Karl

THE WHITE HOUSE
WASHINGTON

April 16, 1992

Dear Kirk:

Many thanks for your letter of February 19 and the copy of your paper entitled **The 90 Degree Excitation Function for Elastic Carbon Scattering and the Importance of Airy Elephants**. There is something almost poetic about your finding that each of our elephants is, in fact, a supernumerary rainbow!

Florent Haas spent two years in our laboratory at Yale and I will be very interested to see what results he finds with the new Strasbourg vivitron. I was in Strasbourg in December of 1991 and, unfortunately, at that time they were running into some significant difficulties with the electrostatics. Obviously this is not unexpected because they are trying out a totally new technology that is, in principle, capable of sustaining a terminal potential of 35 million volts. As it turns out, the new machine at Yale which became operational just before I came here to Washington has been running beautifully at up to 22 million volts and had I remained at Yale I would certainly have extended some of these measurements into the new energy range that it makes available.

Unhappily, the time that I find available to devote to nuclear physics these days is rapidly reaching the vanishing point although I still make a point of trying to read through **Physical Review Letters**.

Thanks again for sending me this delightful piece of work.

Sincerely yours,



D. Allan Bromley
The Assistant to the President
for
Science and Technology

Professor Kirk W. McVoy
Department of Physics
University of Wisconsin-Madison
1150 University Avenue
Madison, Wisconsin 53706

"Document Control"

TYPE: INFORMATION

DOCUMENT NUMBER: 9200622

ORIGINATOR: 02

STATUS C

DIRECTORATE STATUS

FROM: McVOY, Kirk W.: UNIVERSITY OF WISCONSIN, MADISON

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 02/19/92

SUBJECT: RE: EXCITATION FUNCTIONS

DIRECTORATE STAFF
ASSIGNED: ASSIGNED:

ACTION
REQUIRED:

STAFF
ACTION:

OSTP DUE DATE: SENDER'S DUE DATE: STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT:

COPIES TO: D. Allan Bromley
PHYSICAL SCIENCES

WHITE HOUSE TRACKING #:

CONTACT PERSON:
PHONE:

EXT:

REMARKS:

OSTP RECEIVED: 02/25/92 DEPT RECEIVED:
FILE: PHYSICAL SCIENCES-PHYSICS

CENTRAL FILES:

THE WHITE HOUSE
WASHINGTON

April 13, 1992

MEMORANDUM FOR THE HONORABLE EDWARD R. MADIGAN
SECRETARY
DEPARTMENT OF AGRICULTURE

FROM: D. ALLAN BROMLEY *AWB*
THE ASSISTANT TO THE PRESIDENT
FOR SCIENCE AND TECHNOLOGY
AND CHAIRMAN, FEDERAL COORDINATING
COUNCIL FOR SCIENCE, ENGINEERING
AND TECHNOLOGY

SUBJECT: THE PROPOSED INITIATIVE ON NUTRITION RESEARCH
AND EDUCATION

I fully understand your concern and am happy to withdraw this item from the agenda for our April 15 meeting of the Council.

I hope that we may be able to persuade you to personally participate in the Council activities with a number of your fellow Cabinet members. Harry Mussman has been ably representing the Agriculture Department but his rank in the Department is considerably lower than that of the other members of the Council and I believe that you might find the meetings to be of interest if you can find the time.



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

APR 10 1992

Dr. D. Allan Bromley
Assistant to the President
for Science and Technology
Old Executive Office Building
Washington, D.C. 20506

Dear Dr. Bromley:

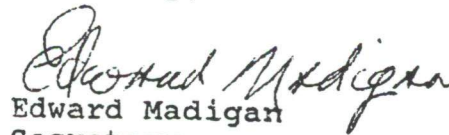
My purpose in writing is to request that the candidate initiative entitled Nutrition Research and Education not be taken up as an agenda item at the April 15, 1992, meeting of the Federal Coordinating Council for Science, Engineering and Technology (FCCSET).

During my time as Secretary I have given special, high priority to four key issues. Nutrition education is one of them. My priority is based on the \$35 billion in food aid programs administered by the Department and the importance I attach to making sure the various recipients of these programs understand how to use that aid to best advantage. A substantial increase in funding for nutrition education has been proposed in the FY 93 budget now before Congress.

I would like to see my nutrition education budget proposal fully funded this fall so that we can focus our attention on delivering expanded educational programs. I believe that moving ahead with the candidate FCCSET initiative would detract from our USDA effort by complicating the matter and even confusing some people.

For this reason I ask that consideration of the FCCSET initiative be put on hold at this time. Perhaps when our Departmental effort is well established we can reconsider the possibility.

Sincerely,


Edward Madigan
Secretary

"Document Control"

TYPE: ACTION

ORIGINATOR: 02

STATUS I

DOCUMENT NUMBER: 9201368

DIRECTORATE STATUS

FROM: MADIGAN, Edward: U.S. SECRETARY OF AGRICULTURE

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 04/10/92

SUBJECT: HE IS WRITING TO URGE THAT THE CANDIDATE INITIATIVE
ENTITLED NUTRITION RESEARCH AND EDUCATION NOT BE
TAKEN UP AS AN AGENDA ITEM AT THE 04/15/92 FCCSET
MEETING.

DIRECTORATE
ASSIGNED: FCCSET
STAFF
ASSIGNED:

ACTION
REQUIRED: AS NECESSARY

STAFF
ACTION:

SENDER'S DUE DATE:
OSTP DUE DATE: 05/01/92
DATE COMPLETED: STAFF DUE DATE
DATE COMPLETED/DEPT:

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
REMARKS: PHONE: EXT:

OSTP RECEIVED: 04/17/92
FILE: FCCSET

DEPT RECEIVED:

CENTRAL FILES:

THE WHITE HOUSE
WASHINGTON

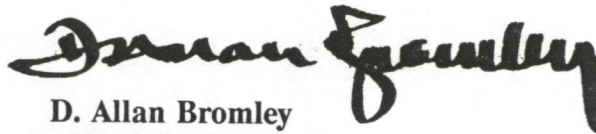
April 13, 1992

Dear Mr. McCloskey:

Many thanks for your nomination of candidates to serve on the Industry/Government Advisory Board on High Resolution Systems. Let me assure you that your nominations have been added to the very long list that we have received and the final selection will be made in the near future by the Operating Committee for the Critical Technologies Institute.

Many thanks for providing me with the names of such excellent candidates. We do very much appreciate your interest and help.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "D. Allan Bromley", written in a cursive style.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Mr. Peter F. McCloskey
President
Electronic Industries Association
2001 Pennsylvania Avenue, Northwest
Washington, D.C. 20006

"Document Control"

TYPE: ACTION
ORIGINATOR: 02

STATUS I

DOCUMENT NUMBER: 9201182
DIRECTORATE STATUS

FROM: McCLOSKEY, Peter F.: ELECTRONIC INDUSTRIES ASSOCIATION

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 04/02/92

SUBJECT: HE IS FORWARDING HIS RECOMMENDATIONS FOR THE HRISAB.

DIRECTORATE STAFF
ASSIGNED: INDUSTRIAL ASSIGNED:

ACTION STAFF
REQUIRED: AS NECESSARY ACTION:

SENDER'S DUE DATE:
OSTP DUE DATE: 04/21/92 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT:

COPIES TO: D. Allan Bromley

WHITE HOUSE TRACKING #: CONTACT PERSON:
PHONE: EXT:
REMARKS:

OSTP RECEIVED: 04/07/92
FILE: P-INDUSTRIAL-HRISAB

DEPT RECEIVED:

CENTRAL FILES:

THE WHITE HOUSE
WASHINGTON

April 7, 1992


Dear Governor Martin:

Thank you for your letter of March 13 inviting me to speak at the opening of your new pulp and paper pilot plant scheduled for October 22, 1992 in Raleigh. I apologize for the much belated response.

As much as I would like to join you for this auspicious occasion, I must regretfully decline due to a longstanding commitment.

I appreciate your thinking of me and would like to offer my best wishes for the event.

Sincerely yours,



D. Allen Bromley
The Assistant to the President
for
Science and Technology

The Honorable James G. Martin
Governor of North Carolina
Office of the Governor
Raleigh, North Carolina 27603-8001



STATE OF NORTH CAROLINA
OFFICE OF THE GOVERNOR
RALEIGH 27603-8001

JAMES G. MARTIN
GOVERNOR

March 13, 1992

The Honorable D. Allan Bromley
Assistant to the President for Science and Technology
Old Executive Office Building
17th Street and Pennsylvania Avenue, N.W.
Washington, DC 20506

Dear Allan:

North Carolina State University will open a new pulp and paper pilot plant on Thursday, October 22, 1992. This effort represents another splendid cooperative relationship between industry and North Carolina State University. Walter Massey was impressed with the Centennial Campus of North Carolina State University and the many efforts the State has made to develop genuine collaborative ventures. The paper industry has long recognized the need to invest in higher education in order to remain competitive. The United States still maintains a global competitive advantage in this industry as one of the lowest cost producers in the world.

I would like to invite you to come and share with us the opening of this partnership venture by speaking for 20 to 25 minutes at 1:30 p.m. on Thursday, October 22, 1992. I was sorry to miss your last appearance in Raleigh when you spoke to the North Carolina Association of County Commissioners, but Earl Mac Cormac tells me that you did an excellent job and you are now an Honorary Tar Heel. Congratulations!

Sincerely,

Jim Martin
James G. Martin

MAIL ROOM
1992

JGM:dma

cc: Earl R. Mac Cormac, Science Advisor
Larry W. Tombaugh, Dean, NC State University
College of Forest Resources

48 22 25 25 25 25

RECEIVED

"INVITATION FOR DR. BROMLEY"

TYPE: INVITATION-SPEECH

DOCUMENT NUMBER: 9200769

ORIGINATOR: 02

SPEECH: YES NO

FROM: MOELLER, Dade W.: HARVARD SCHOOL OF PUBLIC HEALTH

DATE OF EVENT: 11/09/92 THRU: 11/11/92
TENTATIVE DATES:

LOCATION OF EVENT: RITZ CARLTON HOTEL, BOSTON

TIME OF EVENT:

SUBJECT: AN INVITATION TO PARTICIPATE IN THE SECOND ANNUAL
HARVARD CONFERENCE ON COMERCIALIZING BIOMEDICAL
TECHNOLOGIES.

RSVP: 03/24/92

CONTACT PERSON: WITT, Michael

CONTACT NUMBER: 916-487-6745

INVITATION ACCEPTED?

~~YES~~ NO

COPIES TO: D. Allan Bromley
LIFE SCIENCES
Steve Olson

REMARKS:

DATE OF LETTER: 03/04/92

DATE RECEIVED: 03/10/92

FILE: INVITATION-SPEECH

THE WHITE HOUSE
WASHINGTON

March 31, 1992

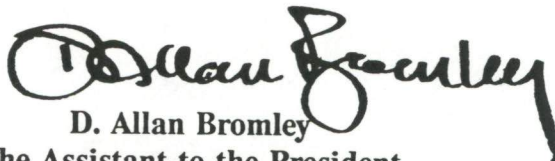
Dear Dean Moeller:

Thank you for your letter of March 4, 1992, inviting me to participate in the Harvard Conference on Commercializing Biomedical Technologies, scheduled to be held in November 1992.

As much as I would like to join you, I must regretfully decline your invitation for scheduling reasons.

I appreciate your thinking of me and would like to offer my best wishes for a successful conference.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "D. Allan Bromley". The signature is fluid and cursive, with the first name "D." being small and the last name "Bromley" being larger and more prominent.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Dr. Dade W. Moeller
Associate Dean for Continuing Education
Harvard School of Public Health
677 Huntington Avenue
Boston, Massachusetts 02115

THE WHITE HOUSE
WASHINGTON

March 18, 1992

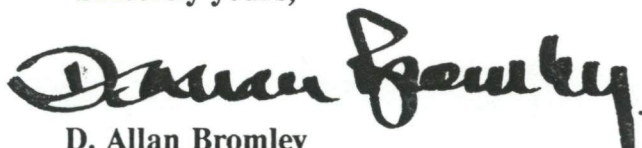
Dear Mr. Murday:

Thank you for your letter of December 18, 1991, inviting me to give a plenary talk at the American Vacuum Society's 39th National Symposium on November 9, 1992, scheduled to be held in Chicago. I apologize for the much belated response.

As much as I would like to join you, the period in question is not a good time for me to be away from Washington so, I must regretfully decline.

I appreciate your thinking of me and wish you a successful symposium.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "D. Allan Bromley". The signature is fluid and cursive, with a large, stylized initial "D".

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Mr. James S. Murday, President
American Vacuum Society
Code 6100
Naval Research Laboratory
Washington, D.C. 20375

"INVITATION FOR DR. BROMLEY"

TYPE: INVITATION-SPEECH

DOCUMENT NUMBER: 9125198

ORIGINATOR: 02

SPEECH: YES NO

FROM: MURDAY, James S.: AMERICAN VACUUM SOCIETY

DATE OF EVENT: 11/09/92

THRU:

TENTATIVE DATES:

Nov. 9

LOCATION OF EVENT: HYATT REGENCY HOTEL CHICAGO, ILLINOIS

TIME OF EVENT: 1:00 P.M. OR 6:30 P.M.

SUBJECT: AN INVITATION TO BE THE PLENARY SPEAKER AT THEIR
39TH NATIONAL SYMPOSIUM.

RSVP: 01/06/92

CONTACT PERSON:

CONTACT NUMBER:

INVITATION ACCEPTED?

☒ YES ☐ NO

COPIES TO: Steve Olson
PHYSICAL SCIENCES
INDUSTRIAL

REMARKS:

DATE OF LETTER: 12/18/91

DATE RECEIVED: 12/23/91

FILE: INVITATION-SPEECH

AMERICAN VACUUM SOCIETY

OFFICE OF THE PRESIDENT

CODE 6100

NAVAL RESEARCH LABORATORY

WASHINGTON DC 20375-5000

RECEIVED

P 3:20

18 December 1991

OSTP
MAIL ROOM

Dr. D. Allan Bromley
Director, Science & Technology Policy
Old Executive Office Building
Room 358
Washington, DC 20506

Dear Dr. Bromley:

We invite you to present a plenary talk at the American Vacuum Society's (AVS) 39th National Symposium on Monday, November 9, 1992 (~~or Thursday, November 12~~) in the Hyatt Regency Hotel, Chicago, Illinois. The talk could be scheduled at either 1 pm or 6:30 pm on Monday or 1 pm on Thursday.

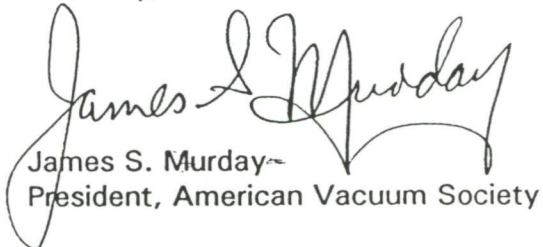
The American Vacuum Society represents several areas of high technology, including electronic materials and processing, nanometer scale science/technology, basic and applied surface science, thin films and surface modification, plasma science, vacuum metallurgy and vacuum technology. It has a multidisciplinary membership which reflects physicists, chemists, materials scientists and technologists. The annual symposium will host 2000 attendees who partake of some 1000 papers, 50 short courses and a large (300 companies) vendor exhibit. A copy of the 1990 Symposium preliminary program is attached to illustrate these points.

Suggestions for appropriate topics would include "The State of US Science" or "The Role of Science, Science Societies (i.e., the AVS) and Science Meetings (this symposium) in Technology Transfer." The latter would be of particular interest, since AVS members work on the cutting edge of half the key technologies identified as critical by OSTP.

The fabrication and properties of nanometerscale structures is one AVS focus. Please accept the enclosed coasters which are mementos of a 1990 AVS sponsored meeting in Baltimore on Nanometer Scale Science/Technology STM'90/NANO I. The letters in each of these figures are approximately 30-40 nm high, small enough to reduce the books in a typical library on to a postage stamp. The pattern colored black on silver was made by Dr. Quate (Stanford) by etching holes in graphite. The pattern colored gold (dots added for ease in viewing) was made by Dr. Guntherodt (Switzerland) by melting/resolidifying amorphous metal under a tip.

If you would be able to accept this invitation, we would be pleased to pay your travel expenses and an honoraria. To aid in our planning, we would appreciate a response by January 15, 1992.

Sincerely,

A handwritten signature in cursive script, reading "James S. Murday". The signature is fluid and elegant, with a large initial "J" and a stylized "M".

James S. Murday~
President, American Vacuum Society

Encls:

"Document Control"

TYPE: ACTION

ORIGINATOR: 02

STATUS I

DOCUMENT NUMBER: 9200780

DIRECTORATE STATUS

FROM: McLATCHIE, William: QUEEN'S UNIVERSITY

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 03/04/92

SUBJECT: HE REQUESTS A COPY OF THE BIO-TECHNOLOGY SCOPE
DOCUMENT.

DIRECTORATE
ASSIGNED: ADMINISTRATION

STAFF
ASSIGNED:

ACTION
REQUIRED: DIRECT REPLY

STAFF
ACTION:

SENDER'S DUE DATE:
OSTP DUE DATE: 03/24/92
DATE COMPLETED:

STAFF DUE DATE
DATE COMPLETED/DEPT:

COPIES TO: D. Allan Bromley
INTERNATIONAL/POLICY

WHITE HOUSE TRACKING #:

CONTACT PERSON:
PHONE:

EXT:

REMARKS:

OSTP RECEIVED: 03/10/92 DEPT RECEIVED:
FILE: ADMINISTRATION-OSTP REPORTS

CENTRAL FILES:



RECEIVED

VICE-PRINCIPAL (RESEARCH)
DEAN OF GRADUATE STUDIES

92 MAR 10 P12:34

Queen's University
Kingston, Canada
K7L 3N6
Tel 613 545-6079
Fax 613 545-6300

March 4, 1992

OSTP
MAIL ROOM

Dr. D. Allan Bromley
Executive Office of the President
Office of Science and Technology Policy
Old Executive Office Bldg., Rm. 360
17th and Pennsylvania NW
Washington, D.C.
20506

Dear Allan:

It was a pleasure to meet with you again last week and to hear your views on a whole variety of matters. Rod Fraser and I found our discussion very stimulating and we think very useful in helping us to improve our approach to U.S. fund raising and advisory committees and the like.

We remain strongly committed to the concept of the Chair in Science and Technology Policy and we would like to work out a strategy which takes into account fund raising opportunities in the U.S. and their dependence on your own movements and aspirations. We see this Chair as a major component of the School of Policy Studies, made even more important by the recent elimination of the Science Council of Canada.

During our conversations you mentioned your office had recently brought out a report containing regulations covering the introduction of genetically engineered substances to the environment. I wonder if you could arrange to send us a copy as its contents will be of immense value to the Insect Biotech Centre here at Queen's?

Once more thank you for your advice and for your continued interest in Queen's.

Sincerely,

A handwritten signature in cursive script, appearing to read "Wm".

Wm. McLatchie
Vice-Principal (Research)
Dean of Graduate Studies

EXERCISE OF FEDERAL OVERSIGHT WITHIN SCOPE OF STATUTORY
AUTHORITY: PLANNED INTRODUCTIONS OF BIOTECHNOLOGY PRODUCTS
INTO THE ENVIRONMENT

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

AGENCY: Office of Science and Technology Policy
Executive Office of the President

ACTION: Announcement of Policy

SUMMARY: Biotechnology is the use of various biological processes, both traditional and newly devised, to make products and perform services from living organisms or their components. Because these diverse processes, products and services may find application in many areas, such as medicine and pharmaceuticals, agriculture, energy, manufacturing, and environmental protection, the attendant planned introduction of biotechnology products into the environment may be subject to federal oversight under the federal statute(s) relating to each such area. The statutory provisions necessarily define the boundaries of the scope of discretion afforded to executive branch agencies to exercise oversight.

In 1986 the "Coordinated Framework" was issued to explain the proper allocation and coordination of oversight responsibilities under the several relevant statutes and among the several relevant federal agencies. The Coordinated Framework thus addressed who shall have oversight authority in each instance, but did not address how that authority should be exercised in the frequent situations in which a statute leaves the implementing agency latitude for discretion.

To fill that need, the present FEDERAL REGISTER notice sets forth the proper basis for agencies' exercise of oversight authority within the scope of discretion afforded by statute. It describes a risk-based, scientifically sound approach to the oversight of planned introductions of biotechnology products into the environment that focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created. Exercise of oversight in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that an organism has been modified by a particular process or technique.

In order to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed. The extent and type of oversight measure(s) will thus be commensurate with the gravity and type of risk being addressed, the costs of alternative oversight options, and the effect of additional oversight on existing safety incentives.

These principles recognize the desirability of appropriate oversight of unreasonable risks, such as current restrictions on the introduction of dangerous pathogens; the principles also confirm the limited extent of current oversight of low-risk activities, such as the traditional breeding of farm animals and plants.

Means for implementing these principles are illustrated; specific implementation must be developed in the context of each agency's statutory programs. Because this Final Statement on Scope addresses the exercise of oversight discretion within the scope of statutory authority, nothing herein displaces agencies' duties under applicable statutes, nor provides additional authority not available under applicable law.



D. Allan Bromley
Director
Office of Science and Technology Policy
Date: February 24, 1992

BILLING CODE FY 1992:

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 - A. Scientific Principles for the Risk-Based Approach
 - B. Risk-Based Approach Ensures Safety
 - C. Risk-Based Approach Avoids Discouraging Useful Innovation
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- IV. IMPLEMENTATION
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 - B. Evaluating Risk
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2. EPA Report on Risk Priorities
3. Summary of Public Comments on Proposed Statement on Scope
4. Report on National Biotechnology Policy
5. Competitiveness Council Fact Sheet on Critical Technologies

I. BACKGROUND

A. STATUTES PERTAINING TO BIOTECHNOLOGY PRODUCTS

Biotechnology is the use of various biological processes, both traditional and newly devised, to make products and perform services from living organisms or their components. See Report on National Biotechnology Policy (President's Council on Competitiveness: Feb. 1991), p. 1. Because these diverse processes, products and services may find application in many areas, such as medicine and pharmaceuticals, agriculture, industry, and environmental protection, the attendant planned introduction of organisms or other biotechnology products into the environment may be subject to federal oversight under the one or more federal statutes relating to each such area. The Federal Register of November 14, 1985 (50 Fed. Reg. 47174) contains a matrix of the many federal authorities related to biotechnology products. There is no single, unified statute governing all introductions of biotechnology products into the environment, just as there is no single, unified statute governing the use of any other basic, multipurpose technology such as chemical engineering, civil engineering, or the use of fire or electricity. A single statute would quickly become obsolete, or an excessive constraint on innovation, as people devised new and useful ways to employ the technology, and would fail to address the important differences in the potential impacts of the technology when used in different ways.

Introductions into the environment of biotechnology products are therefore subject to government oversight pursuant to statutory authority corresponding to the particular type of introduction in question. The Federal Plant Pest Act governs the importation and movement of plant pests; the Federal Food, Drug and Cosmetic Act (FFDCA) governs foods, food additives, cosmetics, human and veterinary drugs, and medical devices; the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) governs pesticides; the Toxic Substances Control Act (TSCA) governs chemicals; several statutes (the Clean Air Act, Clean Water Act, Oil Pollution Act, "Superfund" law, and Resource Conservation & Recovery Act) govern the use of pollution control techniques; and certain statutes govern projects that are federally funded. One or more of these laws may apply to introductions of biotechnology products for research or commercial purposes.

Each of these laws is administered by a federal agency. For example, the Food & Drug Administration (FDA) administers FFDCa; the Environmental Protection Agency (EPA) administers FIFRA, TSCA, and the pollution-control statutes; and the Department of Agriculture (USDA) administers the Federal Plant Pest Act while also funding many research projects involving biotechnology.

Each statute directs the implementing executive branch agency to carry out certain responsibilities. The statutory provisions necessarily define the boundaries of the scope of discretion afforded to executive branch agencies to exercise oversight. Typically each statute leaves the agency discretion within those bounds in exercising oversight.

B. THE "COORDINATED FRAMEWORK" AND THE NEED FOR A SCOPE DOCUMENT

In view of the diversity of federal statutes pertaining to biotechnology products, in 1986 the Coordinated Framework for the Regulation of Biotechnology was issued to describe the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products. It explained that existing statutes provide a basic network of agency jurisdiction over both research and products, assuring reasonable safeguards for the public and the environment. It also explained the coordination among federal agencies to ensure that such safeguards would be generated by a smooth, understandable regulatory oversight process. The Coordinated Framework stated that "to the extent possible, responsibility for a product use will lie with a single agency." (51 Fed. Reg. 23363). The Framework was expected to evolve in light of experience, and modifications to the framework were anticipated. The Coordinated Framework for the Regulation of Biotechnology continues to be Federal Government policy today for the allocation of oversight responsibilities -- which agencies shall have oversight responsibility for which biotechnology products.

But the Coordinated Framework did not fully address how oversight should be exercised within the scope of discretionary authority afforded by statute. The Coordinated Framework recognized that while the statutory bases for regulation among the involved agencies may differ, common principles should govern decisions on how to exercise discretionary oversight over introductions of biotechnology products.

C. PROPOSED STATEMENT ON SCOPE

In order to fill that need, the federal agencies worked closely to devise such a common statement of the basis for exercising oversight within the scope of discretionary authority afforded by statute. This statement has commonly come to be called the "Scope" document. In July 1990, OSTP published a proposed version of the Scope document prepared through the interagency Biotechnology Working Group of the President's Council on Competitiveness, which had been asked to review the scope issues by the Director of OSTP after prior attempts to develop a scope had not reached consensus and because the Director observed the need for attention by an interagency group concerned with policy implications as well as scientific issues. The history of this effort

is detailed in the Proposed Scope document published by OSTP. See "Principles for Federal Oversight of Biotechnology: Planned Introduction Into the Environment of Organisms with Modified Hereditary Traits," 55 Fed. Reg. 31118 (July 31, 1990). The Proposed Scope set forth a risk-based approach to the scope of oversight: "To the extent permitted by law, planned introductions into the environment of organisms with modified hereditary traits should not be subject to oversight ... unless information concerning the risk posed by the introduction indicates that oversight is necessary." 55 Fed. Reg. at 31120. This statement expresses a risk-based approach that focuses on the properties of products introduced into the environment, the characteristics of the target environment, and the confinement measures employed, rather than on the process or technique by which the product was created. Information on the process could provide evidence of likely risk and of quality control in production, but the nature of the process could not be the sole or dispositive criterion for triggering oversight. The Proposed Scope delineated possible criteria for evaluating risk, pertaining to both the organism and the target environment into which it was introduced.

The Proposed Scope also suggested six examples of categories for exclusion from oversight. Five of these categories were defined by modifications such as selective breeding, transformation, deletions and use of noncoding marker genes. The sixth category consisted of modified organisms that present no greater risk than their unmodified parental strains.

D. PUBLIC COMMENTS ON THE PROPOSED SCOPE AND SUBSEQUENT POLICY DEVELOPMENTS

The Proposed Scope was issued for public comment. A summary of the public comments received is provided in the Appendix, below.

In addition, several important policy developments have occurred since the issuance of the Proposed Scope, which have been taken into account in developing the current final statement on Scope. These developments include a decision by the President to approve Principles for Regulatory Review for Biotechnology, and an EPA report endorsing the risk-based approach to environmental policy. These policy developments are also summarized in the Appendix.

Agency proposals that address the introduction of organisms into the environment have also been issued since the Proposed Scope. On February 1, 1991, USDA proposed guidelines (56 Fed. Reg. 4134) which set out points-to-consider for scientists in designing field trials and were intended to provide quality assurance for federally-funded agricultural research.

EPA is considering proposed regulations under FIFRA for small-scale release of microbial pesticides titled: Microbial Pesticides; Experimental Use Permits and Notifications, and proposed regulations under TSCA titled: Microbial Products of Biotechnology; Proposed Regulations under the Toxic Substances Control Act.

The present final statement of principles for the exercise of oversight within the scope of statutory authority is based on interagency deliberations since July 1990 and careful consideration of all the items set forth at greater length in the Appendix, including consideration of comments from public and subsequent policy developments. As indicated below, the fundamental risk-based approach in the Proposed Scope received widespread endorsement and has been retained and strengthened in today's final statement.

II. RATIONALE FOR RISK-BASED APPROACH

The purpose of this statement is to guide the exercise of agencies' oversight, within the scope of authority afforded by statute, to ensure the safety of planned introductions of biotechnology products into the environment while not unduly inhibiting the benefits of such introductions. This approach therefore focuses on the characteristics and risk posed by an introduction, rather than on the process by which a product is created. This is the same fundamental, risk-based approach enunciated in the Proposed Scope in July 1990 (see 55 Fed. Reg. at 31119), and endorsed by the great majority of public comments on the Proposed Scope (see Appendix below). The risk-based approach is scientifically sound, properly protects public health and the environment against risk, and avoids hindering safe innovations. Citing these rationales, the first Principle of Regulatory Review for Biotechnology approved by President Bush in August 1990 requires the federal government to adhere to a risk-based approach. Likewise, the EPA Report on Risk Priorities issued in September 1990 and the Competitiveness Council Fact Sheet on Critical Technologies issued in April 1991 explain the imperative of following a risk-based approach. (See excerpts in Appendix, below.) This section briefly explains the reasoning behind this risk-based approach.

A. SCIENTIFIC PRINCIPLES FOR THE RISK-BASED APPROACH

Introductions of organisms into the environment may pose hazards to humans, wild or domesticated plants and animals, or to the environment generally (for example, algal blooms in ponds or disruptions of natural cycles). The risk posed by an introduction of biotechnology products into the environment is a function of the characteristics of the organisms or other products, the particular application (including confinement measures), and the environment itself. As stated in the Coordinated Framework, "Within agriculture, for example, introductions of new plants, animals and microorganisms have long occurred routinely with only some of those that are not native or are pathogenic requiring regulatory approval." (51 Fed. Reg. 23303). Even many organisms that are pathogenic are routinely used with practices or under conditions that mitigate risk; much of the research within the discipline of plant pathology is in this category. Meanwhile, certain unmodified organisms are of such great risk that they are not allowed into the United States, such as the Foot and Mouth Disease Virus (FMDV).

Just as with traditional breeding techniques, the production of organisms using new molecular techniques of genetic manipulation may or may not pose risk, depending on the characteristics of the organism, the target environment, and the type of application.

The National Research Council's extensive review of the potential risks of introductions of organisms made from new biotechnology processes (NRC, Field Testing Genetically Modified Organisms (1989)) reached the conclusion that organisms that have been genetically modified are not per se of inherently greater risk than unmodified organisms. It elaborated:

1. The same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods. (p. 15)
2. Information about the process used to produce a genetically modified organism is important in understanding the characteristics of the product. However, the nature of the process is not a useful criterion for determining whether the product requires less or more oversight. (pp. 14 and 15.)
3. No conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes. (p. 14)
4. Crops modified by molecular and cellular methods should pose risks no different from those modified by classical methods for similar traits. As the molecular methods are more specific, users of these methods will be more certain about the traits they introduce into the plants. (p.3)
5. In many respects, molecular methods resemble the classical methods for modifying particular strains of microorganisms, but many of the new methods have two features that make them even more useful than the classical methods. **Precision** allows scientists to make genetic modifications in microbial strains that can be characterized more fully, in some cases to the level of DNA sequence. This reduces the degree of uncertainty associated with any intended application. The new methods have greater **power** because they enable scientists to isolate genes and transfer them across natural barriers. (p. 123)

The process of modification is thus independent of the safety of the organism. Although the new biotechnology processes can be used to produce risky organisms, so can traditional techniques; it is the characteristics of the organism, the environment, and the application that determine risk (or lack thereof) of the introduction, not the technique used to produce the organism. Indeed, the new technologies of molecular modification may increase the potential for safe, planned introductions because they employ techniques that are more precise and more efficient than traditional cross-breeding, and that therefore yield a better-characterized and more predictable organism. On the other hand, their great power allows us to transfer genes more readily, thus resulting in organisms with new traits or combinations of traits.

From these scientific observations derive the following fundamental Scope principles:

1. A determination to exercise oversight within the scope of discretion afforded by statute should not turn on the fact that an organism has been modified, or modified by a particular process or technique, because such fact is not alone a sufficient indication of risk.

2. A determination to exercise oversight in the scope of discretion afforded by statute should be based on evidence that the risk presented by introduction of an organism in a particular environment used for a particular type of application is unreasonable.

3. Organisms with new phenotypic trait(s) conferring no greater risk to the target environment than the parental organisms should be subject to a level of oversight no greater than that associated with the unmodified organisms.

B. RISK-BASED APPROACH ENSURES SAFETY

A purpose of government regulation of biotechnology, as with any safety regulation, is to limit unreasonable risks faced by the public and the environment. Yet agency resources are scarce, and cannot be applied to every possible problem; responsible officials must choose carefully the risks of highest concern and find the best ways to combat them. In order to protect the public and the environment, the scope of oversight should help focus agency efforts at reduction of the most important risks (and at least cost, so that society's resources are kept available to combat the next highest risks). As the US Environmental Protection Agency (EPA) recently stated:

There are heavy costs involved if society fails to set environmental priorities based on risk. If finite resources are expended on lower-priority problems at the expense of higher-priority risks, then society will face needlessly high risks. (US EPA, SAB, "Reducing Risk: Setting Priorities and Strategies for Environmental Protection," Sept. 1990, Exec. Sum., (p 2.)

C. RISK-BASED APPROACH AVOIDS DISCOURAGING USEFUL INNOVATION

Determining the scope of oversight on grounds other than risk would also tend to discourage useful innovations. The potential benefits of biotechnology are enormous; as described in the February 1991 Report on National Biotechnology Policy, innovation in biotechnology has begun to make possible great improvements in our ability to grow food, protect the environment, and produce medications, among other applications. Triggering the exercise of oversight based on the use of a specific innovative technology, such as recombinant DNA, will tend to discourage the use of that technology by industry and researchers.

The distribution of oversight burden across technologies is in many ways as important as the total amount of burden: if oversight is aimed only at one type of technology, the burden will be skewed against that technology and hinder its development. New regulations often place greater restrictions on new products or technologies while

grandfathering in older, and sometimes more risky, products or technologies. This uneven regulation encourages the continued use of older products and technologies, while discouraging innovation and potential risk reduction.

Similarly, special oversight directed at "new techniques" in biotechnology could discourage innovations using those techniques.

III. FINAL STATEMENT ON SCOPE

Statutory provisions necessarily define the boundaries of the scope of discretion afforded to executive branch agencies to exercise oversight. Within the scope of authority provided by statute, federal agencies shall exercise oversight of planned introductions of biotechnology products into the environment only upon evidence that the risk posed by the introduction is unreasonable. A risk is unreasonable where the full value of the reduction in risk obtained by oversight exceeds the full cost of the oversight measure. This formulation ensures that limited federal oversight resources will be applied where they will accomplish the most net beneficial protection of public health and the environment while allowing useful, safe innovations to proceed. Evidence of risk must incorporate information about the characteristics of the organism or other biotechnology product, the target environment, and the type of application.

Federal government regulatory oversight should focus on the characteristics and risks of the biotechnology product--not the process by which it is created. Products developed through biotechnology processes do not per se pose risks to human health and the environment; risk depends instead on the characteristics and use of individual products. Where oversight is warranted, the extent and type of oversight measure(s) must be commensurate with the gravity and type of risk being addressed, must maximize the net benefits of oversight by choosing the oversight measure that achieves the greatest risk reduction benefit at the least cost, and must consider the effect that additional oversight could have on existing safety incentives.

The risk-based approach taken in this Final Statement on Scope is the same as the approach enunciated in the July 1990 Proposed Scope, which provided that "To the extent permitted by law, planned introductions into the environment ... should not be subject to oversight ... unless information concerning the risk posed by the introduction indicates that oversight is necessary." 55 Fed. Reg. at 31120. As detailed below, the Final Statement on Scope also retains the "criteria for evaluating risk" suggested in the Proposed Scope. The principal differences between today's Final Statement on Scope and the Proposed Scope are (i) the recognition that there are a variety of oversight measures that agencies might employ, not simply a binary choice between "oversight" and "no oversight," and therefore the provision that agencies choose from among the menu of measures those oversight measures that achieve risk reduction at net benefit and least cost; and (ii) the removal of the examples of "categories for exclusion" in the Proposed Scope, because, as described below under "Implementation," those categories were not explained in the basis of risk and ignored the need for each agency to have the flexibility to fashion its implementation in the context of its statutory program. These

differences are warranted in the interest of sound public policy, and reflect the numerous public comments (summarized in the Appendix) recommending such revisions.

IV. IMPLEMENTATION

A. EXERCISING DISCRETION WITHIN THE SCOPE OF STATUTORY AUTHORITY

As described above, this Final Statement on Scope guides agencies' exercise of oversight within the scope of discretion provided by statute. Nothing in this document displaces agencies' duties under applicable statutes, nor does this document provide the basis for additional authority not available to agencies under applicable law. Rather, this document guides the exercise of discretion within the range of authority left to agencies under their statutes. Each agency will need to implement these guidelines in a manner appropriate to each statutory framework, and to exercise its oversight authority consistent with the risk-based principles of this Final Statement on Scope.

This Final Statement on Scope governs all oversight within the scope of agency discretion afforded by statute of planned introductions of biotechnology products into the environment. It does not relate only to new regulatory initiatives or new categories of organisms introduced into the environment. In addition, the term "planned introduction" as used here includes introductions in the course of research and in commercial and other applications. It is not limited to initial small-scale field trials.

In applying the risk-based approach there will of course be areas in which regulatory interventions are frequent, and areas in which such interventions are legally authorized but are less common because the industry operates safely and the occasions for regulation and enforcement are fewer. Such safety could be the result of longstanding industry practices, and of industry's pragmatic understanding that government intervention -- whether through federal or state law or otherwise -- would occur if safety rules were violated. Although federal oversight for such activities may be legally available, it may be observed that where an industry operates in a safe manner, little or no oversight is commonly exercised. One example of such a safe equilibrium may be traditional agriculture operating with safe organisms following accepted practices and precautions. This is consistent with recommendations made by the National Research Council in the publication, Field Testing Genetically Modified Organisms, 1989, p. 66.

B. EVALUATING RISKS

Products developed through biotechnology processes do not per se pose risks to human health and the environment; risk depends instead on the characteristics and use of individual products. Such determinations should be based on risk factors or criteria like the ones listed below pertaining to the organism's ecological niche, potential for gene exchange, ability to monitor and to mitigate persistence and spread and potential consequences of dissemination into the greater environment. These factors for evaluation of risk are largely derived from the work of the Ecological Society of

America. (See J. Tiedje, R. Colwell, Y. Grossman, et al., 70 *Ecology* 298 (April 1989).)

For the organism: fitness; infectivity, virulence, pathogenicity, toxicity; host range; the type of substrate or resources utilized; the purity of the formulation; environmental limits to growth or reproduction (habitat, microhabitat); susceptibility to control by antibiotics, biocides, by substrate, or by mechanical means; whether and how introduced traits are expressed.

For the target environment: selection pressure for the introduced trait; presence of wild, weedy or feral relatives within dispersal capability of the organism or its genes; presence of vectors or agents of dissemination or dispersal (e.g., mites, insects, rodents, birds, humans, machines, wind, water); direct involvement in basic ecosystem process (e.g., nutrients cycling); whether there are alternative hosts or partners (e.g., the organism is involved in symbiosis or mutualism); range of environments for testing or use in light of potential geographic range; effectiveness of confinement, monitoring and mitigation plans.

The scope principles do not dictate precisely how information on risk should be evaluated. Different ways of making the risk determination are possible. One means of judging the risk posed by an introduction is to compare its risk to an introduction of a comparable organism or biotechnology product previously used in introductions in a comparable target environment. An organism or other biotechnology product can be comparable to a previously used organism or product regardless of the process by which that organism has been modified or product produced. An introduction should be subject to no greater degree of oversight than was a comparable organism or product previously used in past safe introductions in a comparable target environment. Effective confinement techniques in appropriate cases can also reduce the potential risk of an introduction, and accordingly, the need for oversight.

Unreasonable risk is the threshold for exercising oversight within the scope of discretion afforded by statute. The term does not denote a fixed absolute number. Rather, a risk is "unreasonable" where the environmental benefits achieved by oversight measures to reduce the risk are greater than the social cost of those oversight measures. This definition enables, and requires, agencies to choose from among the range of oversight options those measures that obtain net benefits. Thus, a more demanding oversight option may be warranted when the risk reduction to be gained from government intervention is large. If the risk reduction to be gained is small, as will usually be the case with low-level risks, less costly oversight options will need to apply. As described above under "Rationale for Risk-Based Approach," this formulation ensures that oversight resources will be allocated to address priority risks. "If finite resources are expended on lower-priority problems at the expense of higher-priority risks, then society will face needlessly high risks." (US EPA, SAB, "Reducing Risk: Setting Priorities and Strategies for Environmental Protection," Sept. 1990, Exec. Sum. (p. 2.)) It should also be noted that "unreasonable risk" is already a criterion used by federal agencies, such as in exercising oversight under provisions of TSCA and FIFRA.

Of course, in some cases an agency may not have sufficient information to determine whether the introductions of organisms would pose unreasonable risk, and whether additional oversight therefore would be warranted. In cases in which an agency has reason to believe that introductions could pose risk but lacks adequate information to determine if that risk is unreasonable, agencies may need to collect information. Any information requests should be designed to maximize their benefits and minimize their costs by soliciting only the most useful information in the least costly manner.

Certain terms used to characterize risk evaluation in the Proposed Scope, 55 Fed. Reg. 31118, have been dropped because they were ambiguous and raised concerns among the public commenters. Several comments noted the confusing language and potential circularity of the term "similar organism" or "similar introduction." That usage has therefore been removed and, where appropriate, replaced by the more precise idea of an introduction posing comparable risk to a previous introduction. The term "organism with deliberately modified hereditary traits" was intended to encompass any organism with changed hereditary traits, regardless of the technique or process used to effect the change. This term was intentionally broader than terms such as "genetically modified organism" which have come to imply a specific technique of genetic manipulation (namely, use of recombinant DNA methods). Yet, "deliberately modified hereditary traits" might not have encompassed exotic organisms introduced by humans into a vulnerable target environment. Thus, the term has been omitted and the focus is now placed on the risk of an introduction, not the genesis of the organism.

C. ASSESSING OVERSIGHT OPTIONS

Agencies have a wide variety of oversight options with which to fashion their oversight programs consistent with the risk-based approach enunciated here. The term "federal oversight" includes a range of possible Federal activities related to planned introductions: issuance of suggested industry practices, development of guidelines for certain introductions, and requirements for notification, labelling, prior review or approval of certain introductions. This range of federal oversight activity might be undertaken by a Federal agency or by a local entity as directed by or under guidance from a Federal agency. It could involve, for example, a research institution establishing an "institutional safety committee" for review of certain planned introduction experiments.

This menu of oversight options means that agencies can choose oversight measures to be commensurate with the gravity and type of risk being addressed, and fashioned to maximize the net benefits to society and the environment, taking into account the costs of oversight.

In determining the risk reduction that may be achieved by a contemplated oversight measure, it is important to recognize that persons introducing biotechnology products into the environment often face other institutional incentives to ensure that such introductions are safe. Such existing safety incentives may include oversight already being exercised under another regulatory authority, state laws, and marketplace incentives for safety created by the interests of workers and consumers in obtaining

products that are safe. Safety can also be promoted by generally accepted research practices, professional and industrial association standards, and other safety-oriented guidelines and procedures. It is important to take account of the interplay between the new oversight measure and the pre-existing incentive systems. In some circumstances the effect of a new oversight measure may complement existing safety incentives, but in others its effect may be dampened or undercut by its (unintended) displacement of existing safety incentives. For example, imposing new safety standards may in certain circumstances simply displace existing safety incentives provided by state law or by market price differentials for accepting risk. Agencies should account for these potential incentive effects in their calculation of the net benefits of potential oversight measures. Further, agencies should affirmatively design oversight measures to work in concert with pre-existing safety systems, such as by strengthening the information base on which marketplace incentives depend. In appropriate cases agencies might forego additional oversight where existing incentives adequately address the risks posed.

D. USE OF "CATEGORIES OF EXCLUSION/INCLUSION"

1. Treatment of Former Exclusion Examples

The six examples of "categories for exclusion" provided in the Proposed Statement on Scope (55 Fed. Reg. at 31121) have been deleted from the Final Statement on Scope. As these examples were set forth without the context provided by the statutes under which regulations were to be implemented, no rationales were provided in the Proposed Scope relating them to risk. Thus, a certain amount of confusion arose concerning their relationship to risk. Indeed, several commenters suggested that the exclusions were inconsistent with a risk-based approach because they were "process-based." For instance, the first proposed exclusion category contained plants and animals that result from natural reproduction or the use of traditional breeding techniques. Traditional breeding activities, however, are typically of low or trivial risk because the plants and animals chosen for breeding by traditional agricultural breeders are typically of low or negligible risk in their applications and target environments, not because the techniques are themselves intrinsically safe. Because this Final Statement is to be a guidance document to the agencies, it is not meant to provide the risk rationales for these examples. Any agency that wishes to use any of these categories in the context of a specific statute would provide a rationale based on risk.

The five examples of categories for exclusion addressed only various aspects of the introduced organism, whereas the present Final Statement on Scope addresses the entire introduction, necessarily including the characteristics of the target environment and the particular application as well as the nature of the biotechnology product. The five examples for exclusion gave no insight into the critical issue of the potential interactions between an organism's traits and its ecological context. An organism may pose risk in one target environment but be relatively harmless, or beneficial, in another. It is fundamental that the present Final Statement on Scope requires oversight decisions to be made within the scope of discretion afforded by statute based on information about the organism or other product, the target environment and the type of application, not about the organism alone.

The simple binary choice between "oversight" and "no oversight," implied by the notion of a single scope with a single set of exclusions, does not accurately characterize the range of choices open to an agency within the scope of discretion afforded by statute. Oversight measures may include the option of no oversight, or no further oversight in cases where statutes require initial oversight, as well as a range of other measures.

A single list of "exclusions" (or, for that matter, "inclusions") cannot pragmatically be written to apply uniformly to all agencies and all statutes. The specific mechanisms of implementation of the risk-based principles will of course depend on the statute at issue, and accordingly no single list of "categories" can be promulgated for use by all agencies under all statutes. Agencies could, for instance, develop categorical risk-based exclusions from a statute's oversight net, such as where a statute begins by encompassing all of a certain set of activities and then exempts low-risk elements of that set. Or agencies could develop categorical risk-based inclusions in a statute's oversight net, such as where a statute attaches oversight only when an activity creates an unreasonable risk. Or agencies could employ a stratified hierarchy, providing several levels or types of oversight that correspond to levels of risk. The choice of these or other means will depend on the statute and the nature of the activity subject to oversight. Not every statute may be open to all of these options. Indeed, by listing specific "examples of categories for exclusion," the Proposed Scope issued in July 1990 may have given the incorrect impression that some exclusion-oriented approach was mandatory for all agencies, or that the specific categories listed in that proposed document were mandatory, or that an extra burden of persuasion would be borne by agencies seeking to craft a different approach or set of exclusions; none of these was intended.

2. Developing Categories of Exclusion

The concept of categories for exclusion may nonetheless retain usefulness in appropriate statutory circumstances. Where a statute initially casts a wide net over a field of activity, the agency may retain or be delegated authority to exclude some subcategories of activity from oversight on the ground that the potential risks they pose are too low to justify oversight or that such risks are already adequately overseen by another agency.

For example, under TSCA, EPA must receive notice of all "new chemicals"; those that pose "unreasonable risk" are subject to further regulatory restrictions. But TSCA enables EPA to exclude products from review, in at least four ways. First, EPA may determine that certain products are not "new" and thus do not require premanufacturing notice to the agency. For instance, where small changes in genetic or molecular structure are involved, it may be a matter of judgment whether the product is "new." In exercising such judgment, the agency may determine that certain categories of products are not "new" under TSCA because they possess no "new" properties. Second, under TSCA section 5(h)(3), EPA may exclude microorganisms used in small quantities (defined by rule) for research and development. Third, the agency can decline to act during the 90 day period after a notice is filed. Unless the agency acts, after 90 days the product may be produced without further restriction. EPA could develop guidance to its TSCA program to decline action with respect to certain low-risk categories of

introductions of organisms. Fourth, under TSCA 5(h)(4), the agency has the authority to exclude broad categories of products by rulemaking where those products do not pose "unreasonable risk." EPA could propose risk-based 5(h)(4) exclusions for certain categories of introductions, simultaneous with proposing any regulations applying TSCA to organisms.

Similarly, under FFDCA, no "food additive" may be marketed unless it is in compliance with an authorizing regulation promulgated by FDA. However, substances that are "generally recognized as safe," as defined in the statute, are excluded from the definition of "food additive," and therefore from the premarket clearance requirements. For organisms to be used as or to make food ingredients, FDA could describe the criteria by which it will determine whether the organisms or their products will fall into the "generally recognized as safe" exclusion, or will be subject to premarket regulation.

Thus, agencies exercising oversight pursuant to this document should consider employing risk-based exclusions. For example, an exclusion could be fashioned (if its risk basis is appropriately explained in the context of the particular oversight measure) for organisms whose introductions pose low or negligible risk, e.g. domesticated animal and crop varieties used in agriculture.

3. Developing Categories of Inclusion

A different approach could be employed where a statute bases the exercise of oversight on risk and gives the agency the task of affirmatively identifying which particular activities out of a larger universe pose risks sufficient to justify oversight. Agencies could therefore develop risk-based categories of inclusion to define the area of oversight.

For example, the Federal Plant Pest Act governs the movement of plant pests regardless of the process by which the organisms were produced. The Act defines "plant pests" as any organisms "which can directly or indirectly injure or cause disease or damage in any plants or parts thereof ..." In order to implement the Act, USDA has identified specific organisms with these properties and placed them on a published list. Movement or importation of organisms on the list requires an advance permission from the agency. The list is expanded as new plant pests are identified; also, items can be removed from the list when they are believed to no longer present a plant pest risk.

4. Developing Combined Approaches

In some areas, an agency might use both "exclusion" and "inclusion" approaches. It might identify categories of activities for inclusion on the ground that they pose a sufficient risk to justify oversight, and simultaneously exclude other activities on the ground that they do not present risks justifying oversight. Any activities not included in either category could be dealt with on a case-by-case basis, and perhaps addressed explicitly in categorical exclusions or inclusions at a later date. For example, the guidelines on recombinant DNA organisms developed by NIH use both approaches. An appendix to the guidelines lists microorganisms on the basis of likely hazard, an example of the "inclusion" approach. The guidelines also specifically exclude certain organisms,

such as E. coli K-12, B. subtilis and Saccharomyces. As another example, an agency might implement a statute requiring public disclosure of all hazardous introductions by explicitly excluding some trivial-risk activities from the duty to disclose, specifically including some categories of introductions that typically pose a potential hazard, and announcing criteria for deciding whether the remaining introductions are risky enough to require disclosure.

Finally, agencies could employ a "hierarchy" of oversight options to correspond to degrees and types of risk. Some statutes arm the agency with an array of oversight instruments to deploy as the circumstances warrant. In such cases, agencies must decide not only whether or not to exercise oversight but also the appropriate level and type of oversight when it is exercised. Agencies could develop categories or criteria for exercise of varying degrees of oversight, based on the degree of risk posed by an introduction, and the costs of oversight options. For example, oversight options might include: guidance on sound practices, simple notification to a local review committee, application for prior approval by a local review committee, notification to a federal agency, considered deference to another agency already overseeing such introduction, or application for prior approval by a federal agency. Or under its statutory authority an agency might impose (as a requirement of all introductions of a certain risk level or as a condition of prior approval in a specific case) disclosure of information, restrictions on a planned introduction, appropriate prophylactic measures (confinement or containment), or prohibition of certain kinds of activities. Other options could also be available under various statutory programs.

One example of such a hierarchical approach to the degree of oversight is contained in USDA's proposed guidelines for federally-funded researchers (56 Fed. Reg. 4134 (Feb. 1, 1991)). The guidelines calculate the likely risk of an introduction of a modified organism according to the likely risk to health and environment posed by introducing the parental strain, and the change in that risk (increase or decrease) effected by modification of the parental strain. For each of five risk levels, they suggest levels of confinement measures to be applied, and degrees of review by a disinterested party (such as a local safety committee).

APPENDIX: COMMENTS ON PROPOSED STATEMENT ON SCOPE AND SUBSEQUENT POLICY DEVELOPMENTS

Several important statements of government policy on risk and new technology have been published since July 1990. Because these policy guidelines have played a formative role in the development of the current Final Statement on Scope, they are excerpted briefly below. In addition, public comments on the Proposed Statement on Scope were received. The discussion in the present document relies on and refers to the concepts and recommendations contained in these policy guidelines and the views expressed in the public comment letters. The items below are presented in chronological order.

1. PRESIDENT'S PRINCIPLES OF REGULATORY REVIEW

In August 1990 President Bush approved Four Principles of Regulatory Review for Biotechnology, as follows:

(1) Federal government regulatory oversight should focus on the characteristics and risks of the biotechnology product -- not the process by which it is created.

Products developed through biotechnology processes do not per se pose risks to human health and the environment; risk depends instead on the characteristics and use of individual products. Biotechnology products that pose little or no risk should not be subject to unnecessary regulatory review during testing and commercialization. This allows agencies to concentrate resources in areas that may pose substantial risks and leaves relatively unfettered the development of biotechnology products posing little or no risk.

(2) For biotechnology products that require review, regulatory review should be designed to minimize regulatory burden while assuring protection of public health and welfare.

Expedited review procedures should be adopted for products likely to pose lesser risk. The jurisdiction of the several regulatory agencies should be clarified to avoid unnecessary confusion and delay and agencies should use the same standards and apply them consistently. This is especially important where a product could be regulated by several agencies. For example, pest-resistant plants may be subject to regulation by both the Environmental Protection Agency (for pesticidal properties) and by the Food and Drug Administration (for food safety).

(3) Regulatory programs should be designed to accommodate the rapid advances in biotechnology. Performance-based standards are, therefore, generally preferred over design standards.

A performance standard sets the ends or goals to be achieved, rather than specifying the means to achieve it (e.g., through a design standard). This provides firms and researchers with flexibility in choosing the best means of compliance. A performance-based standard for containment, for example, would permit alternative biological approaches for assuring containment in place of a design-based standard requiring specific physical barriers.

The adoption of performance criteria in developing regulations reduces the need to rely on a lengthy and contentious regulatory process to revise regulations. Such unwieldy regulatory procedures inevitably inhibit the changes in regulatory structure needed to accommodate advances in science knowledge. Procedures should be adopted to provide agency decision-makers with up-to-date scientific opinion and knowledge -- for example, through the use of science advisory panels.

(4) In order to create opportunities for the application of innovative new biotechnology products, all regulation in environmental and health areas --

whether or not they address biotechnology -- should use performance standards rather than specifying rigid controls or specific designs for compliance.

"Design-based" requirements may preclude use of biotechnology products even when such approaches may be both less costly and more effective. For example, a requirement to employ specific pollution control equipment would prevent use of innovative biotechnology pollution remediation or control techniques.

2. EPA REPORT ON RISK PRIORITIES

In September 1990 the US Environmental Protection Agency's Science Advisory Board released its report, "Reducing Risk: Setting Priorities and Strategies for Environmental Protection." The report stated (Exec. Sum. p. 2):

There are heavy costs involved if society fails to set environmental priorities based on risk. If finite resources are expended on lower-priority problems at the expense of higher-priority risks, then society will face needlessly high risks.

Setting regulatory policy based on the process used to modify an organism rather than on the relative risk of its introduction, or based on type of technology (e.g., biotechnology versus other technologies) rather than the relative risk of an activity, would be inconsistent with this risk-based approach; it would misallocate oversight resources and thereby burden low-risk activities while exposing society to higher-risk activities.

3. SUMMARY OF PUBLIC COMMENTS ON THE PROPOSED STATEMENT ON SCOPE

By October 1990, the deadline for submissions, forty-four letters of comment on the OSTP Proposed Statement on Scope (55 Fed. Reg. 31118 (July 1, 1990)) were received. The following is a brief summary of these comments.

(A) OVERVIEW

- o The general response to the "Scope Document" and the Administration's effort to define a common approach to oversight of planned introductions was positive.
- o Commentators strongly supported those principles outlined in the body of the document which emphasized a risk-based approach to regulation.
- o The majority of criticisms focused on the "Examples of Potential Exclusion Categories" while other comments related to ensuring implementation of the principles through the regulatory process. Particular words or phrases were cited as vague or otherwise problematic.

(B) SPECIFIC ISSUES

(i) Risk-based Approach

- o Thirty-two letters specifically noted the wisdom of a risk-based approach, particularly if the level of oversight is commensurate with the degree of potential risk.
- o The "Criteria for Evaluating Risk" were deemed adequate and appropriate in that they focused on characteristics of the organism and the environment into which it is being released, rather than on the process by which the organism is produced.
- o Several respondents stated that there is a sufficient body of scientific experience to support risk evaluation as a means for determining need for oversight.

(ii) Examples of Potential Exclusion Categories

- o Several respondents supported the use of categories of introductions that could be excluded from oversight as a move away from case-by-case regulatory review.
- o The most frequent objection to the exclusion categories (10 letters) was that categories 1-5 were process-based, in contradiction with the principles contained in the body of the document. Thus, several respondents proposed deleting the "Examples of Potential Exclusion Categories."
- o At least 3 commenters opposed any regulatory scheme that did not include all of the exclusion categories on the premise that current regulatory inconsistencies and confusion would be retained otherwise.
- o Five commenters proposed employing category 6 as the cornerstone for federal policy on exemptions.
- o It was pointed out that many organisms produced using methods described in categories 1-5 would be subsumed under category 6 if the resulting product posed no greater risk to the target environment than the parental organism.
- o Evidence was offered that organisms produced via methods proposed for possible exclusion under exclusion categories 1-5 may still pose health or environmental hazards and, thus, should not be exempted.
- o One commenter felt that category 2 should be modified to cover only those exchanges "known to occur in nature" and another suggested adding viruses.
- o There was a proposal to add "organisms resulting from mutagenesis by transposable elements" to category 5.

- o A new category was proposed comprised of organisms developed using recombinant techniques (such as PCR, in vitro mutagenesis, homologous recombination, or other self-cloning methods) which result in phenotypes identical to those obtainable through traditional techniques.
- o One letter suggested adding three organisms to the exempt list indicating interest in a process similar to that used by the National Institutes of Health (NIH) whereby conditions under which certain experiments may be performed are considered by petition to the Recombinant DNA Advisory Committee.

(iii) Implementation

- o A recurring theme was the need for consistent implementation across agencies. It was suggested that OSTP remain visible and involved in order to ensure interagency consistency.
- o Three letters noted the past delays in proposing agency regulations and encouraged rapid implementation of the "Scope Document."
- o Four commenters predicted that it would be difficult or impossible to implement this scheme because it was not clear who was responsible for determining the need for oversight.
- o Local Industrial Biosafety Committees (IBCs) or similar institutions were proposed as a venue for determination of risk and need for further oversight.
- o Two commentators suggested that notification be deleted from the description of oversight methods in order to allow for categories of exemption from other, more burdensome forms of oversight.
- o Several respondents stated that a system of licenses or permits was not appropriate for research activities.

(iv) Definitions

- o The most problematic word was "similar" when used to describe the situation in which "the level of risk of an introduction is the same as or less than a previous safe introduction." Suggested alternative language in 3 letters was "comparable to or less than."
- o Two letters questioned the adoption of the term "modified hereditary traits" as opposed to "genetically modified organisms," which implies that modified traits are heritable, regardless of how the modification was achieved.
- o There was a question as to whether or not contained field tests would be included under "planned introductions into the environment."

(v) Additional Issues

- o Four respondents proposed alternate schemes, three of which involved the development of lists of exempt organisms or introductions. Suggested criteria for inclusion on such a list were "familiarity" or inclusion on the list currently maintained by CDC and NIH.
- o OSTP was reminded that this document will play an important role in international negotiations and product export.

4. REPORT ON NATIONAL BIOTECHNOLOGY POLICY

In February 1991, the President's Council on Competitiveness published the Report on National Biotechnology Policy. The Report describes the Administration's policy on biotechnology regulation (p. 11):

In biotechnology, as in many other high technology industries, Federal regulation is a critical determinant of the time and cost to bring a product to market. In serving as "gatekeepers" for the development and use of new products, regulatory agencies may create substantial barriers to product development. These barriers result from the costs of testing to meet regulatory requirements, the potential for delay in regulatory approval, and the uncertainty associated with the possible imposition of extensive restrictions or outright disapproval of new biotechnology research or products. In addition, uncertainty related to the extent or effectiveness of Federal regulation may lead to the enactment of a patchwork of conflicting and burdensome state regulations. Delay, cost, and regulatory uncertainty discourage new research in regulated areas and curtail the development of new products, as well as undermine public confidence.

In general, to avoid unnecessary burdens on biotechnology, the Administration has sought to eliminate unneeded regulatory burdens for all phases of the development of new biotechnology products -- laboratory and field experiments, product development, and eventual sale and use. Existing regulatory structures for plants, animals, pharmaceuticals, chemicals and toxic substances provide an adequate framework for regulation of biotechnology in those limited instances where private markets fail to provide adequate incentives to avoid unreasonable risks to health and the environment. In these instances, regulation also can help shield industry from avoidable incidents that could tarnish its image and impair its development.

5. COMPETITIVENESS COUNCIL FACT SHEET ON CRITICAL TECHNOLOGIES

In April 1991 the President's Council on Competitiveness issued a Fact Sheet concurrently with the OSTP publication of the Report of the National Critical Technologies Panel. The Fact Sheet stated:

Because technological innovation holds the promise of providing new and better ways to meet the very objectives of particular health, safety, or environmental regulations, those regulations that discourage or penalize innovation are self-perpetuating burdens on American industry.

While appropriate regulation in response to market failures can serve valuable social and economic functions, it may also impose significant costs that particularly affect the ability and incentive of firms to develop new high technology products. Some regulatory regimes are no longer appropriate to new technologies, while others were developed without adequate consideration of the burdens placed on international competition, and many regulations explicitly impose greater burdens on new facilities and products.

Regulation inhibits innovation most when the regulatory agency takes on the task of specifying which technologies or designs industry must employ. Further, once a technology is enshrined in regulation, firms have little incentive to invest in better techniques.

The following principles were offered to minimize disincentives to innovation:

- o Regulations should be issued only on evidence that their potential benefits exceed their potential costs. Regulatory objectives, and the methods for achieving these objectives, should be chosen to maximize the net benefits to society.
- o Regulations that seek to reduce health or safety risks should be based upon scientific risk-assessment procedures, and should address risks that are real and significant rather than hypothetical or remote.
- o Voluntary private standards and disclosure should be relied on where possible instead of inflexible regulation.
- o Health, safety and environmental regulations should address ends rather than means. They should employ performance-based incentives that harness the creativity of market actors to design and continually innovate better ways of reducing excess risks. They should not specify technologies or designs that firms must employ.
- o Licensing and permitting decisions and review of new products should be made swiftly and should be based on standards that are clearly defined in advance.



OFFICE OF THE VICE PRESIDENT
WASHINGTON

THE PRESIDENT'S COUNCIL ON COMPETITIVENESS
STREAMLINING FEDERAL REGULATION OF BIOTECHNOLOGY PRODUCTS
FACT SHEET

"Today, I am announcing major new ground rules for regulation of biotechnology. This 4 billion dollar industry should grow to 50 billion by the end of the decade -- if we let it. The rewards we will reap include new medicines, safer ways to clean up hazardous wastes, and a revolution in agriculture. The United States leads the world in biotechnology, and I intend, through sensible regulation, and in some instances, deregulation, to keep it that way."

President George Bush
February 24, 1992

Noting the Bush Administration's initiative to increase FY '93 funding for biotechnology R&D by 7%: "Were federal agencies to regulate products simply because an innovative process such as rDNA technology had been used, we would be unable to reap the benefit of our own research investments. The degree of oversight should be commensurate with risk, and the need for oversight should be properly supported by credible scientific evidence of reasonably foreseeable risk to health or the environment."

D. Allan Bromley, Advisor to the President for
Science and Technology, February 24, 1992

The President announced a plan to streamline federal regulation of new biotechnology products today. The plan developed by the Council on Competitiveness, which is chaired by Vice President Quayle, will protect safety, health, and the environment and at the same time removing unnecessary regulatory barriers to development of biotechnology products.

There are three phases to the Council's initiative:

Phase I -- The Final Scope Document for Planned Introductions of Biotechnology Products in to the Environment will be published by the Office of Science and Technology Policy this week. The Final Scope document sets forth a scientifically sound risk-based policy for the exercise of statutory discretion by federal agencies

in the oversight of biotechnology products used outside of the laboratory. Completion of the Scope was recommended in the Council's 1991 Report on National Biotechnology Policy.

Phase II -- Complete review and publish proposed rules by agencies responsible for oversight of various biotechnology products (for example EPA's upcoming regulation of biotechnology products that act as pesticides). These rules will reduce the burden of current federal oversight.

Phase III -- Develop of detailed "road-maps" based on the principle of "one stop shopping" to clearly describe the pathway for obtaining federal approvals to commercialize biotechnology products including foods, animals, microorganisms and plants.

Background on Biotechnology

The US is the world leader in new biotechnology, the use of various biological processes to make products and perform services with living organisms or their components. Sales of the US biotechnology industry produced reached \$4 billion in 1991, and are expected to be \$50 billion by the year 2000 assuming appropriate federal oversight.

Advances in molecular technology over the past two decades have added new tools to the biotechnology techniques traditionally used in agriculture, food production, and other processes. The first new biotechnology products were innovative pharmaceuticals and medical devices developed during the last 15 years. Increasing efforts are underway to develop and bring to market biotechnology products for a broad range of agricultural and environment applications ranging from improved plant varieties to environmental clean-up.

To ensure that the US retains its competitive lead in this industry, the Council's plan establishes the general principles for federal regulation of new products. All federal oversight for products used in the environment should be based on risk, and not on any specific biotechnology process used to develop a product. This policy seeks to avoid the burden on innovation that could occur were oversight to be simply triggered by the use of an innovative new technology.

FOR FURTHER INFORMATION
PLEASE CONTACT

John Cahrssen (202) 456-6222

THE WHITE HOUSE

March 18, 92

Dear Bill:

It was great to be back at
Queen's and to see so many old
friends. Here with the requested
SCOPE document.

Best regards Allan

THE WHITE HOUSE
WASHINGTON

Professor William McLatchie
Dean of Graduate Studies
Queen's University
Kingston, Canada
K7L 3N6

THE WHITE HOUSE

July 12, 1942

Dear Cora:

Welcome to Washington. I
am delighted to learn that you
have accepted the leadership of
NSF's new Division and look

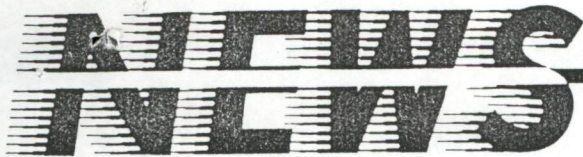
forward to working with you
with all best wishes

Sincerely

William B. Ewald

National Science Foundation

Atlanta
FYE
Pine



Michael Fluharty
(202) 357-9498

February 5, 1992
NSF PR 92-12

CORA BAGLEY MARRETT NAMED NSF ASSISTANT DIRECTOR FOR SOCIAL BEHAVIORAL AND ECONOMIC SCIENCES

Walter E. Massey, director of the National Science Foundation, has announced the appointment of Cora Bagley Marrett as the first NSF assistant director of its new Social, Behavioral and Economic Sciences (SBE) division, created last October. Marrett, professor of Sociology and Afro-American studies at the University of Wisconsin since 1974, will begin at NSF as a part-time consultant in February and as full-time assistant director in May.

In her new position, Marrett will be responsible for four divisions representing the following major research areas: social and economic science, behavioral and cognitive sciences, international cooperative scientific activities, and science resources studies. Disciplines funded within SBE include: anthropology, archaeology, linguistics, psychology, sociology, economics, geography and political science. Marrett, among her other major responsibilities, will oversee the SBE portfolio of NSF-supported research which in FY 92 totaled \$85.87 million.

"The Foundation is very fortunate to have an eminent social scientist of Dr. Marrett's standing as its first Assistant Director for the Social, Behavioral and Economic Sciences,"

-more-



Massey said. "Her stature in the sociological community and her active participation in professional associations and other activities that span the spectrum of the social, behavioral and economic sciences make her an ideal choice to build the new directorate into a dynamic organization dedicated to the support of the best research in these fields."

Before coming to the University of Wisconsin Marrett served on the faculties of Western Michigan University and the University of North Carolina, Chapel Hill. She has served on a number of NSF advisory panels and was the first Chair of the NSF Committee on Equal Opportunities in Science and Engineering. She was a member of the Board of Governors at Argonne National Laboratory, from 1983-1990 and was chosen as a member of the President's Commission on the Accident at Three Mile Island in 1979.

Her research interests include the structure and operation of formal organizations and issues of racial, ethnic and gender equity in engineering and the sciences. She has been an active member of many professional societies including: the American Sociological Association, the American Association for the Advancement of Science, and the American Educational Research Association. She has served as the director of the United Negro College Fund/Andrew W. Mellon programs since 1990.

Marrett received a Ph.D., and M.A. in Sociology from the University of Wisconsin at Madison (1968 and 1965 respectively) and a B.A. from Virginia Union University in Richmond (1963).

THE WHITE HOUSE
WASHINGTON

February 12, 1992

Dear Walter:

It was good seeing you at the PCAST meeting. I appreciate your willingness to take time from your schedule to join our meetings. I hope everything is going well at NSF.

I have enclosed a copy of a letter I have received a letter from Senator Barbara Mikulski, in which she endorses a proposal from Johns Hopkins University for the Critical Institute. In my response to Senator Mikulski, which I have also enclosed, I explained that the selection process is being managed by NSF, and therefore I have forwarded her letter to you.

Again, thank you for all your work at NSF and on PCAST, and I look forward to continuing to work with you.

Sincerely yours,



D. Allan Bromley
The Assistant to the President
for
Science and Technology

The Honorable Walter Massey, Director
National Science Foundation
1800 G Street, NW
Washington, D.C. 20550

Enclosures

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

February 12, 1992

Dear Madam Chair:

Thank you for your letter regarding the proposal by Johns Hopkins University for the Critical Technologies Institute (CTI). I appreciate your support for the Institute and for Johns Hopkins.

The selection process for the CTI contractor is being handled exclusively by the National Science Foundation, which will serve as sponsor of the Institute. For this reason, I have forwarded your letter to NSF Director Dr. Walter Massey for proper consideration.

The contractor is expected to be chosen by this spring. In the meantime, I appreciate your interest, and I welcome any questions or comments you may have. I look forward to discussing this and other issues with you and your Subcommittee during our hearing in March.

Sincerely yours,



D. Allan Bromley
Director

The Honorable Barbara Mikulski, Chair
Subcommittee on Veterans Affairs, HUD,
and Independent Agencies
Committee on Appropriations
United States Senate
Washington, D.C. 20510

cc: The Honorable Walter Massey, Director
National Science Foundation

"Document Control"

TYPE: INFORMATION

ORIGINATOR: 02

STATUS C

DOCUMENT NUMBER: 9200301

DIRECTORATE STATUS

FROM: MORI, Wataru: PRIME MINISTER'S COUNCIL FOR SCIENCE AND TECHNOLOGY

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 01/10/92

SUBJECT: A LETTER EXPRESSING HIS REGRET THAT DR. BROMLEY WAS
UNABLE TO COME TO TOKYO.

DIRECTORATE STAFF
ASSIGNED: ASSIGNED:

ACTION STAFF
REQUIRED: ACTION:

SENDER'S DUE DATE: STAFF DUE DATE
OSTP DUE DATE: DATE COMPLETED/DEPT:
DATE COMPLETED:

COPIES TO: D. Allan Bromley
INTERNATIONAL/POLICY

WHITE HOUSE TRACKING #: CONTACT PERSON:
REMARKS: PHONE: EXT:

OSTP RECEIVED: 01/28/92
FILE: INTERNATIONAL-JAPAN

DEPT RECEIVED:

CENTRAL FILES:

Withdrawal/Redaction Sheet

(George Bush Library)

Document No. and Type	Subject/Title of Document	Date	Restriction	Class.
01. Letter	To: Allan Bromley From: Wataru Mori Re: Visit to Japan [personal information redacted] (1 pp.)	1/10/92	(b)(6_	

Collection:

Record Group: Bush Presidential Records
Office: Science and Technology Policy, Office of (OSTP)
Series: Bromley, D. Allan, Files
Subseries: Correspondence Files
WHORM Cat.:
File Location: D. Allan Bromley Correspondence - J-S [2 of 4] [1992]

Date Closed:	2/5/2010	OA/ID Number:	62002-006
FOIA/SYS Case #:	2005-0336-F	Appeal Case #:	
Re-review Case #:		Appeal Disposition:	
P-2/P-5 Review Case #:		Disposition Date:	
AR Case #:		MR Case #:	
AR Disposition:		MR Disposition:	
AR Disposition Date:		MR Disposition Date:	

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P-1 National Security Classified Information [(a)(1) of the PRA]
 P-2 Relating to the appointment to Federal office [(a)(2) of the PRA]
 P-3 Release would violate a Federal statute [(a)(3) of the PRA]
 P-4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
 P-5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
 P-6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Removed as a personal record misfile.

Freedom of Information Act - [5 U.S.C. 552(b)]

(b)(1) National security classified information [(b)(1) of the FOIA]
 (b)(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
 (b)(3) Release would violate a Federal statute [(b)(3) of the FOIA]
 (b)(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
 (b)(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
 (b)(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
 (b)(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
 (b)(9) Release would disclose geological or geophysical information

THE WHITE HOUSE
WASHINGTON

February 3, 1992

Dear Wataru:

I too am sorry that I was unable to see you during President Bush's visit to Japan but, as you know, the planning for that trip changed markedly from what had originally been the case and what I anticipated would be the case when I talked to you last in Tokyo in October.

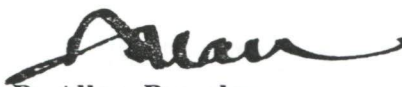
I am including herewith some of the promised materials from our last Carnegie Group meeting and apologize for the long delay in getting these to you. I do hope, however, that you will find them of interest.

I look forward to talking with you about a number of important problems when we meet in the United Kingdom for the next meeting of that group.

In the meantime, let me wish you a very happy and productive 1992.

With all best wishes,

Sincerely yours,



D. Allan Bromley
The Assistant to the President
for
Science and Technology

Professor Wataru Mori
Prime Minister's
Council for Science and Technology
Kasumigaseki 2/2/1
Chiyoda-ku, Tokyo, 100
Japan

Enclosures

THE WHITE HOUSE
WASHINGTON

January 6, 1992

Dear Dr. Murday:

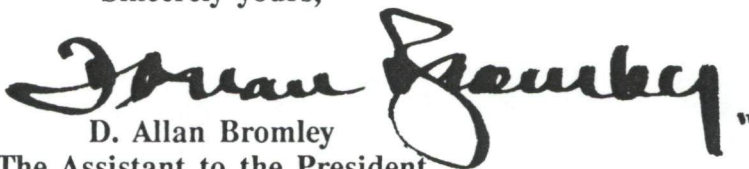
Thank you for your kind invitation to address the American Vacuum Society's 39th National Symposium scheduled for Monday, November 9, 1992.

I am happy to accept your invitation but must caution you that occasionally I have to cancel engagements at the last moment due to Presidential scheduling that requires my presence. I sincerely hope that this does not happen.

As the time of the symposium approaches, my office will contact you to work out details for the event. The date is on my calendar and I hope that I will be available to be with you and your colleagues during this special event.

I am pleased that you thought of me and look forward to the occasion.

Sincerely yours,


D. Allan Bromley
The Assistant to the President
for
Science and Technology

Dr. James S. Murday
President, American Vacuum Society
Code 6100
Naval Research Laboratory
Washington, D.C. 20375-5000

"INVITATION FOR DR. BROMLEY"

TYPE: INVITATION-SPEECH

DOCUMENT NUMBER: 9125198

ORIGINATOR: 02

SPEECH: YES NO

FROM: MURDAY, James S.: AMERICAN VACUUM SOCIETY

DATE OF EVENT: 11/09/92 THRU:
TENTATIVE DATES:

LOCATION OF EVENT: HYATT REGENCY HOTEL CHICAGO, ILLINOIS

TIME OF EVENT: 1:00 P.M. OR 6:30 P.M.

SUBJECT: AN INVITATION TO BE THE PLENARY SPEAKER AT THEIR
39TH NATIONAL SYMPOSIUM.

RSVP: 01/06/92

CONTACT PERSON:

CONTACT NUMBER:

INVITATION ACCEPTED? YES NO

COPIES TO: Steve Olson
PHYSICAL SCIENCES
INDUSTRIAL

REMARKS:

DATE OF LETTER: 12/18/91

DATE RECEIVED: 12/23/91

FILE: INVITATION-SPEECH

511
INV

AMERICAN VACUUM SOCIETY

RECEIVED
OFFICE OF THE PRESIDENT
CODE 6100
NAVAL RESEARCH LABORATORY P 3: 20
WASHINGTON DC 20375-5000

18 December 1991
OSTP
MAIL ROOM

Dr. D. Allan Bromley
Director, Science & Technology Policy
Old Executive Office Building
Room 358
Washington, DC 20506

Dear Dr. Bromley:

We invite you to present a plenary talk at the American Vacuum Society's (AVS) 39th National Symposium on Monday, November 9, 1992 (or ~~Thursday, November 12~~) in the Hyatt Regency Hotel, Chicago, Illinois. The talk could be scheduled at either 1 pm or 6:30 pm on Monday or 1 pm on Thursday.

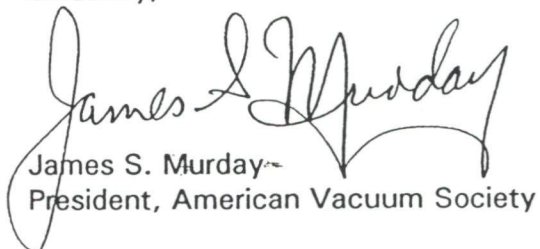
The American Vacuum Society represents several areas of high technology, including electronic materials and processing, nanometer scale science/technology, basic and applied surface science, thin films and surface modification, plasma science, vacuum metallurgy and vacuum technology. It has a multidisciplinary membership which reflects physicists, chemists, materials scientists and technologists. The annual symposium will host 2000 attendees who partake of some 1000 papers, 50 short courses and a large (300 companies) vendor exhibit. A copy of the 1990 Symposium preliminary program is attached to illustrate these points.

Suggestions for appropriate topics would include "The State of US Science" or "The Role of Science, Science Societies (i.e., the AVS) and Science Meetings (this symposium) in Technology Transfer." The latter would be of particular interest, since AVS members work on the cutting edge of half the key technologies identified as critical by OSTP.

The fabrication and properties of nanometerscale structures is one AVS focus. Please accept the enclosed coasters which are mementos of a 1990 AVS sponsored meeting in Baltimore on Nanometer Scale Science/Technology STM'90/NANO I. The letters in each of these figures are approximately 30-40 nm high, small enough to reduce the books in a typical library on to a postage stamp. The pattern colored black on silver was made by Dr. Quate (Stanford) by etching holes in graphite. The pattern colored gold (dots added for ease in viewing) was made by Dr. Guntherodt (Switzerland) by melting/resolidifying amorphous metal under a tip.

If you would be able to accept this invitation, we would be pleased to pay your travel expenses and an honoraria. To aid in our planning, we would appreciate a response by January 15, 1992.

Sincerely,

A handwritten signature in cursive script, reading "James S. Murday". The signature is fluid and elegant, with a large initial "J" and a stylized "M".

James S. Murday
President, American Vacuum Society

Encls:

THE WHITE HOUSE
WASHINGTON

January 2, 1992

Dear Nick:

Clearly both of our situations have changed substantially since we last communicated. Let me begin by congratulating you on your new appointment at Harvard and even more, let me congratulate you on becoming a grandfather. I would appreciate it if you would let me have Julia's address because I have lost touch with her since the days when we were all at the Wright Laboratory in the early 1960s.

The material in your letter concerning the possible use of new bioscience to make possible more stringent enforcement of the international ban on trade on elephant ivory is certainly interesting and I was impressed by the specificity that you demonstrate in your article in *Nature*.

My problem, however, is that it is not clear to me how, in a practical sense, customs officers would actually use this new expertise at the actual point of entry.

As I understand it, ivory flows through a great many channels in Africa with little possibility of control except when it finally passes through customs into industrialized countries. To date, my informants here tell me that a ban at this point has proved to be surprisingly effective but in large part because it is simply a go, no-go, call that customs inspectors make readily and on the spot. How customs inspectors at the very many different points of access into the U.S., for example, just to take this country alone, could possibly avail themselves of and interpret the laboratory analysis that you propose with its relatively high level of sophistication is not yet clear to me.

I suspect that the Federal agencies will be reluctant to provide financial support for the database project you suggest until they can be convinced that it will be an essential component of a practicable and feasible actual application on the front line of customs officials activities. I would suspect that the kind of studies they would want to see would necessarily involve a full-scale review of past and present trafficking issues, possible means of enforcement, and availability in costs testing to the respective countries.

I am intrigued and delighted by the science but, I suspect that you have a substantial way to go before you will be able to convince the appropriate agencies here in Washington to provide the kind of support that will be require for the project that you have mind.

It was good to hear from you and in the meantime warmest best wishes to you, to Kerstin, to her daughter, and, of course, to Julia.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'D. Allan Bromley', with a stylized, flowing script.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Professor Nikolaas K. van der Merwe
Peabody Museum of Archaeology and Ethnology
Harvard University
11 Divinity Avenue
Cambridge, Massachusetts 62138



PEABODY MUSEUM OF ARCHAEOLOGY AND ETHNOLOGY

HARVARD UNIVERSITY, 11 DIVINITY AVENUE, CAMBRIDGE, MASSACHUSETTS 02138 U.S.A.

Telephone (617) 495-~~2248~~ 8921/8920

FAX (617) 495-~~2336~~ 8925

RECEIVED

91 DEC 16 A10:54

12 December 1991
MAIL ROOM

The Honorable Dr. D. Allan Bromley
Assistant to the President for Science and Technology
Old Executive Office Building, Suite 360
17th Street and Pennsylvania Avenue, NW
Washington, DC 20500

Dear Dr. Bromley:

The last time we corresponded I was at the University of Cape Town; I moved to Harvard in 1988. In the meantime, Kerstin, daughter of Julia and me, has had a daughter of her own. There were clearly no loose neutrons wandering around the Wright Nuclear Structure Laboratories way back in the 1960s to interfere with the production of succeeding generations.

I write this time about the issue of reconsidering the international ban on trade in elephant ivory; the ugly political confrontation that promises to erupt around the issue; and the scientific developments that are required to defuse the issue in the short and long term. I seek your involvement in the scientific side of the issue, if you consider it appropriate.

In March 1992, the Convention on Trade in Endangered Species (CITES) meets in Kyoto to consider applications from South Africa and Zimbabwe that their elephant and rhino populations (of which they have a surplus) be removed from Appendix I of the Convention treaty. This would allow them to sell ivory and rhino horn obtained from natural deaths and culling in their parks, the income to be used for the benefit of wildlife parks and their rural African neighbours. The Bush administration will apparently support these applications, a position I strongly endorse as consonant with sound wildlife management practices. This position will draw a lot of political heat, particularly from assorted animal rights groups, Greenpeace, the European Greens, and so forth. A half-page advertisement in the *New York Times* of Sunday, 8 December, paid for by the International Wildlife Coalition (whoever they may be), fires the opening shot: "The return of the African chainsaw massacre! Bush administration caves in to trophy hunters and ivory cartel to re-open *elephant slaughter*!" In October 1989, a coalition of people like these turned the CITES meetings into a circus and produced the ivory trade ban.

The argument for lifting the ban for countries with well-managed wildlife populations is compelling. The U.S. negotiating position will not be written in final form until January, but will likely be that the countries of southern Africa be allowed to market their surplus ivory and rhino horn. The opposite argument, when rationally presented, is that any form of legal trade makes it possible to bring illegally poached materials to market, and that these would come from the countries where the animals are endangered.

There is a scientific solution to this political impasse. It involves (1) a forensic technique based on stable isotope ratios that makes it possible to trace elephant ivory or rhino horn to the source where the animal lived and (2) a control system that uses such a technique to establish that wildlife products in international trade come from those countries that may legally sell them. To allow a legal trade without such controls will, in fact, have serious repercussions in countries where wildlife management is inadequate or corrupt.

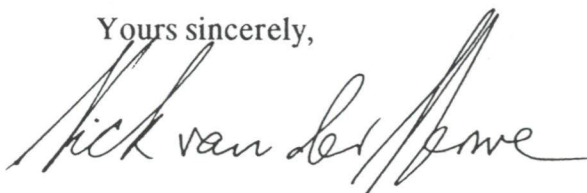
I have successfully completed, with international teams of isotope chemists and wildlife biologists, the feasibility studies for tracing elephant ivory and rhino horn to source. These provenience techniques rely on a combination of stable isotope ratios in tusks and horns, acquired by the animals from their environment. Three isotope pairs are usually sufficient to pinpoint the park from which an animal came. The tracing technique for elephant ivory utilises carbon, nitrogen, and strontium isotope ratios. It was prominently published in *Nature* (reprint enclosed) and has been widely reported in the news media. A similar study for rhino horn is still in press and is less well known, although not less successful.

In a burst of misplaced optimism the South African and Zimbabwe wildlife people have cited these studies as an argument in their favour. The fact is, however, that these forensic techniques can be deployed only if a database for the entire African continent is compiled first. The pilot project for elephants involved about 100 animals. A full database for the continent, which can hold up in court, will require at least 1,000 animals. I calculate that a database for elephants will take one to two years to produce and will cost \$400,000. (A database for a second species like rhino will cost about half that, if done as a piggyback project.) The obvious sources of funds for this type of research are organisations such as the World Wildlife Fund, Wildlife Conservation International, International Union for the Conservation of Nature, etc. They will not touch it, mostly because of the politics involved.

On 19 December I will make a presentation about these techniques to a biological research committee of the U.S. Fish and Wildlife Management Authority. The meeting was called by Mr. Ken Stansell of the Fish and Wildlife Authority, 4401 Fairfax Drive, Arlington, VA 22203, telephone 703-358-2095. It is my perception (entirely unsubstantiated) that this agency may not have the resources to commission such a database on their own. It may take coordination of two or more government agencies to make this work, and the people I am talking to may not be able to achieve such coordination.

I consider it vital to put some scientific backbone into policy in this case. If it is appropriate for your office to involve itself in this matter, I would appreciate your help. You will know much better than I what form such help could take.

Yours sincerely,

A handwritten signature in dark ink, appearing to read 'Nick van der Merwe', with a stylized, flowing script.

Nikolaas J. van der Merwe
Clay Professor of Scientific Archaeology
and
Professor of Earth and Planetary Sciences

"Document Control"

TYPE: ACTION DOCUMENT NUMBER: 9125122
ORIGINATOR: 02 STATUS I DIRECTORATE STATUS

FROM: van der Merwe, Nikolaas J.: PEABODY MUSEUM OF ARCHAEOLOGY AND
ETHNOLOGY

TO: DR. D.A. BROMLEY

DATE OF
CORRESPONDENCE: 12/12/91

SUBJECT: HE IS WRITING ABOUT THE ISSUE OF RECONSIDERING THE
INTERNATIONAL BAN ON TRADE IN ELEPHANT IVORY. HE
WOULD APPRECIATE THE ASSISTANCE OF OSTP IF AT ALL
POSSIBLE.

DIRECTORATE STAFF
ASSIGNED: INTERNATIONAL/POLICY ASSIGNED:

ACTION STAFF
REQUIRED: FOR DAB'S SIGNATURE ACTION:

SENDER'S DUE DATE:
OSTP DUE DATE: 12/30/91 STAFF DUE DATE
DATE COMPLETED: DATE COMPLETED/DEPT:

COPIES TO: D. Allan Bromley
LIFE SCIENCES

WHITE HOUSE TRACKING #: CONTACT PERSON:
REMARKS: PHONE: EXT:

OSTP RECEIVED: 12/16/91 DEPT RECEIVED:
FILE: P-INTERNATIONAL
CENTRAL FILES:

THE WHITE HOUSE
WASHINGTON

December 10, 1992

Dear Senator Nunn:

I am forwarding herewith a preliminary report on a study carried out by an OSTP consultant, Mr. Willis Shapley, now retired after extensive experience at OMB/BOB and AAAS.

I asked Mr. Shapley, as in the past two years, to examine the FY 1993 appropriations in order to obtain a measure of the amount and kind of earmarks as well as how these have changed in recent years.

It bears emphasis that this report is still in a preliminary state and that reasonable persons might well differ over definitions and identification of specific earmarks. However, the same criteria have been used for all three years during which Mr. Shapley has carried out this analysis so that the trends are clear and credible.

As the table on page 2 of the summary shows, while academic earmarks have remained reasonably stable, nonacademic ones have increased rapidly so that there has been a dramatic increase in the total resources earmarked.

I am sending you this preliminary report because I thought that you would find the results both interesting and distressing.

Sincerely yours,

A handwritten signature in black ink, reading "D. Allan Bromley". The signature is fluid and cursive, with the first name "D." being small and the last name "Bromley" being larger and more prominent.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

The Honorable Sam Nunn
United States Senate
Washington, D.C. 20510

THE WHITE HOUSE

October 23, 92

Dear Jan:

Although the forthcoming
Nov. 3 election leaves my position
next March 30 somewhat
uncertain I would indeed be
interested in giving the opening
talk at the 75th anniversary

of the Prallenberg Foundation.
I am honored by your interest
in asking me and would very
much look forward to seeing
you again after a much too
long hiatus.

With all best wishes

Sincerely

Edman

THE WHITE HOUSE
WASHINGTON

September 10, 1992

Dear Rod:

Thank you for your letter of August 7 inviting me to speak at a breakfast meeting of the Science Policy Association sometime in the near future. My apologies for the much belated response.

I would be delighted to address the Association with the understanding that it is always possible that Presidential scheduling may force a change in my plans. Please have your secretary contact Ralph Brescia, who may be reached at 202/456-7116, to arrange a mutually convenient time for me to come to New York.

I look forward to joining you.

Sincerely yours,

A handwritten signature in black ink that reads "D. Allan Bromley". The signature is written in a cursive, flowing style.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Dr. Rodney W. Nichols
Chief Executive Officer
The New York Academy of Sciences
2 East 63rd Street
New York, New York 10021

TYPE: INVITATION-SPEECH

DOCUMENT NUMBER: 9202441

ORIGINATOR: 02

SPEECH: YES NO

FROM: NICHOLS, Rodney: NEW YORK ACADEMY OF SCIENCES

DATE OF EVENT: THRU:
TENTATIVE DATES: 09/92, 10/92

LOCATION OF EVENT: NEW YORK, NY

TIME OF EVENT:

SUBJECT: AN INVITATION TO ADDRESS A BREAKFAST MEETING OF
THEIR SCIENCE POLICY ASSOCIATION.

RSVP: 09/04/92

CONTACT PERSON:

CONTACT NUMBER:

INVITATION ACCEPTED? YES NO

COPIES TO: INTERNATIONAL/POL

REMARKS:

Perhaps
Good to before
the election
Agued
DOB

DATE OF LETTER: 08/07/92

DATE RECEIVED: 08/21/92

FILE: P-INVITATION



THE NEW YORK ACADEMY

Possible dates:

August 7, 1992

Oct 13, 29.

Nov 17, 19, 24.

RODNEY W. NICHOLS
Chief Executive Officer

Dr. D. Allan Bromley
Assistant to the President
for Science and Technology
Old Executive Office Building, Room 358
17th Street and Pennsylvania Avenue, N.W.
Washington, D.C. 20506

Dear Allan:

I was in your good offices last week for a with Tom Ratchford. I had a tight schedule that day for returning to my son's summer baseball or I would have stopped by and said hello, hoping to catch you for a minute.

What prompts this note is to invite you to speak at a breakfast meeting of the Science Policy Association of the New York Academy of Sciences. If you're game, we would love to have you be one of early speakers this fall, say in September or October. If your schedule this fall is just impossible, it would be fine for you to come any time. And if you'd prefer to speak after the Presidential election, I will, of course, understand.

Tom and I talked a bit about what you might prefer to have as your theme. We concluded that you might be in mood to talk about "national technology policy." If this is a subject you would like to discuss, that would be great. There is much interest in the subject and in your balancing views on the unfolding federal outlook.

Our format is informal. I think it is best for speakers to talk for no more than twenty minutes, and leave another forty minutes for questions. Breakfast begins at 8:00 a.m., and the program runs from 8:30 - 9:30 a.m.

Please tell me if this is an agreeable prospect and we can compare notes on dates.

Before closing, I should say that I think your reports (dated March) about OSTP, and science and technology generally turned out quite well. I picked up a few extra copies from Ginny Rosell in Tom's office and I'm circulating them to a few key people in New York.

Warmest personal regards,

Sincerely,

Rodney W. Nichols

RWN/tc
cc: J. Thomas Ratchford

Svetlana Stone
(212)
838-0230

175th Anniversary 1817-1992

2 East 63rd Street, New York, N.Y. 10021 • Phone (212) 838-0230 • Fax (212) 753-3479 • Cable NYACSCI

THE WHITE HOUSE

WASHINGTON

August 11, 1992

Dear Rodney:

I have just nominated J. Thomas Ratchford for membership in the Council on Foreign Relations and would much appreciate it if you would be good enough to provide a seconding letter on Tom's behalf to:

Mr. Kempton Dunn
Director of Membership and Fellowship Affairs
Council on Foreign Relations, Incorporated
58 East 68th Street
New York, New York 10021

For your convenience, I am enclosing herewith a copy of a recent curriculum vitae that Tom prepared. As you know, the Council's membership group in particular is interested in international experience and the letters are particularly helpful when they contain some personal experience or anecdote that might add to the formal sort of material that usually comes to the committee with the nominating initiative itself.

Tom has done an outstanding job as my Associate Director for Policy and International Affairs and I believe that he would be a very effective and interesting member of the Council on Foreign Relations. Your support would be much appreciated.

With warmest best wishes,

Sincerely yours,



D. Allan Bromley
The Assistant to the President
for
Science and Technology

Enclosure

Dr. Rodney Nichols
Carnegie Corporation
437 Madison Avenue
New York, New York 10022

THE WHITE HOUSE
WASHINGTON

July 16, 1992

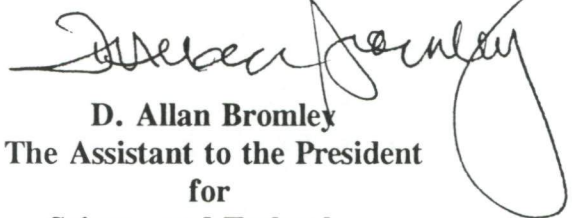
Dear Professor Newman:

Many thanks for sending me a copy of your book **An Advanced Organic Laboratory Course**. I have indeed studied your comments in the preface and the points you make are extremely well taken.

I know exactly the sense of satisfaction that you describe in connection with your course in laboratory organic chemistry. Since I have had rather remarkably similar experiences during my 30 years as a faculty member at Yale there is nothing that quite matches having an enthusiastic group of very bright young people catch fire during your course and really begin to demonstrate what they can do when stimulated.

With all best wishes,

Sincerely yours,

A handwritten signature in dark ink, appearing to read "D. Allan Bromley", with a large, sweeping loop at the end.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Professor Melvin S. Newman
Emeritus Professor of Chemistry
The Ohio State University
120 West 18th Avenue
Columbus, Ohio 43210



Department of Chemistry

120 West 18th Avenue
Columbus, OH 43210-1173

Phone 614-292-2251
FAX 614-292-1685
TELEX 332911
Answer Back Code: OSU CHEM UD

June 23, 1992

D. Allan Bromley
The Assistant to the President
for Science and Technology
The White House
Washington

Dear Mr. Bromley:

In partial answer to your letter of June 8, 1992, regarding the Science and Technology report, I am enclosing a copy of my book "An Advanced Organic Laboratory Course".

This course was developed mainly by me and other faculty members on the organic staff mainly because I felt that graduate students in chemistry were so poorly trained in laboratory work that this course could be very useful for any scientist whose work would require laboratory practice. After a few years I realized that this course should be presented to undergraduates at the sophomore level. I urge you to digest my comments in the Preface.

I presented briefly the laboratory course I was developing to students majoring in chemistry and pre-med. I stated that the usual organic course had three three-hour meetings per week for 3 hours credit. However the new course could be worked on as much as any student wanted. The laboratory used in their course was supervised at all times by two of my graduate students and by myself. It was mentioned that the credits for this course would be 3 hours per quarter but that students volunteering to take this course would be expected to spend a minimum of 15 hours per week for the same 3 hours credit per quarter. The first time this course was offered (in the early 1950's) only four students took it. Within a couple of years word got around that this was an excellent course. In the laboratory used there was only space for 25 students but soon 40 to 50 students indicated interest. The number of students was limited to 25 by talking to those interested. This number held at 25 for every year until I retired (1978). Quite a few students dropped by to see me after my retirement to say that they thought this course was the best course in the university.

Sincerely yours,

Melvin S. Newman

Melvin S. Newman
Emeritus Professor
of Chemistry

cag

THE WHITE HOUSE
WASHINGTON

May 7, 1992

Dear Ayako:

On behalf of President Bush, I wish to congratulate you on your award in The Environminute Competition in Broadcast Journalism, sponsored by Eastman Kodak Company. The future of our Nation is dependent on a responsible and enlightened citizenry, and your effort has shown that you are meeting those requirements yourself and demonstrating an ability and interest to share knowledge with others.

I wish you continued success as you further your education and challenge you to meet the great potential you have shown through your participation in The Environminute Course and Competition. Once again, congratulations on a job well done.

My best wishes,

Sincerely,

A handwritten signature in dark ink, appearing to read "D. Allan Bromley". The signature is fluid and cursive, with the first name "D." and last name "Bromley" clearly distinguishable.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Ms. Ayako Narita
Novi High School
24062 Taft Road
Novi, Michigan 48375

THE WHITE HOUSE
WASHINGTON

January 31, 1992

Dear Yuval:

Many thanks for your letter of December 29. I am very much looking forward to attending the June 23rd festive meeting of the Binational US-Israel Science Foundation in Jerusalem celebrating its 20th anniversary. I very much appreciate your invitation to extend the visit for a few days but I have, unfortunately, no flexibility in my schedule for that particular period because of a series of Congressional hearings at which I am a primary witness.

I deeply regret this because I would very much like to take you up on your invitation. It has been far too long since I was last in Israel and I know that there would be an enormous amount of good science and technology that I would be delighted to have the opportunity to see.

With very deep regret then let me say that I simply cannot accept the invitation at this time but I hope that at some later time it might turn out to be possible. Let me also take this opportunity to wish you and your family a very happy, healthy and rewarding 1992. I shall look forward to seeing you in Jerusalem, if not before.

Sincerely yours,



D. Allan Bromley
The Assistant to the President
for
Science and Technology

The Honorable Yuval Ne'eman
Member of Keneset
Jerusalem, Israel

"INVITATION FOR DR. BROMLEY"

TYPE: INVITATION

DOCUMENT NUMBER: 9200044

ORIGINATOR: 02

SPEECH: YES NO

FROM: NE'EMAN, Yuval: ISRAELI MINISTER OF SCIENCE AND TECHNOLOGY

DATE OF EVENT: 06/17/92 THRU:
TENTATIVE DATES:

LOCATION OF EVENT: ISRAEL

TIME OF EVENT:

SUBJECT: AN INVITATION FOR AN EXTENDED VISIT TO ISRAEL IN CONJUNCTION WITH DR. BROMLEY'S ATTENDANCE AT THE 1992 MEETING OF THE BINATIONAL US-ISRAEL SCIENCE FOUNDATION.

RSVP: 01/21/92

CONTACT PERSON:

CONTACT NUMBER:

INVITATION ACCEPTED? YES NO

COPIES TO: INTERNATIONAL/POL

REMARKS:

DATE OF LETTER: 12/29/91

DATE RECEIVED: 01/07/92

FILE: B-INVITATION



0044 INV

RECEIVED

פרופ' יובל נאמן

92 JAN 7 P 2: 15

PROF. YUVAL NE'EMAN

MINISTER OF SCIENCE AND TECHNOLOGY

OSTP
MAIL ROOM

29 December 1991

Prof. Allan Bromley
Science Advisor to the President
of the United States of America
Director of the Office of
Science and Technology Policy
Executive Office of the President
Washington, DC 20506
USA

Dear Allan,

I hear that you will attend the June 23, 1992 Jerusalem Festive meeting of the Binational US-Israel Science Foundation, celebrating its 20th anniversary. Could I invite you to turn your stay into a more extensive visit to Israel as our guest? A stay of several days would enable you to get a first hand feeling for the present status of the scientific and technological potential of this country, and to review US-Israel collaborations.

Personally, I am scheduled to lecture at Erice on June 24-29, so that I would prefer having you arrive here prior to the BSF meeting - say on June 17, 1992.

Can you make it? Please let me know if you can fit such a visit in your plans.

Yours very cordially,

Prof. Yuval Ne'eman

Withdrawal/Redaction Sheet

(George Bush Library)

Document No. and Type	Subject/Title of Document	Date	Restriction	Class.
02. Letter	To: Shoji Nagamiya From: Allan Bromley Re: Japanese support of SSC (3 pp.)	1/21/92	(b)(1)	

Collection:

Record Group: Bush Presidential Records
Office: Science and Technology Policy, Office of (OSTP)
Series: Bromley, D. Allan, Files
Subseries: Correspondence Files
WHORM Cat.:
File Location: D. Allan Bromley Correspondence - J-S [2 of 4] [1992]

Date Closed:	2/5/2010	OA/ID Number:	62002-006
FOIA/SYS Case #:	2005-0336-F	Appeal Case #:	
Re-review Case #:		Appeal Disposition:	
P-2/P-5 Review Case #:		Disposition Date:	
AR Case #:		MR Case #:	
AR Disposition:		MR Disposition:	
AR Disposition Date:		MR Disposition Date:	

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P-1 National Security Classified Information [(a)(1) of the PRA]
P-2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P-3 Release would violate a Federal statute [(a)(3) of the PRA]
P-4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P-5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
P-6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Removed as a personal record misfile.

Freedom of Information Act - [5 U.S.C. 552(b)]

(b)(1) National security classified information [(b)(1) of the FOIA]
(b)(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
(b)(3) Release would violate a Federal statute [(b)(3) of the FOIA]
(b)(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
(b)(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
(b)(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
(b)(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
(b)(9) Release would disclose geological or geophysical information

Columbia University in the City of New York | New York, N.Y. 10027

DEPARTMENT OF PHYSICS

538 West 120th Street

January 15, 1992

Dr. D. A. Bromley
Executive Office of the President
Office of Science and Technology Policy
Old Executive Office Building, Room 360
17th and Pennsylvania Ave.
Washington DC, 20506

Dear Allan:

I have not written to you for a long time, not in fact since you were appointed as Science Advisor for President Bush. However, recent news on President Bush's travel to Japan, together with recent news on the movement of the Japanese Government toward basic science, has prompted me to write this letter to you. I would like to discuss two issues, one on SSC and the other on RHIC, particularly in relation to the US-Japan collaboration in basic sciences.

The first subject is SSC. After the visit of President Bush to Japan, the New York Times reported that SSC would have deep troubles, because President Bush failed to obtain any strong hints on the anticipated Japanese contribution to SSC (in terms of \$'s). On the other hand, Japanese newspapers reported that the Japanese Government took a positive step toward SSC (although the SSC matter was reported only in 1-2 columns in these newspapers). I therefore called some influential Japanese scientists to determine the truth. Within a limited conversation I had the following mixed impression:

- a) On a positive side, everyone said that Japan will contribute strongly to SSC.
- b) However, an influential scientist who has been involved deeply in SSC said that it was disappointing that President Bush did not take along with him any significant person (like you) to correctly handle the issue of the SSC at the last moment in Tokyo. This fact weakened the final conclusion for the SSC. According to him, although the preparation before the visit of President Bush was done reasonably well, the physical absence of SSC-related personnel at the time when the "Action Plan" was created in Tokyo significantly weakened the scope of the SSC-related agreement.
- c) Nevertheless, in the future, many detailed issues are going to be discussed positively in the planned "Study Group". I am sure that you are involved in selecting people for this group. There, the US side must present a clear, coherent and constructive picture of what the US expects from Japan.
- d) In this process, please keep in mind that the Japanese Government together with the Japanese scientists are very sensitive to the point that, if Japan contributes to SSC, it must be an international project and must not be a US domestic project. In order to make the SSC matter successful, this point has to be kept clearly in mind. In the future, frequent interactions between your office and someone like Professor T. Nishikawa,

Professor H. Sugawara and/or Professor A. Arima will be very important. Also, the inclusion of Japanese scientists in a visible management structure at SSC will help.

Let me move now to the subject of RHIC. Recently the Japanese Government started to take action to increase the budget for domestic projects and international collaboration projects in basic sciences. This action is independent of SSC, but will help moderate a conflict between non-SSC scientists and SSC scientists inside Japan. Clearly, RHIC, KAON, CERN projects, etc. are related to this category.

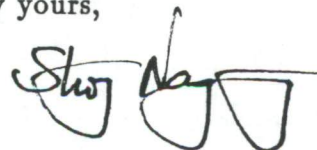
Speaking about RHIC, the Japanese contribution has been very strong, as you well know. Currently, about 50 Japanese physicists have signed up for a RHIC experiment in which I am also involved. This number is about 50% of the SSC physicists from Japan. These Japanese physicists at RHIC took strong initiative in designing the detector from a very early stage of the project. I personally believe that the degree of commitment of Japanese physicists in RHIC is as strong or stronger than that in SSC. First of all, therefore, I would like to ask your warm and positive support on this US-Japan RHIC collaboration. So far, the RHIC project was ignored completely at the Government level.

Clearly, the SSC's need in budget is an order of magnitude higher than that for RHIC (we are requesting from Japan on the order of $\simeq 20M\$$). However, I would like to emphasize one important point. The Government of Japan is eager to have a global picture on the scientific merits of all possible collaborations between the US and Japan in "Big Science". They are certainly concerned on the budget scale but more on the intellectual gains that Japanese scientists would have. One of the influential scientists in Japan privately told me that, if projects other than SSC, such as RHIC, KAON, were brought up by President Bush, the case for SSC would have been stronger. I am not trying to mix the issue of RHIC with SSC at the level of budget, but I am suggesting that the promotion by your office of greater collaboration in smaller projects such as RHIC will expedite Japan's involvement in SSC, as well as advancing frontier science and avoiding the appearance of a purely financial arrangement.

The above description is a personally biased one and I might have ignored what you have already done in your office. If I can be of any use to you, however, I could be delighted to help you on any detailed matter. I can be reached by Tel. (212) 854-3334 or Fax (914) 591-8120.

Thank you for taking time to read this letter.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Shoji Nagamiya', with a stylized flourish at the end.

Shoji Nagamiya
Professor of Physics and
Chair, Department of Physics

cc Dr. Karl A. Erb, OEOB-428

Withdrawal/Redaction Sheet

(George Bush Library)

Document No. and Type	Subject/Title of Document	Date	Restriction	Class.
03. Letter	To: Jan Nilsson From: Allan Bromley Re: Response to 1/3/92 letter [personal information redacted] (3 pp.)	1/21/92	(b)(6)	

Collection:

Record Group: Bush Presidential Records
Office: Science and Technology Policy, Office of (OSTP)
Series: Bromley, D. Allan, Files
Subseries: Correspondence Files
WHORM Cat.:
File Location: D. Allan Bromley Correspondence - J-S [2 of 4] [1992]

Date Closed:	2/5/2010	OA/ID Number:	62002-006
FOIA/SYS Case #:	2005-0336-F	Appeal Case #:	
Re-review Case #:		Appeal Disposition:	
P-2/P-5 Review Case #:		Disposition Date:	
AR Case #:		MR Case #:	
AR Disposition:		MR Disposition:	
AR Disposition Date:		MR Disposition Date:	

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

Freedom of Information Act - [5 U.S.C. 552(b)]

P-1 National Security Classified Information [(a)(1) of the PRA]
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C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Removed as a personal record misfile.

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(b)(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
(b)(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
(b)(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
(b)(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
(b)(9) Release would disclose geological or geophysical information



0122 1

RECEIVED

January 3, 1992

92 JAN 13 21:11

HAD Dr. D. Allan Bromley
Assistant to the President for
Science and Technology
360 Old Executive Office Building
17th and Pennsylvania Avenue, NW
Washington, D.C. 20506, USA

Dear Allan:

Upon receipt of your letter of 3 December, 1991, concerning the IUPAP sponsorship of the meeting "Baryons '92" I have tried to contact Yuri Ossipyan in vain. Realizing the difficult times in Moscow presently it now seems to me that I must take it upon myself to decide to sponsor the meeting as a type-C conference without any financial support. This is in line with my recommendation to Yuri and I see no reason why he would be of a different opinion.

It is my hope that I shall be able to see you later in the spring. As I believe I have mentioned I shall gradually move from my present position as president of the University of Göteborg to assume office as head of the Wallenberg Foundation, a two-billion dollar foundation supporting primarily the basic sciences in Sweden. On a part time basis I have already taken up this new job and I shall devote myself full time to the foundation as of 1 July. As part of my new assignment I should like to visit some of the more important foundations in the US. I have already made contact with the MacArthur Foundation through Murray Gell-Mann. Maybe you could suggest suitable people to contact within some of the other foundations supporting the sciences. In any case I shall contact you well before I leave for the US.

With best wishes for 1992 and warm personal regards.

Sincerely,


Jan S Nilsson

Encl.

cc Yuri Ossipyan

432-3522

THE WHITE HOUSE
WASHINGTON

January 13, 1992

Dear Mr. Minister:

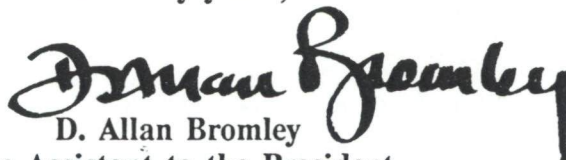
I much appreciate your letter of November 5 that has just been passed along to me by the Japanese Embassy here in Washington.

As you look back on your tenure as Minister of Foreign Affairs you have every reason to be proud of what you have accomplished. It has been a great privilege working with you as co-chairman of the Joint High Level Committee in Science and Technology and I shall certainly look forward to continuing the high level of friendship and cooperation that we have established when your successor takes over. I believe that our discussions have contributed in significant fashion to improving the understanding between our two peoples and to establishing channels of communications that have importance far beyond the explicit matters of science and of technology.

Let me then take this occasion to wish you every success in your new ventures and may 1992 be a year of health and happiness to you and all your family.

With warmest best wishes,

Sincerely yours,

A handwritten signature in dark ink, appearing to read "D. Allan Bromley". The signature is fluid and cursive, with the first name "D." being small and the last name "Bromley" being larger and more prominent.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

His Excellency
Taro Nakayama
Former Minister of Foreign Affairs
Tokyo, Japan

THE WHITE HOUSE
WASHINGTON

September 10, 1992

Dear Dr. Olsen:

Thank you for your letter of July 23, inviting me to visit the University of Notre Dame. I apologize for the much belated response.

I would, indeed, be interested in visiting Notre Dame and presenting a lecture on the "National Needs for R&D." I would suggest the late November-December time period. Please contact Ralph Brescia at 202/456-7116 to arrange a mutually convenient time.

I look forward to joining you.

Sincerely yours,

A handwritten signature in dark ink, reading "D. Allan Bromley". The signature is fluid and cursive, with the first name "D. Allan" and last name "Bromley" clearly legible.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Dr. James J. Olsen
Department of Aerospace and
Mechanical Engineering
The University of Notre Dame
Notre Dame, Indiana 46556

"INVITATION FOR DR. BROMLEY"

TYPE: INVITATION

DOCUMENT NUMBER: 9202341

ORIGINATOR: 02

SPEECH: YES NO

FROM: OLSEN, James J.: DEPARTMENT OF THE AIR FORCE

DATE OF EVENT: THRU:
TENTATIVE DATES: AUGUST-JANUARY

LOCATION OF EVENT:

TIME OF EVENT:

SUBJECT: HE IS WRITING TO SEE IF DR. BROMLEY WOULD BE
INTERESTED IN PRESENTING A LECTURE ON "THE NEEDS FOR
R&D" TO THE FACULTY AND STUDENTS OF THE UNIVERSITY
OF NOTRE DAME.

RSVP: 08/26/92

CONTACT PERSON:

CONTACT NUMBER:

INVITATION ACCEPTED? YES NO

COPIES TO: PHYSICAL SCIENCES

REMARKS:

*Perkins
After the
clerk
Agued
DAB*

DATE OF LETTER: 08/23/92

DATE RECEIVED: 08/12/92

FILE: P-INVITATION-SPEECH



DEPARTMENT OF THE AIR FORCE

WRIGHT LABORATORY (AFMC)
WRIGHT-PATTERSON AIR FORCE BASE, OHIO

92 AUG 12 AM 1:15

23 July 1992

Dr Arthur Bromley
Science Advisor to the President
Room 358, Old Executive Office Building
17th & Pennsylvania Avenues
Washington, DC 20500

USAF
MAIL ROOM

Dear Dr Bromley;

A few years ago I attended your lecture to the new crop of Air Force "STs", the federal government's scientific equivalent to the Senior Executive Service (SES). The purpose of this letter is to determine if you might be interested in presenting another lecture on "The National Needs for R&D" to the faculty and students of the University of Notre Dame.

At the time I first heard you I was the newly appointed Chief Scientist in the Air Force's Flight Dynamics Laboratory, the federal R&D laboratory that specializes in the science and technology related to the next generation military aircraft (fluid dynamics, aeronautical structures, structural dynamics, active control systems ... etc).

After a few years in that position as a leader of R&D, I have decided to return to "the bench", and the Air Force is helping me to make the transition by allowing me to take a "sabbatical" at the University of Notre Dame. I'll try to clear the cobwebs out of the research side of my brain and will be teaching "Aeronautical Dynamics and Aeroelasticity".

I'll be teaching in the University's Department of Mechanical - Aerospace Engineering. It's an excellent Department, particularly in the aspects of experiments and their integration with theory and computation. I'm sure that you would be very interested in their facilities and programs. For their part, the faculty and students are vitally interested in the directions that their research should take.

At this point I have no official capacity with the University, and when I do it will be merely as a Visiting Professor in the "Melchor Chair". Therefore, I have to "weasel-word" my invitation to merely inquire if you might be interested. Of course, I'm quite positive that the University would jump at the opportunity to hear your views.

If you might be interested, from mid-August through mid-January you can reach me at:

Dr James J. Olsen
Dept of Aerospace and Mechanical Engineering
The University of Notre Dame
Notre Dame, Indiana 46556
Phone: (219) 239 - 5433


James J. Olsen, Chief Scientist
Flight Dynamics Directorate (WL/CA-F)
W-P AFB, Ohio 45433

THE WHITE HOUSE

WASHINGTON

June 9, 1992

Dear Mr. op den Brouw:

Thank you for your kind letter of May 18 inviting me to address the annual Dutch A-1 Conference scheduled for November 19, 1992 at the Technical University of Delft.

Because my schedule has become increasingly consumed with election year activities as well as my regular duties, I must regretfully decline.

Thank you for thinking of me. With best wishes.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "D. Allan Bromley". The signature is fluid and cursive, with the first name "D. Allan" and last name "Bromley" clearly distinguishable.

D. Allan Bromley
The Assistant to the President
for
Science and Technology

Mr. Paul M. op den Brouw
Counselor for Science and Technology
Royal Netherlands Embassy
4200 Linnean Avenue, N.W.
Washington, D.C. 20008

"INVITATION FOR DR. BROMLEY"

TYPE: INVITATION-SPEECH

DOCUMENT NUMBER: 9201868

ORIGINATOR: 02

SPEECH: YES NO

FROM: OP DEN BROUW, Paul M.: ROYAL NETHERLANDS
UNIVERSITY

DATE OF EVENT: 11/18/92 THRU: 11/20/92
TENTATIVE DATES:

LOCATION OF EVENT: TECHNICAL UNIVERSITY OF DELFT

TIME OF EVENT:

SUBJECT: AN INVITATION TO ADDRESS THE PARTICIPANTS OF THE
ANNUAL DUTCH AI-CONFERENCE.

RSVP: 06/08/92

CONTACT PERSON:

CONTACT NUMBER:

INVITATION ACCEPTED?

YES

NO

COPIES TO:

INDUSTRIAL
INTERNATIONAL

REMARKS: ENCLOSURES TO DR Bromley

DATE OF LETTER: 05/18/92

DATE RECEIVED: 05/26/92

FILE: P-INVITATION-SPEECH

Handwritten:
6/8/92
Do letter.