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EXECUTIVE OFFICE OF THE PRESIDENT
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DATE: 5/27/93

SUBJECT: EPA's Answers to Questions from Senator Glenn on S. 171, EPA Cabinet Bill and related matters

Please review the attached EPA answers and provide comments/clearance by 10:00 AM Monday, June 7, 1993.

Selected answers are being sent out to agencies and OMB staff to review as indicated below.

cc: DOC and TCJ (Payne) - pages 1, 18, 19-33, 47-50.
DOI and NR (Cameron) - pages 1, 19-33, 47-50, (Tuccillo) 58-61.
USDA and NR (Weatherly) - pages 1, 19-23, 26-31, 47-50.
DOE and ES (Bennethum) - pages 1, 26-33, 41-42.
DOD and NS (Haber) - pages 26-33, 63.
COE and NR (Kazel) - pages 43-50.
Labor and LVE (VanWie) - pages 56-57.
State, AID, and Treasury and IA (Sasser) - pages 16-18.
DOJ - pages 13, 15, 16-18, 32, 43-48.
NRC - pages 41-42.
OSTP and ES (Fellows) - pages 26-31.
OFPP - pages 7-10.
ESNR/SS (Pfeiffer) pages 32-33.
J. Coffey - pages pages 19-23.

Q. 1: In general, we have heard suggestions that the organization of environmental policy activities throughout the Federal government could stand a good scrub at the least and a wholesale reorganization at the most. This might include placing the National Oceanic and Atmospheric Administration (NOAA) into the new Department. What are your feelings about any such reorganization?

A. 1: I noted in my testimony one of the primary reasons for elevating EPA to cabinet status is to improve environmental policy integration and coordination among Federal agencies. However, I would not envision a restructuring of environmental programs from other Departments as part of the EPA Cabinet legislation. Major improvements in integration and coordination across Departments can be made through better communication, information sharing, and joint problem solving. For instance, I now meet personally on a monthly basis with the Secretary of the Department of Interior, the Department of Agriculture, and the Department of Energy, to foster this type of collaboration across the Executive Branch. It is possible that restructuring the Federal government may ultimately be the most efficient way to make needed improvements. But it's not clear to me at this time that there is any clear rationale -- or consensus -- for the basis or form that such a major reorganization would take.

Q. 2: With respect to the EPA itself, our bill requires a Commission to study, among other things, environmental function organization within the agency. How do you view such an effort? Also, what are your thoughts about the way the Agency is organized now? Should we, for example, be contemplating a different way to organize the assistant administrator function -- instead of by media (air, water, radiation, etc.) by source or sector of pollution (industrial, agricultural, municipal, etc.) or some other formulation?

A. 2: My view is that the Commission has a number of important things to consider. I welcome its recommendations on how to make more efficient or effective environmentally related programs. And I welcome its recommendations on prevention, ecosystem, and multi-media approaches that would help to improve environmental protection in this nation. Some of its recommendations would obviously have organizational implications if the Department were to adopt them. However, I believe it is the privilege of the Executive Branch to organize itself to meet its statutory and other administrative requirements. I would look to the Commission's report to help frame the dialogue and issues related to how environmental work could most effectively be achieved in the Department so that I could use that as a springboard for discussion and decision about the organizational implications.

With respect to the way the Agency is organized now, I am aware of interest and discussion both internal and external to the Agency on restructuring our work along non-media lines. EPA's mission and legislative base are enormously complex, particularly when viewed within the context of non-source pollutants, the adequacy of science and research, the severity of old technological effects, and the ambiguities of new technologies.

As you well know, EPA was organized by media in the early 70's because it was the easiest way to both blend disparate organizations from across the Federal government into the new agency and to meet its media-specific statutory requirements. Although the current media structure requires more effort in order to look at broader environmental issues and impacts, I am not in a position at this time to state whether or how the current structure should be revised. I am committed to making the current organization in EPA responsive to the needs of our statutory mandates and to the citizens of this country. Through cross-media programs like our policy clusters, by strengthening our risk-based and pollution prevention policies, and through continued agreements with other Federal agencies, I believe we can continue to address pollution problems from media perspectives, sector perspectives, ecosystem perspectives, and source perspectives. I want to withhold judgment on a more formal restructuring away from a media orientation until I can better assess the strengths and weaknesses of the current structure.

Q. 3: Do you think the number of Assistant Secretaries allowed in the bill is adequate and, if not, how many would you propose?

A. 3: The bill currently provides me three additional Assistant Secretaries beyond what I currently have. I believe this is an adequate number to provide me the flexibility to reorient the Agency and its management structure in new ways.

Q. 4: It has been suggested that because EPA does not have a formal, overarching legislative mission but instead is guided by a dozen or so separate pieces of environmental legislation, it has set up program offices that have tended to focus solely on reducing pollution within a particular environmental medium for which the office has responsibility. One solution to this problem might be to enact a unified environmental statute whose focus would be reducing overall emissions. What are your thoughts about this idea?

A. 4: EPA has four media-specific program offices. Our offices of Air, Water, Solid Waste and Emergency Response and Pesticides and Toxic Substances all share in the responsibility of meeting the statutory goals and commitments contained in the 12-14 major environmental statues under our purview. We also have a number of cross-media offices, such as our Offices of Enforcement, Research and Development, and Policy, Planning and Evaluation. Together, these program offices focus on preventing and reducing pollution across all media. There's no doubt that having an organic environmental statute in place which provided a clear legislative statement of EPA's mission, goals and priorities would be beneficial in improving program efficiency and intra-agency coordination.

In its absence, however, the Agency has taken steps to address environmental problems that warrant multi-media consideration. For example, the Agency's planning and budget development process considers comparative risk issues across and within media; our regulatory development system allows for cross-media review and analysis when it appears to be warranted; and we have applied a "clusters" management approach to key issues like lead, pulp and paper, and contaminated media to assure cross-media deliberations.

An organic environmental statute that would enable EPA to better set priorities among different programs, that facilitated pollution prevention across media, that allowed EPA to better address multi-media environmental problems, and that supported our efforts to anticipate and identify new environmental problems would be good for EPA. At this time, however, it is not my top legislative priority.

Q. 5: Some criticisms have been raised over the course of EPA's existence about the way in which regional offices function and a perceived lack of coordination and good communication between headquarters and the regions. Could you comment on this and tell us how you think a Department will be able to better integrate the functions of the regional offices with headquarters' mission objectives?

A. 5: The relationship between Headquarters and the Regional offices is complex, and does have some inherent tensions. The Agency strives for balance between providing a nationally consistent policy/program, and allowing flexibility to address varying needs. Inevitably, some conflicts will arise. New laws have required extensive rule development while greatly increasing requirements on field offices (inspections, enforcement, permits, plan review, grant oversight, etc.). As a result, coordination and discussion between Headquarters and regional offices about the proper allocation of responses and the allocation of limited resources is inherent to achieving workable solutions.

Communications and interactions between HQ and the Regions are facilitated in several ways. Each program area has an identified Lead Region, which provides HQ with program advice on budget and policy issues from the regional perspective. Senior managers across the agency meet on a regular basis to discuss priorities and cross-cutting issues, and make adjustments to Agency direction if needed.

Perhaps most important to our HQ/Regional integration are efforts underway to articulate a set of overarching national environmental goals, from which EPA will develop an integrated Agency plan for the future. Constructing a plan that will provide the flexibility to address unique and/or highest risk areas, while demonstrating progress toward meeting national mandates, presents a tremendous challenge as well as a singular opportunity for EPA. Agency goals and an integrated plan will provide a common basis/framework for making budget, policy, and future legislative decisions that will guide the environmental agenda for the country.

Q. 6: How well is the Agency currently organized, and how might this change with respect to extramural and intramural Research funding and programs? Can EPA do a better job in this area and do you have any specific organizational suggestions for how this might be done?

A. 6: In the FY 1993 appropriation, ORD was required to prepare a report on the organization of the laboratories. That report is attached. In addition, the FY 1994 President's request contains $500,000 for a more indepth study on the organization and structure of EPA's research office. We are in the process now of determining the scope of that study. Once we have completed that study we hope to reach conclusions on whether we are organized in a way that is most effective for conducting the research needed by the Agency and to have specific suggestions for how to do a better job with respect to research funding and organization within EPA.

 # 7: Administrator Browner, this Committee last year held a hearing which concluded that the EPA was essentially held captive by some of its contractors. Agency officials testified that, at least when it came to its major computer operations, EPA could not perform the tasks itself and would have to immediately hire another contractor if for any reason the initial contractor was barred or could no longer provide the services. And while contractors may not be managing the Agency, EPA has not done a good job of managing the contractors -- this has been going on since EPA was created 20 years ago.

Q. 7: A) What are you going to do to ensure that a Department of the Environment is not held captive by its contractors?

A. 7: A) As promised in my testimony, I will conduct a baseline review and an independent assessment of the Agency's budget and staff resources. A primary purpose of these reviews will be to ascertain the ability of the Agency to properly manage its extramural resources, including contracts. If the Agency does not have adequate resources to manage its contractors in a manner so that we are not held captive, we will either need to obtain the resources required or limit the amount of our contracted activity.

Q. 7: B) Last year, in response to this hearing, EPA created a standing panel on contract management to institute reforms. Have you reviewed these reforms and do you support them?

A. 7: B) I have reviewed the Standing Committee on Contracts Management report, "Contracts Management at EPA: Managing our Mission", and support the recommendations completely. The Agency has made significant progress toward implementing many of the reforms. The impact of the reforms will take time, however, to alleviate serious problems in contract management within the Agency which have persisted over a number of years.

Q. 8: It is my understanding that the EPA Inspector General is about to release additional reports on contracting abuses and mismanagement by the Agency, which would seem to indicate that these issues are far from resolved. What additional steps will you take, and report back to this Committee on, so that we can get beyond contracting and back to cleaning up the environment?

A. 8: As stated earlier, the impact of the reforms initiated last year will take time to have an impact across the Agency. If any new findings by the Inspector General indicate that our reform activities are or will be inadequate, I am committed to reexamining the reforms and taking new directions if necessary.

Q. 9: I should note that we will be holding hearings later this year on EPA contracting. Will you testify before the Committee at these hearings?

A. 9: I look forward to testifying before the Committee on the Agency's management of its contracts on June 17, and to continuing our work together to address this issue.

 # 10: The EPA Inspector General and others have concluded that in many cases EPA has paid more for work done by contractors than if the work had been done by Agency personnel.

Q. 10: A) Do you agree that the Agency should know if the work done by contractors will cost more than the work done by the Government before awarding major contracts?

A. 10: A) I agree that we should know if contract work is more expensive than performance by Agency personnel before award of a major contract. Such information is vital in reaching a decision to contract out. However, the Agency would still need staff resources before consideration could be given to performing contracted work by its own employees.

Q. 10: B) As part of its efforts to constrain costs, would you support EPA undertaking a cost/benefit analysis on major pending contracts to better understand how to best spend its limited resources?

A. 10: B) I believe such an analysis could be beneficial, but would be meaningful only if the size of the Agency's staff were large enough so that serious consideration could be given to performing work within the Agency that would otherwise be contracted out.

Q. 11: A critical feature of improved environmental management is establishing priorities among programs on the basis of risk of public health and the environment. There have to be adequate scientific bases on which these priorities are determined. What will a new Department of the Environment do to undertake this critical activity?

A. 11: The new Department will take the actions recommended in the 1990 report, Reducing Risk: Setting Priorities and Strategies for Environmental Protection to ensure that this nation uses all the tools at its disposal in an integrated, targeted approach to protecting human health, welfare, and the ecosystem. A new Department of the Environment will maintain and improve information on environmental stressors, exposures and health and ecological effects and use this information to communicate to the public and to Congress what is known and not known about particular environmental hazards. EPA's Environmental Monitoring Assessment Program should strengthen the Agency's capability to assess the health of ecological systems and the effects of different environmental hazards. EPA has also continued to refine its cancer risk assessment methodology and to better understand and assess the effects of threshold (non-cancer) toxicants on human health. The Department will use scientific methods to estimate which hazards appear to pose the greatest risks to society and use this information as a key component in developing environmental priorities with Congress and the public. The challenge for EPA will be to use this information more effectively in its planning, budgeting and performance measurement systems. Another challenge is to better communicate this information to state and local environmental decision makers.

Q. 12: One of the greatest management weaknesses in EPA is the Superfund program. GAO's report to us in January indicated that EPA has continually failed to utilize basic cost control techniques including invoice reviews, audits, and independent cost estimates. What specifically will you do about these weaknesses, which EPA itself characterized as material weaknesses in its 1991 Federal Managers' Financial Integrity Act report?

A. 12: Along with GAO, several EPA groups, including the *Standing Committee on Contract Management (SCCM)* and the *Administrator's Task Force on Superfund Alternative Remedial Contracting Strategy (ARCS)* Contracts, have made recommendations as to how basic cost control techniques may be strengthened. In response to these recommendations, the following actions have been taken:

1) Invoice Review: An OSWER directive, issued 01/31/92, requiring standard review of cleanup contractor invoices is expected to result in improved cost control through withdrawal of unreasonable costs. In addition, in 1992, all Superfund managers were trained in contract cost control techniques. Over the next ten months, our goal is to train all Superfund staff in contract management and cost control.

2) Audits: EPA's Office of Inspector General (OIG) has developed a strategy and schedule to complete pending financial audits by 10/30/93. To increase control over the scheduling of audits, those firms having EPA as their largest single client will have audit responsibility transferred from the Defense Contracting Audit Agency (DCAA) to EPA's OIG.

3) Independent Government Cost Estimates: An OSWER Directive issued 01/31/92 requires use of independent government cost estimates on all projects valued over $25,000. Superfund has also trained all of the Agency's Cost Estimators in use of state-of-the-art cost estimating software. Finally, to ensure consistency, Superfund has developed a cost estimating guidance for use by cleanup project managers and support personnel.

Continuing the implementation of these and subsequent recommendations of the *ARCS Task Force* and *SCCM* will remain one of the program's highest priorities.

Q. 13: GAO also notes that EPA's indemnification of its Superfund contractors has been virtually unlimited, even though the law intended there be some limitation and it is certain that Superfund contractors would work for much lower limits. What do you intend to reduce Superfund's exposure to the unlimited liabilities implied in these indemnifications?

A. 13: On January 25, 1993, EPA published Indemnification Guidelines in the Federal Register. The Guidelines provide that:

- No indemnification will be offered in new solicitations unless it can be shown that the lack of indemnification was a prime cause of insufficient competition.

- Existing response action contracts will be renegotiated within 180 days to incorporate limitations and deductibles as specified in the Guidelines (e.g., maximum indemnification is $75 million for large, 5-year contracts, with a $3.2 million deductible).

To reduce Superfund's exposure to unlimited liabilities, I intend to implement these guidelines.

Q. 14: In 1991, EPA's Inspector General found that an integrated financial management system had still not been implemented at the Agency because of inadequate resources and management attention. What is the priority you attach to this effort and what role will the Senior Council on Management Controls play?

A. 14: The full implementation of the Agency's Integrated Financial Management System (IFMS) received high priority in the FY93 operating plan. Despite the significant reduction taken in EPA's Management and Support budget this year, we were able to hold the $5.4 million in contract funding set aside for IFMS harmless.

We recognize there have been continual problems, and for the first time reported certain aspects of IFMS as material weaknesses in the Agency's December, 1992, FMFIA Assurance letter sent to the President and Congress. The Senior Council on Management Controls and the IG were actively involved in the process which identified both accounts receivable and accounting system, and related financial management problems as reportable material weaknesses.

We have developed corrective action plans with timetables to rectify these problems. The Senior Council on Management Controls will be briefed during their quarterly meetings, and will be actively involved in monitoring the plans and helping to resolve any roadblocks we may encounter.

Q. 15: This lack of follow-through also characterizes EPA's enforcement program. After numerous government reviews pointing out that EPA's regional offices were not assessing penalties against violators at least as great as the amount by which the companies benefit by not being in compliance, the agency sent around a memo urging them to adhere to agency policies and to document reasons for any penalty reductions. However, as GAO reported to us last month, little has changed; two-thirds of closed cases did not document penalty calculations. What will the new Department do about this very important problem?

A. 15: Office of Enforcement believes that the cases identified by GAO as lacking documentation of economic benefit were largely matters in which the economic benefit component was nominal and thus not required. Unfortunately, there was no reference in the case file to the determination regarding whether to seek to recover the economic benefit. To address this concern, we will issue guidance that clarifies the need to document the economic benefit determination whether or not its recovery is required based on the facts of the particular matter. This documentation will be included in the case file along with the other penalty documentation. EPA continues to pay close attention to the issue of penalty documentation. On August 9, 1990, for example, the Office of Enforcement issued a policy entitled "Documenting Penalty Calculations and Justifications in EPA Enforcement Actions." This document established a uniform system for documenting penalty calculations by requiring the submission of a written "penalty justification" in every settlement package submitted to Headquarters. OE requires that each case file, whether administrative or civil judicial, contain documentation of the current bottom line settlement amount agreed to by the members of the litigation team. With respect to civil judicial cases, OE has been particularly successful in ensuring that the case files contain penalty documentation.

GAO's continuing concerns relate principally to administrative cases and revolve around the failure to regularly document the economic benefit component of the penalty calculation. Significantly, under its policies, EPA does not require recovery of economic benefit in all cases. Where, for example, the economic benefit of noncompliance is calculated to be under $5,000, economic benefit is deemed to be "nominal" and thus not a critical component of the penalty.

Moreover, the Office of Enforcement is exploring vehicles for improving the monitoring of administrative penalty matters generally. One possibility may be to require that, upon settlement of administrative cases, OE, in coordination with the appropriate Program office, will ask that the Regions send copies of the settlement agreements to Headquarters. OE will monitor and review these case settlements to ensure that national policy concerns, including penalty documentation, have been met. In this way, OE will afford "real time" audit and monitoring of settlements.

Q. 16: S.171 includes a provision respecting EPA international activities and responsibilities. Specifically, the bill calls for the Secretary of Environment to assist the Secretary of State in carrying out international negotiations and discussions on environmental matters. We also authorize the new Department to provide technical environmental assistance to foreign governments and international bodies. How important do you think this provision is?

A. 16: EPA believes that the international authorities of the Department of the Environment are extremely important. It is essential that the Department of the Environment play an active international role in order to assure that U.S. policy on important international environmental issues is fully integrated with, and in furtherance of, the Department's mission to protect the environment.

U.S. international environmental policy needs to be closely coordinated with our domestic environmental program, both because the international policy should be informed by and seek to further the U.S. domestic environmental agenda, and because the international obligations of the United States can be honored only through development and implementation of domestic laws and regulations. A subordinate international role for the Department of the Environment would diminish its ability to ensure that the United States pursues a vigorous international environmental policy that it consistent with, and implemented by, its domestic program. It is also critical that the new Department's prestige and effectiveness in the U.S. and abroad be retained.

Currently, EPA's authority to conduct international activities is derived from a patchwork of statutory sources whose international scope is not always well defined. S. 171 would clarify and simplify the new Department's authority to conduct the activities enumerated in §103(f) (1) (B) which include those currently engaged in by EPA. The language of §103(f)(1)(B)(ii) authorizes the Department of the Environment to improve the quality of the environment through: a) the use of contracts, assistance agreements, interagency agreements, international agreements, and other arrangements for supporting or conducting activities such as education, training, monitoring, research, development, investigations, experiments, demonstrations, surveys, studies and emergency response; b) the provision of technical, financial, legal and other assistance; and c) cooperation with foreign governments and international organizations.

Q. 17: Can you give us some specific examples of where such assistance may be rendered?

A. 17: EPA currently renders environmental assistance, sharing its accumulated expertise, to the countries in transition in Central and Eastern Europe, through the Asian Environmental Partnership to developing countries in Asia, and through the Enterprise for the Americas Initiative to developing countries in Latin America and the Caribbean. This environmental assistance is rendered in concert with the Agency for International Development, the Department of the Treasury and other U.S. agencies. The work with A.I.D. will carry on, and will be expanded to include the countries of the former Soviet Union. Assistance to Mexico in connection with the 1983 Border Environment Agreement and the 1992 Border Environmental Plan is continuing, and increasing as a result of supplemental activities in connection with the North American Free Trade Agreement and the proposed North American Commission on the Environment. The new Department would continue this important bilateral assistance work.

Q. 18: Environmental concerns are obviously very important in trade agreements and will likely become more so in the future. Existing trade agreements may not adequately address these concerns. Conflict and disparities in enforcement and monitoring capabilities are and will remain critical issues. What role can the new Department play in ensuring environmental protection issues receive adequate attention in these proceedings?

A. 18: The new Department will be able to play three roles, if it is given adequate funding and access to the appropriate processes. First, the Department will be able to evaluate enforcement and monitoring programs in and to engage in cooperation and training activities with other countries to help improve enforcement and monitoring functions. Second, if EPA has access to the Trade Policy Review Group (TPRG) and related bodies (EPA currently is not a member of the TPRG, but is sometimes invited to participate), the new Department will be able to ensure that environmental concerns raised by trade policy and trade agreements are identified and considered. Third, if EPA can play a meaningful role in negotiating future trade agreements (as occurred with the North American Free Trade Agreement), the new Department will work to ensure that environmental considerations are taken into account in the text of those agreements.

Q. 19: The Toxic Substances Control Act gives EPA authority to obtain information about effects on human health and the environment of chemicals. However, since the law's enactment 16 years ago, EPA has identified for testing less than 1 percent of more than 70,000 chemicals and has complete test data for only 22 chemicals. This is just one example of how EPA has not collected adequate data in the risk assessment area. The Bureau we create in our legislation would certainly aid this situation. What is EPA currently doing to improve its databases? And do you support our Bureau of Environmental statistics provision?

A. 19: There are three aspects to the question. The first relates to the adequacy of EPA's efforts to date to acquire the data needed to do meaningful risk assessments of chemicals or other contaminants that may pose hazards to human health or the environment (hereafter referred to as potentially toxic substances). The Bureau will play little or no role since it will not have direct regulatory responsibilities. Instead, determinations as to the adequacy of the data available for making risk assessments for potentially toxic substances will remain in the offices of the Department of the Environment with regulatory responsibilities. Similarly, specific actions to require additional testing of potentially toxic substances will continue to be made by these same regulatory offices.

The second questions relates to the adequacy of EPA's efforts to keep track of these potentially toxic substances and of the information available about the risks posed by each of these substances or class of substances. EPA has already made progress in assembling and disseminating information on potentially toxic substances and risks posed by each of these substances or classes of substances. Following are some specific examples.

The Office of Regulatory Management and Evaluation (with significant support from the Environmental Statistics and Information Division) has led an Agency-wide effort to design and implement the Register of Lists, a new EPA-wide electronic data base that is intended to serve as a central repository of information about the various chemical lists established by EPA for regulatory purposes. The Register of Lists provides information about the purpose of the list, identifies the substances contained on each list, and identifies the EPA regulatory office responsible for each list. The Register of Lists currently contains over 3437 chemicals and chemical categories contained on 31 major EPA lists.

The Integrated Risk Information System (IRIS), maintained by the Office of Health and Environmental Assessment within EPA, contains a comprehensive summary of available risk information for a smaller number of substances. IRIS currently contains information on 509 chemicals, and OHEA continues to increase the number of chemicals included in it.

A third major data base is the Inventory of Chemicals in Commerce, discussed above, which is maintained by the Office of Pollution Prevention and Toxic Substances in its role as the EPA office with principal responsibility for carrying out the requirements of TSCA.

In answer to the 3rd Question of what EPA is doing to strengthen it database, EPA is working to strengthen its information resources management (IRM) program. The strategic IRM planning process is being revamped to provide a consistent, integrated planning process, linked to the budget, for the direction, control, and coordination of IRM resources across the Agency. EPA's Information Management/Data Administration Program is applying a structured approach to implement Agency-wide improvements in data administration. At the same time, EPA is strengthening its central management of IRM policies, standards, and procedures, as well as its IRM oversight program to ensure the quality of its information programs and systems. EPA is also implementing technical solultions to facilitate data integration, such as development of a common software interface (Gateway), application of Geographic Information Systems (GIS) to various analyses, and implementation of a locational data policy to facilitate the link between geographic and programmatic data. These activities, combined with the IRM elements of the Cabinet legislation, will have a beneficial impact on EPA's management and use of information.

The Chief Information Management Officer and the Bureau will clearly be major participants in building on these on-going efforts to improve the Department's ability to identify, retrieve and disseminate information it possesses about potentially toxic substances. The improved accessibility of this information will in turn allow the Department to make better determinations regarding the existence of major information gaps and to take the necessary measures to fill these gaps.

Q. 20: Should EPA. itself, have better data collection capabilities?

A. 20: Yes. Existing statutes for the various EPA programs have extensive authorities for the collection of data; nevertheless, the coverage is a "crazy quilt" pattern with duplicate coverage in some cases and gaps in coverage in others. This is not unexpected since these statutes are primarily intended to support specific regulatory activities (rather than provide comprehensive assessments of environmental quality). This patchwork of authority makes it difficult to collect data for cross-media statistical purposes that would provide information needed for national environmental policy making.

Data Collection Authority Limitations. At present, EPA's, statutory authorities to collect, compile, and analyze environmental data are primarily for regulation development, pollution abatement and control, or enforcement. The authority for pollution abatement and control and enforcement is largely delegated to state and local governments. Some statutes put the onus of data collection on chemical manufacturers, sewage treatment plants, and other regulated entities. In addition, data collection components of many environmental protection statutes are specific and limited which makes it difficult to collect the types of ambient measures, demographic measures, economic measures and human health information needed to support environmental decisions and strategic planning.

EPA needs to be able to collect data from all media consistent with its decision requirements at every stage of the pollution release, transport, and impact process, i.e. discharge quantity, ambient concentrations, and health or ecological impact. A broad, flexible authority for data collection is needed -- authority that will allow EPA to collect data of the type and quality needed for informed decision making and strategic planning. Such authority will allow the Agency to implement new monitoring and data collection activities to fill in missing information.

Q. 21: The management of available environmental data has also been a problem at EPA. EPA, has three data bases for regulating disinfectants, yet EPA officials have told the GAO that as much as 60 percent of the data on disinfectant product claims are inaccurate or incomplete. In another case, EPA maintains nine separate database management systems to track information about pesticides awaiting reregistration, including the results of health and environmental studies. Yet, when, in 1991, a trainload of metam sodium spilled into the Sacramento River, EPA was unaware of information in its files indicating that metam sodium can cause birth defects. As a result the agency could not warn pregnant women and workers of the pesticide's hazards. What will a new Department do to better manage data it collects or compiles?

A. 21: EPA is already working to strengthen its information resources management (IRM) program to support integrated data needs of holistic environmental protection. The strategic IRM planning process is being revamped to provide a consistent, integrated planning process, linked to the budget, for the direction, control, and coordination of IRM resources across the Agency. EPA's Information Management/Data Administration Program is applying a structured approach to implement Agency-wide improvements in data administration. At the same time, EPA is strengthening its central management of IRM policies, standards, and procedures, as well as its IRM oversight program to ensure the quality of its information programs and systems. EPA is also implementing technical solutions to facilitate data integration, such as development of a common software interface (Gateway), application of Geographic Information Systems (GIS) to various analyses, and implementation of a locational data policy to facilitate the link between geographic and programmatic data.

These activities, combined with the IRM components of the Cabinet legislation which elevate the management attention and focus on IRM, will significantly improve th Program-specific, as well as cross-media, management of environment information across the Agency.

Q. 22: Throughout the Agency and within specific programs, EPA lacks performance measures and information for assessing the effectiveness of its programs in improving environmental quality. Sen. Roth and I have introduced legislation to institute such performance measures throughout the Federal government through a pilot program. I believe a centralized bureau devoted to collecting such information could be extremely helpful in establishing such performance measures. Would you comment? Do you think EPA would participate in our bill's pilot program?

A. 22: EPA is presently engaged in an Agency-wide process to modernize its system of performance measures. The goal of its Strategic Targeted Activities for Results System (STARS) is to develop "families" of performance measures for each of a dozen or so major, measurable environmental goals, which are also under development. These families of performance measures will track Agency progress toward:

- improvements in environmental quality,
- changes toward more responsible behavior by industry, government and the public, and
- toward institutional goals for EPA, such as better management, employee morale, and customer satisfaction.

EPA will begin pilot scale implementation of the new system in early FY 1994. EPA would therefore be well positioned to pilot a new government-wide system of strategic planning, performance measurement and budgeting on the schedule in the proposed "Government Performance and Results Act" (S20).

The Bureau of Environmental Statistics would be an excellent repository for performance measurement data developed by individual environmental programs. A Bureau could provide methodological expertise in the collection and interpretation of such data. Also, because the Bureau would not be affiliated with the programmatic and policy offices at EPA, it would ensure the objectivity of performance measurement data.

Q. 23: A proposal has been made to establish a National Institute for the Environment to support interdisciplinary research, assess current environmental knowledge on policy, and improve access to environmental information through education and training. How well do you do these things now and what is your opinion of this proposal?

A. 23: Many of the activities mentioned in the proposal are currently part of the Agency's programs. The extent to which these activities are carried out is related to the level of resources directed at these activities. It is felt that within the existing resource constraints, these activities are currently being carried out well.

The proposal also introduces a number of new activities and management options which will require a thorough evaluation. This is expected to require a substantial effort plus the leadership of the Administration's new appointees. This evaluation will be one of the priorities of the new Assistant Administrator for Research and Development once he has been confirmed by the Senate.

Q. 24: Would you consider the creation of such an entity (the NIE) more useful if it were somehow affiliated with the new department?

A. 24: The Administration supports an elevation of the Agency to department status. However, affiliation with new entities, such as a National Institute for the Environment, should only be considered after this elevation and after a thorough study of all of the pros and cons of any such option.

Q. 25: A) Traditionally, when it comes to receiving attention and resources at EPA, do you think that science and technology has been treated as a stepchild?

A. 25: A) EPA has recognized that science and technology are critically important for decision makers to have objective scientific information as a basis for their activities. In support of that concern, the level of resources for research and development has grown steadily from $347 million in FY 1988 to $508 million in FY 1993.

Q. 25: B) The Carnegie Commission advocates the establishment of a Federal Interagency Environmental Technologies Program to support the development of environmental technologies by other agencies, the labs, and the private sector. Is this approach preferable to creating a new agency? Why?

A. 25: B) The approach is preferable to creating a new agency because it would be more cost effective to build on EPA's current infrastructure, scientific and technical capabilities, and expertise to undertake such a program.

Q. 25: C) In your opinion, is the new Department the best place to locate the Interagency Program? Why?

A. 25: C) In our opinion, any program to support the development and/or coordination of interagency efforts, such as the proposed Interagency Program, should be part of the new Department of the Environment because an important function of the Department will be to coordinate the Nation's environmental research program. Having the Interagency Program in the Department will facilitate that coordination, and reduce duplication and overlapping of efforts and jurisdictions. Further, the regulatory and enforcement programs at EPA as well as the Agency's expertise shape environmental technology, making the new Department the best place for the Interagency Program.

Q. 25: D) What things can we do to ensure that the program receives cooperation from other Federal agencies that conduct R&D?

A. 25: D) The Carnegie Commission Report entitled "Enabling the Future" recommends that Federal departments and agencies should integrate considerations of long-term science and technology goals into annual budgeting and planning efforts. The report encourages open communication and cooperation among senior R&D administrators within the Federal government. Further, the report charges the Office of Science and Technology Policy (OSTP) and the Office of Management and Budget (OMB) to actively contribute to the establishment of Federal science and technology goals and to monitor progress of the Federal agencies in attaining these goals. The report urges OSTP to extend its efforts to use the Federal Coordinating Council on Science, Engineering, and Technology (FCCSET) to shape multi-agency, long-term science and technology goals.

EPA has been an active participant in the several FCCSET subcommittees and would welcome an expansion of FCCSET's scope to generate specific longer-term Federal science and technology goals and performance measures. In addition, EPA has demonstrated a strong interest in harmonizing environmental research and development efforts among those agencies and departments that have extensive environmental interests and programs.

On March 25, 1993, laboratory directors and senior program officials from EPA met for the second time with the Department of Energy's (DOE) laboratory directors and program secretarial offices to identify opportunities for collaboration. Participants formed focus groups to examine the most promising environmental research-in-progress in the areas of: pollution prevention; remediation; ecology and monitoring; radon; and risk assessment. The expected result of this meeting is a joint environmental research action plan to be submitted to Secretary O'Leary and Administrator Browner for their consideration. Agency-to-agency senior level participation and commitment is vital to our efforts to harmonize on-going work, redirect planned projects to be more responsive to a broader federal science and technology interest, and shape longer-term interagency environmental research and development goals.

We have begun preliminary discussions with USDA's Agricultural Research Service (ARS) to establish a similar dialogue. Meetings are planned with Department of Defense's Advanced Research Projects Agency (ARPA), Department of Commerce's National Institute of Standards and Technology (NIST), and the National Oceanic and Atmospheric Administration (NOAA).

EPA is eager to take a leadership role in promoting interagency cooperation in environmental science and technology. We need strong support from OSTP and OMB to achieve a totally integrated Federal environmental science and technology agenda, but direct agency-to-agency contact at the headquarters and laboratory level is an essential element for success.

Q. 25: E) In strengthening the new Department's scientific and R&D capability, how do we ensure that "science drives regulation" and not the other way around?

A. 25: E) Science encompasses a wide range of activities in EPA including research and development, technical and regulatory support, monitoring, data collection, review and interpretation of technical studies, and assessments of health and environmental risks. Science activities occur within the Office of Research and Development (ORD) as well as the program, policy and regional offices. In addition to the physical, chemical and biological sciences, EPA is also involved in the quantitative social sciences such as economics. The decentralized nature of science at EPA and the close relationship that exists between science and policy means that efforts must be taken to ensure that science is never adjusted to fit policy.

A 1992 report (***Safeguarding the Future: Credible Science, Credible Decisions)*** prepared by a group of prominent scientists examines the role of science at EPA. The report calls for EPA leadership to undertake" ...a deliberate and continuing effort to create the climate, culture, and incentives necessary to encourage superior science." The panel recommended several specific structural changes to better enable EPA to obtain and use the high-quality science it needs to realize its mission.

The relevant ***Credible Science*** recommendations include:

- Preparation of a coherent science agenda and operational plan to guide scientific efforts throughout the Agency and support its focus on relatively high risk environmental problems. Up-front planning on how to acquire and use the best scientific information, is a crucial step in ensuring that science drives policy.

- Clear definition of the science advice function (i.e., the process of ensuring that policy decisions are informed by a clear understanding of the relevant science) for the political leadership.

- Earlier science advice and information in decision process.

- Better career tracks for scientists and science managers. Although ORD has upgraded career tracks for research scientists over the past few years, scientists and engineers in program and regional offices need a more clearly defined career pathway that enables maintenance and growth in their disciples (e.g., rotational assignments to sharpen skills, participation in professional societies, etc.)

- Agency-wide QA and peer review for all key agency and technical efforts. Although research products are required to undergo peer review, EPA is developing a peer review policy for the planning and results of all scientific and technical efforts. This is essential if EPA is to be perceived as a credible, unbiased source of environmental and health information, both in United States and the world.

- Recruitment of several research scientists and engineers with world-class reputations in science areas that are vital to the Agency's long-term strategy and direction.

- Increased scientific contact and openness with other organizations -- other agencies, appropriate industrial and academic research organizations, professional societies, etc.

- Commitment to evaluate the environmental improvement brought about by major regulations and other policy decisions. EPA has recently initiated some new programs in this regard -- such as the Environmental Monitoring and Assessment Program (EMAP), and the National Human Exposure Assessment Survey (NHEXAS) -- and additional emphasis is planned.

EPA is currently reviewing the process used to develop environmental regulations and non-regulatory policies. One goal of this effort is to identify improvements in the way science and economics impact policy decisions. Revisions to the regulatory development process will likely include reforms that strengthen the applied research, scientific analysis and scientific review that is conducted to support major environmental policy decisions

Q. 25: F) Can the Department -- given its traditional role as a regulatory [agency] -- overcome its past image to work closely with industry in this area?

A. 25: F) Although it is a regulatory Agency, EPA has developed the capability to work with industry in a non-regulatory way to reduce pollution. Three years ago, EPA began a program in Pollution Prevention based on cooperation from the industrial sector for its implementation. The program has demonstrated that industry responds positively to environmental protection programs when appropriate incentives are present. The innovative technology programs also have demonstrated that the Agency and industry can work together effectively to protect the environment. The Department can use this experience to identify new and constructive ways to work with industry for a healthy environment. Specific examples include:

- **Green Lights** The Green Lights program encourages the use of the most energy-efficient lighting technologies that can dramatically reduce energy consumption and prevent pollution. EPA works with private companies to install energy efficient lighting wherever it is profitable. Over 750 corporations have already committed to the program;

- **33/50** The 33/50 program is part of a broad EPA program designed to encourage pollution prevention as the best means of achieving reductions in toxic chemicals emissions. The program has an interim goal of a 33% reduction by 1992 and an ultimate goal of a 50% reduction by 1995 in emissions of 17 high-priority toxic chemicals, using 1988 Toxic Release Inventory reporting of 1.46 billion pounds of pollution as a baseline. To date, 1,135 companies are participating in this program;

- **Water Alliance for Voluntary Efficieny (WAVE)** The WAVE program will encourage commercial businesses to use water efficient equipment to reduce

water use and associated energy use. The program is just starting up and will initially be targeted to the lodging industry. Several large hotel companies have already committed to the program.

- **Golden Carrot** The Golden Carrot Super-Efficient Refrigerator Program is focusing manufacturing research and development toward efficiency in a manner never before seen for refrigerators. Under the program, which EPA helped develop with utilities and others, utilities have pooled almost $30 million in rebate incentives to the refrigerator manufacturer that can produce the superior product. The manufacturer that can build the largest number of the most efficient, chlorofluorocarbon-free refrigerators the quickest and cheapest wins the contract. This program will ultimately save consumers $240-480 million in annual electricity payments.

- **Energy Star Computers and Buildings.** Computers: Partnerships with 40 manufacturers will help create a market for energy-efficient desktop computers that cut energy use by 50% without sacrificing performance or raising prices. Clear market incentives are provided to manufacturers to improve the efficiency of their products and an effective mechanism for consumers to make informed purchasing decisions. Buildings: This initiative will stimulate the market for highly efficient heating, ventilation, air conditioning (HVAC), and water heating technologies. The program's first technology target will be variable speed motor drives for ventilation systems.

Q. 26: Does the Administration have a position on Senator Mikulski's proposal specifically to create an independent agency to fund environmental technology R&D?

A. 26: In general, EPA supports enhanced environmental technology initiatives, such as those recommended by Senator Mikulski, because they improve environmental quality and strengthen the competitiveness of US technologies internationally. In this case, however, it is felt that using the framework of an existing agency or department is more cost effective and strengthens the linkage between R&D and environmental programs. The creation of a new Department of the Environment would build on current infrastructure, scientific and technical capabilities, and expertise to carry out the Nation's environmental program.

A Department of the Environment would enable the Nation's environmental agency to maintain a leadership role in environmental technology for a number of reasons:

1) The environmental technology market is created and shaped by EPA's (and State) regulatory and enforcement programs. EPA is in the best position from a Federal Government perspective to know the technology needs, and to adopt rules and other programs to meet those needs. For example, marketable emissions credits or similar economic instruments can be a major incentive to encourage use of innovative technologies.

2) To be adopted, innovative technologies must gain regulatory acceptance by permit writers, on-scene coordinators, and rule developers. EPA involvement in development and evaluation of the technologies lends credibility to the innovations and enhances a new technology's ultimate acceptability.

3) EPA is viewed as an objective, honest broker whose reputation can enhance the worldwide acceptance of new technologies. EPA scientists and engineers have substantial experience, and EPA has existing laboratories and testing facilities that would be critical to the success of such a program.

4) The development and commercialization of environmental technologies require the joint efforts of agencies, such as EPA, DOC, and DOE. The establishment of a new Agency with overlapping functions would result in additional complexity and duplication to the hindrance of furthering innovative technology development.

Q. 27: Our Committee has scheduled a hearing on pollution liabilities and characterization problems throughout the Federal government. We are just beginning to learn the magnitude of the unknown universe of problems in every Federal agency. The Department of Interior, for example, has one of the largest environmental problems in terms of characterization and likely cost of cleanup in its Bureau of Land Management. The Department of Energy's environmental problems continue and grow in complexity and cost. What is EPA's and the new Department's role in helping other Federal agencies identify and begin efforts to remediate these problems?

A. 27: In order to assist Federal agencies in identifying environmental liabilities, and ensure a compliant and effective response to environmental problems, the Office of Federal Facilities Enforcement has begun building the Federal agency/EPA environmental partnership through a variety of both formal and informal mechanisms. These mechanisms provide Federal agencies with an opportunity to identify high priority environmental needs as well as an opportunity to demonstrate leadership among the regulated community.

Formal mechanisms include EPA's participation in a Memorandum of Understanding (MOU) with DOE, DoD and DoI and the Western Governors Association to establish a more cooperative approach to develop technical solutions to environmental remediation and waste management problems shared by states, commercial entities, and the Federal government. The regional approach serves as a demonstration of principles and practices which may be adopted nationally.

Through informal mechanisms such as the Civilian Federal Agency Task Force, The Experts Work Group, and the Federal Remediation Technologies Roundtable, the Office of Federal Facilities Enforcement is working with Federal agencies in identifying deficiencies in Federal environmental management programs and cleanup efforts and forming workgroups consisting of EPA and Federal agency representatives to solve problems and meet high priority needs. In addition, EPA's OFFE convenes a monthly Federal Facility Policy Roundtable to brief Federal agencies and provide copies of new and imminent regulatory developments or other pertinent initiatives and programs that enhance agency compliance programs (e.g., environmental auditing and pollution prevention). EPA is also partnering with DoD and DoE on joint planning goals and to test innovative approaches to expedite cleanups including streamlining review of documents, test different decision making models, and test innovative technologies.

Future initiatives include the "Green Government" program intended to promote voluntary programs to improve environmental compliance through pollution prevention and encourage total quality environmental ("beyond compliance") management at Federal agencies. The Department of the Environment is the mandated agency to monitor and respond to Federal Agency environmental compliance activities and needs.

Q. 28: Last year the Congress finally enacted the Federal Facility Compliance Act (FFCA), which should strengthen EPA's hand in dealing with other agencies violations of RCRA and other environmental statutes. Could you comment on what the EPA is currently doing to implement this law and what future plans you have?

A. 28: The FFCA became law on October 6, 1992. This new Act only amends the Resource Conservation and Recovery Act (RCRA). There are several new authorities that will make RCRA Federal facility enforcement actions more consistent with actions currently used in the private sector.

The FFCA also requires the Administrator to undertake inspections at all Federal facilities that treat, store, and dispose of hazardous waste. EPA is determining the appropriate interpretation for this provision. On March 17, 1993 EPA sent out guidance regarding implementation of the new RCRA inspection requirements to the EPA Regions. In addition, EPA is also working on the appropriate mechanism for reimbursement of EPA by the Federal agencies for the cost of performing inspections. The RCRA Land Disposal Restrictions require treatment technologies and capacity be developed for mixed waste.

DOE, within 180 days of October 6, must submit two inventory reports: 1) a national inventory of all of its mixed wastes regardless of the time they were generated, on a state-by-state basis; and 2) a national inventory of its mixed waste treatment capacities and technologies. DOE submits these reports to EPA and the appropriate state. Both EPA and the state have 90 days to comment. DOE shall consider and publish the comments before finalizing the two inventories.

DOE will then develop a PLAN for developing treatment technologies for treating the inventory wastes where no treatment exists and also for developing more treatment capacities where technologies are available. DOE will submit the plan to either or the delegate/State.

Upon approval of the plan, EPA or the delegated state shall issue an Order requiring compliance with the approved plan.

In the FFCA, Congress further instructed EPA to create new regulations for munitions regulations. Within 24 months of April 6, 1992, the Office of Solid Waste has convened a workgroup to address the munitions requirements, and the workgroup has already met once with representatives from the Department of Defense.

Q. 29: A good example of EPA's lack of adequate resources is its approach to implementing plans for addressing pollution. The agency believes that nonpoint sources of pollution resulting from agriculture and urban runoff are what account for our nation's water quality problems. EPA has a plan to deal with nonpoint

pollution. However, the plan has gone basically unimplemented, mainly for want of adequate resources. Where else has this been a problem in the agency?

A. 29: As you know, all Federal departments and agencies -- including all the offices and programs within the Environmental Protection Agency -- are making extraordinary efforts to effectively manage necessarily limited resources in meeting its statutory and regulatory obligations. For example, at the Environmental Protection Agency, the risk-based and watershed protection approaches are being developed and refined to focus Congressionally appropriated resources on priority environmental problems identified at the national, state and sub-state levels. The risk-based and watershed approaches seek to focus efforts on the most serious environmental problems first. The watershed protection approach seeks to identify priority pollution problems in a discrete geographic area and to then concentrate available Federal, state, local government, and private resources to address the problems.

Implementation of other EPA plans and programs have been hampered by lack of adequate resources. Examples include the Comprehensive Ground Water Protection Program, Near Coastal Waters Program, Comprehensive Conservation and Management Plans (CCMPs) developed under the National Estuary Program , the Stormwater Program, Contaminated Sediment Identification and Remediation/ Dredged material management programs, and Wetlands and other Critical Habitat Protection and Restoration efforts.

Q. 30: A) Will you make it a priority to address the needs and concerns of small governments when developing these alternative approaches? *(Refers to Administrator's statement in confirmation hearing that there was a need to move away from prescriptive "command and control" regulation toward alternative regulatory approaches)*

A. 30: A) Yes, in many cases, achievement of our nation's environmental goals is dependent on implementation at the local government level, and the vast majority of these governments are small governments. So it is essential that their needs, concerns and ideas are carefully considered when we design and implement environmental programs. I am committed to forging the type of Federal, State and local government partnership that will ensure we all get the most bang for the buck and that environmental programs truly work at the local level where they matter most.

Q. 30: B) Will you keep the Reg-Flex policies and functions of the previous Administration in place?

A. 30: B) I strongly support the mandate of the Regulatory Flexibility Act of 1980: when developing regulations, federal agencies must fully consider any significant economic impacts on small businesses, small governments, and other small organizations. And I want EPA to be a leader in demonstrating that the nation can achieve environmental quality goals while benefiting the economy. This inherently includes minimizing adverse economic impacts of regulations on small business and small governments. As I mentioned previously, one of my goals is to build partnerships that succeed in designing and implementing environmental programs that are effective and efficient in use of resources.

In April, 1992, my predecessor adopted new agency guidelines for implementing the Regulatory Flexibility Act. These guidelines actually go beyond the minimum requirements of the Regulatory Flexibility Act. The Act requires consideration of regulatory alternatives only if the Agency believes there would be a "significant impact on a substantial number" of small entities. In contrast, with new environmental statutes, we will consider regulatory alternatives if there would be any impact on any small entity. I support this approach, because I believe it will help us find the most effective means of achieving the nation's environmental goals.

The career staff of the Agency have proposed a series of "pilot projects" for assisting in implementing these new regflex guidelines. There are two especially important objectives of the pilot effort: (1) demonstrate efficient means of developing regulatory alternatives which minimize adverse economic impacts on small entities while accomplishing environmental goals and objectives; and, (2) identify innovative ways to effectively involve small entities in the rulemakings which affect them. I strongly agree with these objectives. Additionally, I support the pilot project effort because I believe it will help illuminate how we can be even more effective in achieving the spirit and intent of the Regflex Act.

Q. 30: C) Will you build on them? How?

A. 30: C) In coming weeks, I will be reviewing issues related to both regulatory flexibility and our relations with small governments. And as indicated above, I will carefully follow the progress of the Regflex Pilot Projects. These reviews will enable me to formulate long term policies and programs for ensuring successful environmental programs in partnership with state and local governments and the private sector.

Q. 31: A) Is this [the use of the industry market-basket survey in determining the extent of dietary health risk and therefore in deciding which uses could be retained] the way that EPA normally makes such decisions?

A. 31: A) Yes, the EBDC decision is wholly consistent with the manner in which EPA makes its regulatory decisions regarding pesticides. EPA bases its decisions on the best scientific evidence available to the Agency, considering both the risks and the benefits of a pesticide, as mandated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

By way of background, under FIFRA, EPA registers pesticides on the basis of data adequate to demonstrate that their use will not pose unreasonable risks to public health or the environment. When evidence is raised which calls into question the safety of a registered pesticide, EPA may initiate a process to determine if cancellation or some other regulatory action is warranted. FIFRA requires that the Agency's regulatory decision be based upon a consideration of both the potential risks and the benefits of a pesticide's use. The Agency's action on the EBDCs, therefore, came after careful consideration of both the risks and the benefits of these pesticides.

To arrive at its final decision on the EBDCs, EPA conducted a Special Review of these pesticides. Special Review is a public administrative review process by which the risks of a pesticide are weighed against its benefits to determine the appropriate regulatory action.

As part of a Special Review, a Preliminary Determination is often issued long before issuance of a Final Determination. The intent of a Preliminary Determination is to publicly announce the Agency's position, based upon available data. At this stage, among other actions the Agency may take, EPA may do the following: 1) describe the available data and the conclusions it would reach based upon those data alone; 2) identify additional data needed to refine the assessment; 3) request comment. Comments can often be accompanied by additional data. A Final Determination can differ significantly from a Preliminary Determination if data received in the interim substantially alters the balance of the pesticide's risks and benefits.

EPA's Final Determination on the EBDCs in 1992 differed significantly from the action proposed in the Preliminary Determination in 1989, because the final action was based upon additional data submitted in response to the Preliminary Determination, as well as a revised estimate of the toxicity of the EBDCs. Changes in information between the Preliminary Determination and the Final Determination included the following:

- "Market Basket Survey" data, indicating the concentrations of EBDCs that are found in food in the grocery store, rather than at the time of harvest.

- A revised cancer potency factor, as recommended by the Scientific Advisory Panel (SAP), EPA's panel of independent scientific experts.

- Additional benefits and residue data from grower groups.

- Additional data on worker exposure, including data submitted by the registrant on dermal exposure and dermal absorption.

Following is a more detailed discussion of each of these areas in which data were improved:

Market Basket Survey. At the time of the Preliminary Determination, the Agency indicated that actual residues of the EBDCs might be significantly lower if the food samples for residue studies were taken closer to the "dinner plate" than the "farm gate." Therefore, pursuant to its authority under Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) the Agency required the registrants to generate market basket data to determine the levels of EBDC residues in marketplace produce.

Before the market basket survey data were available, EPA based its risk assessment upon residue levels found in field residue trials. Field residue trials are designed to measure the highest residue resulting from the most extreme use pattern on the label. Their primary function is for use in setting tolerances (maximum legal pesticide residue levels). Most pesticide residues resulting from registered uses will be well below the tolerance level.

The market basket survey was the largest of its kind ever conducted, reflecting analysis of almost 6,000 food samples. In fact, the number of analyses performed in the survey rivals the FDA and CDFA (California Department of Food and Agriculture) surveillance monitoring programs. The survey cost the registrants about $10 million. As expected, the market-basket findings indicated that, in general, the EBDC residues in foods on the grocery shelves were much lower than the field trial data indicated. These new residue data were used to refine the preliminary residue estimates.

Cancer Potency Factor. In addition to updating the dietary and occupational/residential exposure estimates, the Agency reevaluated the cancer potency factor (referred to as the Q_1^* -- read "Q Star") for the Final Determination, based on further analysis of animal laboratory data on ETU, the breakdown product of the EBDCs. The cancer potency factor is a measure of a chemical's potential to induce cancer and is used in conjunction with the dietary and worker exposure to estimate risk.

Because the Q_1^* resulting from EPA's reevaluation would have been significantly lower than the preliminary Q_1^* used in the Preliminary Determination,

and because Agency scientists were divided on the scientific issues, EPA returned to the SAP in September 1991. As a result of OPP's Health Effects Division Peer Review Committee decisions and the recommendations of the SAP, the Agency included in its analysis data from a low-dose group that had been analyzed previously. This low-dose group of animals were fed ETU levels closer to those that might actually be consumed by people. The effect of including these data was to lower the cancer potency factor for the Final Determination from 0.60 $(mg/kg/day)^{-1}$ to 0.11 $(mg/kg/day)^{-1}$.

Data from Growers. Grower groups also played an important role in providing information for the Final Determination for the EBDCs. By the fall of 1990, more than 300 comments had been received including benefits information and residue data from various grower organizations. For example, Hawaiian papaya growers described the limitations of chlorothalonil (the EBDC alternative for papayas) on papayas grown in Hawaii. Without such information, the Agency could have underestimated the benefits of EBDCs for papaya cultivation in Hawaii. The residue information provided by the growers was mainly used to corroborate the results of the market basket survey. The International Apple Institute however, provided residue data from an altered use pattern that was used as a primary source of data. Without these data, it is likely that the Agency would have pursued cancellation of the use of EBDCs on apples. Instead, the use of EBDCs on apples was retained, with an altered use pattern.

Worker Exposure. The Agency also revised its exposure estimates for people who handle EBDC products in a number of occupational or residential settings involving: agricultural and industrial applications, tank-mixing, commercial lawn applications, and homegardening. The new data for the revised worker exposure estimates include information received from commenters and data that were submitted by the registrants on dermal absorption and dermal exposure.

Q. 31: B) Do you consider EPA's reliance on the industry that they are responsible for regulating proper and objective?

A. 31: B) Yes. EPA generally bases its pesticide regulatory decisions upon data generated by pesticide registrants. Under FIFRA, registration applications must be accompanied by certain data submitted by registrants. Also, FIFRA has given EPA the authority under Section 3(c)(2)(B), at least since its amendment in 1978, to require pesticide registrants to generate and submit data in support of existing pesticide registrations.

It is clearly critical that the studies submitted in support of pesticide registrations be conducted in accordance with current scientific standards for integrity and quality. EPA has implemented a number of measures to assure the quality of pesticide data used by the Agency, including Good Laboratory Practice

standards, the data review process, EPA's inspection and audit programs, and EPA's enforcement options. These are all described in the informational bulletin titled, "Ensuring the Quality of Studies Submitted to EPA in Support of Pesticide Registration."

EPA's Office of Compliance Monitoring audited every one of the four laboratories that generated data for the EBDC market basket survey, as well as the contracting firm responsible for managing the conduct of the study. The EBDC Task Force who contracted for this study brought to EPA's attention alleged improprieties at Craven Laboratories, one of the laboratories performing residue analysis for the survey. A joint investigation conducted by the Department of Justice, the U.S. Attorney's office and the EPA led to the indictment by a Federal grand jury of Craven Laboratories, Inc., its President, and three employees on 20 felony counts in connection with pesticide testing. Several Craven employees have admitted to wrong-doing and the matter is nearing the trial stage. Where requested by EPA, the EBDC Task Force replaced the data generated by Craven Laboratories for the EBDC survey.

EPA's audits confirmed that the data used in the final results of the market basket survey met scientific standards for integrity and quality. EPA was further able to verify the market basket data by comparison with data available from other sources. In addition to the registrant's market basket study, EPA reviewed monitoring data from FDA and the States, and studies from other interested parties, such as monitoring data from the National Food Processor's Association and commercial processing studies. All supported the results of the market basket survey.

Q. 31: C) Are there deficiencies in the way the human health concerns about EBDCs have been handled by EPA, and, if so, do these deficiencies apply to other pesticides decisions EPA has made where concerns about human health or the environment were at stake?

A. 31: C) No. The EBDC decision followed the most extensive review, analysis and assessment of data ever undertaken on any pesticide. Because of this rigorous analysis, EPA is confident that the risk reduction measures implemented -- decreased application rates, reduced number of applications on a crop, and longer intervals between the last EBDC treatment and harvesting the crop, as well as the cancellation of certain uses -- are protective of public health.

Q. 32: EPA has an important role, but no statutory authority, in setting standards for exposure to and cleanup of radionuclides. A process is actually now underway (involving the Office of Radiation and Indoor Air) for EPA to be a major player in this effort. Do you support this process and how can we be assured of its completion?

A. 32: EPA has statutory authority under a number of statutes to set exposure standards for the cleanup of sites contaminated with radiation and the protection of drinking water. The Atomic Energy Act, the Comprehensive Environmental Response, Compensation,and Liability Act, the Toxic Substances Control Act, and the Resource Conservation and Recovery Act each give the Agency authority, although each statute excludes some radionuclides or some radioactively contaminated sites. The Agency is currently considering which statute, or combination of statutes, can best be applied to developing cleanup regulations. The Office of Radiation and Indoor Air is taking the lead in developing radiation cleanup standards, including:

o Regulatory Development Efforts

- Regulations are being developed which will set forth cleanup procedures and criteria, including residual radioactivity levels.
- Waste management regulations are also being developed and will address the disposal and recycle of radioactively contaminated waste resulting from cleanup.
- EPA is participating in the NRC's participatory rulemaking workshops for the development of their Decommissioning rulemaking. NRC can be exempted from the EPA regulation if EPA concludes that the NRC regulation provides a sufficient level of protection for the public health and environment.
- EPA is chairing a high-level Interagency Steering Committee to address coordination of effort in the cleanup of radioactively contaminated sites. This committee was proposed by the Office of Management and Budget to address this multi-agency issue. In addition to EPA, the committee consists of representatives from the Departments of Defense and Energy and the Nuclear Regulatory Commission (NRC).

o Atomic Energy Act Federal Guidance

- EPA chairs the committee on the development of Federal Guidance governing radiation issues. Once the committee issues its guidance, all Federal Agencies must implement them.
- This committee is actively pursuing the revision of existing Federal radiation protection guidance for the general public, including technical and policy issues relevant to radiation cleanup.

I strongly support all of these initiatives. Cabinet status of the EPA would greatly improve the Agency's ability to respond to this important public health and environmental issue in a cost effective and timely manner.

Q. 33: A) Which Federal agency -- EPA or the Corps -- has final authority to determine whether dredging and disposal projects are "environmentally acceptable"?

A. 33: A) The determination of environmental acceptability of dredging and disposal projects is made by a number of Federal and State agencies, depending in part on the nature of the activity, in what waters it occurs, and at what point one is in the decisionmaking process.

In most cases, dredging projects involve a subsequent discharge of dredged material into waters of the United States or into ocean waters. When such a discharge is involved (including the runoff or overflow from a contained land or water disposal site), the Corps is the permitting authority,[1] and makes a determination with the input of Federal agencies, State agencies, and the general public through the Public Notice process. If EPA disagrees with the Corps, EPA retains the ultimate authority, pursuant to Section 404(c) of the Clean Water Act (CWA) for waters of the U.S., or pursuant to Section 103 of the Marine Protection Research, and Sanctuaries Act (MPRSA) for ocean waters, to determine the acceptability of environmental impacts of the discharge on certain aquatic resources.

Dredging projects that do not subsequently involve a discharge of dredged material into waters of the United States are not subject to Section 404, but are subject to Section 10 of the Rivers and Harbors Act. The Corps makes the final determination of acceptability when an activity is governed only by Section 10, subject to the paragraphs below.

Pursuant to CWA Section 401, the States provide water quality certification for federally permitted or licensed (or conducted) dredging activities under CWA Section 404 and River and Harbors Act Section 10. Both authorities are subject to CWA Section 401 review including State water quality standards adopted pursuant to CWA Section 303(c), other CWA requirements, and appropriate requirements of State law.

EPA also reviews required environmental impact documentation prepared for Corps regulatory decisions and Civil Works dredging and disposal projects, pursuant to NEPA. At present, if EPA determines that a decision is

[1]Note that for Corps Civil Works navigation and maintenance projects (as opposed to regulatory review of other proposed discharges), the Corps of Engineers conducts the equivalent of the CWA Section 404(b)(1) Guidelines or MPRSA §103 analysis to determine environmental impacts, even though they do not issue themselves a permit.

"environmentally unacceptable," the Agency may elevate the issue to the President's Council of Environmental Quality.

Q. 33: B) Are Federal agencies, such as the Corps, under an obligation to carry out their actions in compliance with Federal water quality standards? Is the same true for EPA-approved State water quality standards? If these two types of standards are treated differently, what is the legal authority or other justification?

A. 33: B) Federal agencies, such as the Corps, are under an obligation to carry out their actions in compliance with both types of these standards. A Federal water quality standard is promulgated when a State fails to adopt EPA-approved water quality standards.

In the case of the CWA, Section 301(b)(1)(C) requires Corps compliance with Federally promulgated water quality standards in the issuance of permits to the same extent as for EPA-approved State water quality standards.[2] This requirement is contained in the Corps' regulations as well. In the case of the Marine Protection, Research, and Sanctuaries Act (MPRSA), Section 102 prohibits dumping which would violate applicable water quality standards and does not distinquish between federal or state water quality standards.

Pursuant to CWA Section 304(a), EPA issues Federal water quality criteria to the States. States use this guidance and other information to adopt criteria into State law to support designated uses. The criteria (adopted as water quality standards) are subject to EPA review and approval. The Corps obtains State Section 401 certification (or waiver) for Corps-permitted (or conducted) activities which may involve a discharge to a State's waters. In addition, as part of demonstrating compliance with the CWA Section 404(b)(1) Guidelines or the regulations governing ocean dumping under MPRSA §103, the activity regulated or conducted by the Corps is required to meet applicable State water quality standards.

Q. 33: C) Must any Corps determination of its "least costly and environmentally acceptable" Federal standard embody from the outset the minimum of environmental acceptability defined by compliance with Federal and EPA-approved State water quality standards? Please explain.

A. 33: C) Yes, the Corps' concept of "environmental acceptability" embodied in their Federal Standard includes compliance with State water quality standards.

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[2]The most recent federal promulgation of water quality standards was for toxic pollutants in 14 States (see 57 FR 60848, December 22, 1992).

Likewise, compliance with the CWA Section 404(b)(1) Guidelines or MPRSA regulations for dumping in ocean waters, is a requirement for "environmental acceptability." Projects that do not comply with State water quality standards, or the Section 404(b)(1) Guidelines or MPRSA regulations, are not consistent with the Federal Standard.

Q. 33: D) What happens in the case such as at the Port of Toledo where an EPA-approved State water quality standard is interpreted differently by the Corps than by the State? Does EPA have a position on which entity -- the Corps or the State -- has the ultimate authority to interpret a State's water quality standards as they may relate to a Corps navigational dredging and disposal project?

A. 33: D) Where a State has an EPA-approved water quality standard, the State has the authority to "interpret" that standard. In the case of the Port of Toledo, the disagreement between the Corps and the State (and EPA which supports the State) concerns the "validity" of a narrative standard. Narrative standards are valid and authorized in 40 CFR 131.11. Therefore, Section 401 certifications relying on narrative water quality standards are valid.[3]

Q. 33: E) What, if any, recourse does the Corps have if it considers an EPA-approved State water quality standard -- that may constrain its dredging and disposal options -- excessive?

A. 33: E) As previously discussed, the Corps must comply with State water quality standards, regardless of whether or not the Corps considers them "excessive." If a State requests conditions addressing chemical, physical, or biological water quality concerns, on a Federal project that would result in the Corps carrying out the project in excess of their Federal Standard (i.e., conducting a project that costs more than another environmentally acceptable alternative), the Corps would not honor the State's request, because they would believe it violates their regulations. There are several courses a project could take if the Corps and a State disagree: (1) a local sponsor could pay the increased costs associated with a project, to carry out that alternative; (2) the Corps could pay certain additional costs with other funds, if these are available; (3) the Corps could modify their calculation of the least cost, environmentally acceptable alternative to incorporate compliance with State water quality standards as interpreted by the State; or (4)

[3]We understand that the Corps believes that they are complying with all of the State of Ohio's standards and that the State of Ohio does not have a valid standard in place concerning the goal of eliminating all open-water disposal of dredged material. This goal is part of the State of Ohio's Phosphorus Reduction Strategy, which is contained in the narrative portion of the water quality standards.

Congress could appropriate additional funds to conduct the project in a specific manner.

If the Corps cannot comply with conditions requested by the State, there are several additional courses a project could take: (1) the Corps could refuse to conduct the project; (2) the State could waive its certification (or grant a variance under State procedures) for the project to allow it to proceed; or (3) in the case of the CWA §404 regulated activities, the Corps could invoke authority under CWA Section 404(t) to maintain navigation, in spite of State requirements (to our knowledge, this authority -- which we regard as emergency -- has never been exercised).

Q. 33: F) Are EPA-approved State water quality standards somehow different from Federal water quality standards such that Federal agencies can selectively refuse to pay specific costs associated with EPA-approved State water quality standards?

A. 33: F) No. (see response to Question B which discusses the difference between EPA-approved State water quality standards and Federally promulgated water quality standards) Federal agencies cannot selectively refuse to comply with portions of a standard due to cost, but must comply with the entire standard, whether State or federally promulgated.

Q. 34: What thoughts do you have on the Great Lakes Sediment Control Act of 1993? (S. 75)

A. 34: In general, EPA supports the goals and objectives of the Great Lakes Sediment Control Act (GLSCA). Many of the activities mandated by the proposed GLSCA are already underway in response to mandates of the National Environmental Policy Act (NEPA) and Section 404 of the Federal Water Pollution Control Act (FWPCA), and through less formal mechanisms. As such, the GLSCA complements the direction and goals of our Great Lakes programs. However, the Agency is concerned that the mandates of the GLSCA will require extensive resources which the Act does not provide, and will in many cases, require timeframes beyond those specified. In particular, those mandates concerning the development of sediment disposal guidance and the management of confined disposal facilities on the Great Lakes cannot realistically be completed by the December 31, 1994, deadline imposed by the GLSCA. In addition, while we consider existing confined disposal facilities to be worthy of the type of attention outlined in the bill, we also believe that they pose much less of a risk to the environment then the large amount of unconfined contaminated sediments that are currently in place in the Great Lakes system. If the impact of the bill is to divert limited resources from in place contaminated sediment remediation to confined disposal facility certification, the Great Lakes environment will suffer.

EPA is not opposed to concurrence authority on matters of sediment management, but wishes to note that the Corps of Engineers currently seeks EPA input and concurrence on most such matters in the Great Lakes. In addition, the imposition of EPA concurrence authority for sediment management matters in the Great Lakes Basin, but not for such matters in other waters of the United States, may lead to significant variations in the government's response to such matters.

We wish to note one area of potential confusion in the GLSCA. Subsection 2(A) of Section (n) Sediment Load Reduction, implies that the Administrator of EPA shall award grants to achieve such reductions under authority of Section 319 of the FWPCA. However, Subsection 4(A) of Section (n) implies that the Secretary of the Army will award such grants with EPA concurrence. Only EPA is authorized to award Section 319 grants.

Q. 35: What are your views on the Great Lakes Federal Effectiveness Act which would create a Great Lakes Research Council to coordinate research among Federal agencies? (S. 3290 - from 102nd Congress)

A. 35: Research into the ecological processes of the Great Lakes is critical to both our understanding of the Great Lakes and to our efforts to protect and restore these unique resources. However, EPA does not believe that the establishment of an additional committee under the auspices of the International Joint Commission will ensure the promotion of an ecosystem approach among the responsible Federal agencies. Rather, the Agency believes such a committee to be unnecessary. Scarce public resources can be better spent through directed research programs supporting ongoing U.S. regulatory efforts.

Q. 36: A) How would you organize and what priority would you give to geographically-targeted programs?

A. 36: A) Geographically-targeted programs, such as EPA's Great Water Body programs in the Great Lakes, Chesapeake Bay and the Gulf of Mexico; the National Estuary program; and smaller scale Clean Lakes; Near Coastal Waters, and other watershed projects have been very successful at refocussing attention on water resources in need of protection or restoration and tailoring solutions to those needs. Often the larger-scale efforts have involved several Regions and States, requiring a cooperative team effort to their management. Experience-to-date suggests that these efforts, as well as ground water protection, should be managed from the "most local level" embracing the effort, i.e., the Regions if Regional in scope, or State if intrastate. Experience has also taught us that there must be a clear lead or chairperson and staff support for these efforts. Based on our success with geographically-targeted efforts and our need to move to a more holistic approach to ecosystem protection to resolve our remaining problems, we are promoting a Watershed Approach (including ground water protection) on a much broader-scale across the nation. For instance, in the Office of Water, we define that approach as: 1) viewing the natural resources within a watershed as an interconnected ecosystem; 2) establishing protection and management goals for the system; 3) identifying priority problems and implementing tailored solutions to restore or protect the system; 4) involving and obtaining the commitment of appropriate stakeholders. The integration of this approach into the way we deal with water resources is a high priority for the Office of Water.

Q. 36: B) What role would you give to ecosystem research?

A. 36: B) Ecosystem research is a high priority. Watershed management and geographically-targeted programs are two very important approaches to achieving long-term sustainability of our nation's ecological resources. They incorporate the multimedia and biological system considerations that are essential in order to restore damaged resources and prevent future degradation. Research is critical for EPA's agency-wide ecosystems management initiatives and continuing efforts to develop biological criteria, new bioassessment protocols, and environmental indicators, which will significantly enhance the agency's ability to measure conditions of ecological resources and to make progress in meeting specific environmental goals. Other ecosystem research efforts currently underway include: ecotoxicology (which examines the effects of toxicants on both plants and animals); ecological restoration; ecological risk assessment and management; and environmental monitoring.

Q. 36: C) Would it be possible to better coordinate the work of other natural resource agencies, such as the Fish and Wildlife Service, NOAA, and the Army Corps of Engineers?

A. 36: C) Yes, it is possible to have better interagency coordination. This should be accomplished through all levels of communications and cooperation. We are doing several things to promote this. High-level management meetings involving these and other Federal agencies on an ongoing basis are helping to improve coordination and consistency and particularly helpful in resolving environmental disputes which cross jurisdictional lines. For instance, I now meet personally on a monthly basis with the Secretary of the Department of the Interior, the Department of Agriculture, and the Department of Energy, to foster this type of collaboration, and our respective staff meet weekly.

Interagency cooperation/collaboration can be further expanded in efforts such as joint regulatory responsibilities, mutual science and research projects, information management systems and data sharing, monitoring and assessment strategies, and other opportunities. EPA participates in interagency efforts for ecological protection in leadership capacities, as equal partners, or simply in a supportive role. Interagency partnerships are also well suited for implementation at the regional office level, and are occurring in all EPA regions.

Memoranda of Understanding (MOUs), like the one signed between my predecessor William Reilly and John Turner of the Fish and Wildlife Service, and long-term personnel exchange programs involving relevant agencies also enhance agency cooperation and should be pursued. Other programs like EPA's Environmental Monitoring and Assessment Program (EMAP) maintains more than 20 MOU's and Interagency Agreements (IAGs) with 12 Federal Agencies. Additionally, conferences like Watershed '93, which was sponsored by EPA and 13 other Federal agencies, will improve coordination. Other examples include the National Estuary Program, which involves interagency coordination to address priority problems in our Nation's estuaries. In the dredge material management programs, the EPA and Army Corps of Engineers are working closely together on several technical guidances and a strategy to address management of dioxin-contaminated dredged materials.

Q. 37: A recent National Law Journal study, released on September 21, 1992, reported that superfund cleanup activity began from 12% to 42% later at minority sites for over half of the ten autonomous regions. How does Region 5 compare with those statistics and what other comments do you have on this matter?

A. 37: The National Law Journal (NLJ) reported that in six of EPA's ten regions, the pace of EPA action from discovery of the site to the beginning of cleanup is from eight percent to 42 percent faster at white sites than at minority sites. The NLJ found that in one EPA region, the pace of cleanup for minority and white sites was even, and that in three Regions, the cleanup began more quickly at minority sites. For Region 5, the NLJ found the pace of cleanup from discovery to cleanup was 13.8 years for minority sites compared to 9.7 years for white sites (42 percent longer at minority sites.)

There are several methodological flaws in the NLJ's work that call into question these results. For example, the NLJ relied on the ZIP codes as a surrogate for location to determine the demographics around a site. In some cases, ZIP codes represent a mailing address but not the actual location of a site. Another example is the use by the NLJ of discovery dates that were well before the Superfund law was passed and therefore before Superfund action was possible. Also, the NLJ did not look at other site variables that affect cleanup decisions such as type of site.

It is important to note that these flaws in the NLJ analysis do not explain why the NLJ found cleanup activities take longer at minority sites in some regions. The NLJ has raised an important issue that needs to be examined carefully. For this reason, EPA is making a serious commitment to determine whether inequities exist in the Superfund program. We are using the most current and reliable data available to study the demography around Superfund sites, and comparing these data with the historic performance of the Superfund program. By this summer, we plan to link minority status with site variables such as time from discovery to first removal activity, and type of remedy selected to determine whether there are biases in the program.

In addition, the Agency is taking a proactive approach to equity by providing site decision makers with demographic information early in the site identification process.. We believe that getting this information out early will provide opportunities for EPA to improve communication with members of minority communities.

Q. 38: What environmental equity strategies are being developed for the Great Lakes region by the Office of Environmental Equity?

A. 38: The Office of Environmental Equity is particularly concerned with the health effects on minority and low-income human populations resulting from the consumption of contaminated fish. The Office of Environmental Equity is addressing equity concerns by coordinating with the Agency for Toxic Substances and Disease Registry's (ATSDR) Great Lakes Human Health Effects Research Program. The goal of this program is to:

1) Identify human populations residing in the Great Lakes Basin who may be at risk due to higher comsumption rates of fish contaminated with pollutants present in one or more of the Great Lakes, and to prevent any adverse health effects. In particular, Native Americans, African Americans, and Asian Americans are believed to be at risk due to their high subsistence and cultural fish consumption rates. In addition, fetuses and nursing infants of mothers who consume contaminated Great Lakes fish are believed to be at risk. The Office of Environmental Equity is coordinating its involvement with EPA's Office of Water, Region 5 offices, and the Great Lakes National Program Office.

2) Enhance training and awareness of Federal, Tribal, State and local officials dealing with minority and low-income populations believed to be at risk due to their high subsistence fish consumption rates;

3) Support the collection of demographic and research data which identifies the populations at risk and documents the specific health effects;

4) Encourage the dissemination of outreach materials, public notices and public hearings in multi-languages, where appropriate, to make information more accessible to non-english speaking populations living in the Great Lakes Region;

5) Review and monitor all reports involving equity issues from the Great Lakes Program and;

6) Provide consultation to the Great Lakes staff on equity matters.

Q. 39: Under Superfund, how are submerged sites treated in the hazard ranking system? How many submerged sites are currently on the National Priority List?

A. 39: The evaluation of sediment contamination at Superfund sites is an area that has received increasing attention as public concerns, health impacts, costs, and challenges of remediation have evolved. The original Hazard Ranking System (HRS) [the primary tool used to support the placement of sites on to the NPL] did not explicitly evaluate contaminated sediments. However, surface water contamination was evaluated and sites with contaminated sediments could be scored under the surface water pathway. In revising the HRS, the EPA has made the evaluation of contaminated sediments more explicit in the following ways:

- Sediments are evaluated to determine if contaminant levels are above background. If concentrations exceed background levels, additional points are assigned in the site scoring.

- Sites that show contamination levels above background levels are also evaluated to determine if concentrations exceed levels that exceed risk/regulation based cleanup goals. These goals include cancer and non-cancer risks.

- Chemicals that have a tendency to bioaccumulate receive additional points within the HRS scoring process.

The first two bullets reflect evaluation processes that are consistent with the evaluations that are performed for all pathways in HRS scoring. The consideration of bioaccumulation is also provided for the surface water pathway evaluations as they evaluate water contamination. Thus, the revised HRS provides explicit consideration for the evaluation of contaminated sediments. The evaluation of contaminated surface water is an area that has received considerable attention during the revisions to the HRS. Results from the scoring of field test sites indicate that the current HRS should provide slightly more points to sites with surface water contamination than did the original HRS. The pathway is divided into the Drinking Water, Food Chain, and Environmental threats. Thus between the changes to the HRS in the area of surface water and contaminated sediments, sites with either surface water contamination or contaminated sediments should receive higher scores.

Over 90 percent of the sites scored with the original HRS are adjacent to surface water bodies. Less than half of the sites scored with the revised HRS were identified through the scoring of sites. It is reasonable to expect that scoring for the surface water pathway would lead to an underestimate of sites near surface water because pathways are not likely to be scored unless data is available and scoring is expected to lead to a noticeable contribution to the overall site score.

There are also a group of sites that have been associated with radioactive waste in the ocean. Several of these sites have received repeated attention. These sites include the Farallon Islands, which is over a 100 miles off the California coast from San Francisco, and several sites off the East Coast.

Q. 40: Last year, I introduced legislation (S.3336) to establish a pilot program for the government to acquire and demonstrate the use of products made from recovered materials in the construction and retrofitting of Federal buildings. What thoughts do you have on how to best make this a successful pilot program? Will you work with the Committee to help craft and implement this proposal?

A. 40: EPA believes that its current Design and Construction Program serves as a model for acquiring and demonstrating the use of products made from recovered materials. All newly constructed EPA facilities not only require use of recycled products through Agency procurement policy, but also utilize other pollution prevention initiatives, such as water conservation, and energy conservation features utilizing a "green lights" approach.

EPA would be delighted to work with the Committee to help craft and implement this proposal.

Q. 41: Ms. Browner, in October, 1992, GAO reported to this Committee on the status of efforts to protect workers from asbestos hazards. Some of its conclusions included the fact that no single agency is responsible for maintaining information on asbestos materials in buildings, no agency surveyed was fully implementing either the EPA's recommendations for managing asbestos or OSHA's requirements for protecting against potentially harmful exposure, and only two of the agencies visited have issued guidance to worksite managers informing them of what actions to take to manage asbestos. Would you comment on the status of EPA's efforts to improve this situation and what you will do to help ensure that workers are adequately protected against potentially harmful exposure?

A. 41: EPA continues its strong support of programs helping to ensure that workers are adequately protected against potentially harmful exposure to asbestos fibers. Some of that support is in the form of guidance documents and recommendations; other support comes through regulation. EPA staff meet regularly with other Federal agencies at meetings such as the Federal Asbestos Task Force (FATF) and the Asbestos Design and Development Initiatives Group (ADDIG). New EPA regulations and guidance materials are discussed.

1. OSHA has primary responsibility for regulations applicable to employee exposure in the workplace. However, because OSHA lacks jurisdiction over workers in the public sector, under the EPA Asbestos Worker Protection Rule (WPR), EPA extends coverage comparable to that of the OSHA asbestos standards to State and local government (public sector) workers in 27 states. (23 states extend OSHA regulations under OSHA-approved state plans.)

The current (1987) EPA WPR provides worker protection coverage only for asbestos abatement projects. A revision of the WPR, now undergoing Agency review, will extend all of the coverage provided under the OSHA Asbestos Standard for the Construction Industry to all public sector workers in the 27 states covered by the EPA WPR. Protection will be provided for all "construction work activities," including building operations and maintenance, repair, renovation, demolition, and removal work, where asbestos is encountered in the workplace.

Also, EPA's revised Model Accreditation Plan (MAP) will extend training and accreditation requirements to workers and others who are not now required to have extended training.

2. EPA provided financial support and staff oversight to the National Institute of Building Sciences (NIBS) in their development and publication (September 1992) of a new guidance manual. The NIBS "Asbestos Operations & Maintenance (O&M) Work Practices" manual is a practical supplement to the Agency's 1990 guidance manual, "Managing Asbestos in Place" (the Green Book). With the guidance provided to building asbestos program managers and workers, and with the detailed, specific, and appropriate work practices for asbestos O&M workers that

are set forth in the new manual, EPA believes this represents another major step forward in worker protection.

3. EPA has increased its communication with OSHA to help coordinate issues of mutual concern to both agencies as OSHA works to revise their asbestos worker protection regulations. We anticipate publication of OSHA's revised standards sometime this summer.

Q. 42: I'm interested in your thoughts on how the EPA can better address environmental problems on Indian reservations. Would you agree that a major problem is that more resources need to be targeted for enforcement and technical assistance on reservations?

What percentage of the EPA's funding and staff are targeted on Indian Tribes?

A. 42: EPA currently provides resources for environmental protection on Indian lands in three ways. First, it provides resources through Congressional appropriations and set-asides such as those provided under Section 319 and Title VI of the Clean Water Act (CWA) and funds appropriated in support of the multi-media/general assistance program. Second, EPA provides resources through regulatory set-asides such as the up to 3% of CWA Section 106 funds that are set-aside under that Act's Indian Program regulations. Finally, individual EPA offices review their grant funds on a yearly basis and include tribes along with states within their discretionary programs.

Currently, 100% of EPA's multi-media/general assistance funds go to tribes. Other program funding directed to tribes include: about 2-3% of the funds for state, local and tribal programs, about 0.9% of the Agency's Superfund monies, and 0.5% of the wastewater treatment construction funds are reserved for tribes. Approximately 0.8% of EPA's FTEs are used to support the Indian Program. EPA has increased its support of tribal programs by over 600% since the adoption of its Indian Policy. As tribes continue to develop their capacity to participate in EPA programs, the Agency will need to continue to increase its efforts to support the development of tribal regulatory systems.

Q. 43: In light of the magnitude of environmental problems in Indian country, would you have a recommendation for an appropriate policy position to address them if the EPA becomes a Department?

A. 43: In 1984, EPA was the first Federal agency outside of the Bureau of Indian Affairs and the Indian Health Service to adopt an Indian Policy. The Agency's policy recognizes the sovereignty of tribal governments and commits EPA to working with tribal governments on a government-to-government basis. If EPA becomes a department, these basic foundations of the Agency's Indian Policy will be the cornerstones of any Departmental approach which the Agency will take in the conduct of its affairs with Indian nations.

Q. 44: Do you feel that Natives Americans deserve a voice and a strong advocate at the policy-making level of a new "Department of the Environment?"

A. 44: For the past several years EPA has had individuals in the role of Special Assistant to the Administrator who have advocated the inclusion of Indian tribes in all appropriate areas of the Agency's programs. If the Agency is elevated to Departmental status, this advocacy role will, along with other appropriate program areas, be reviewed to determine how it can best be institutionalized within the framework of the new Department. To facilitate the process of ensuring an Indian voice as the Agency implements its Indian Policy, and in support of the President's policy of having government reflect the essential character of the American people, the Agency will increase its efforts to recruit qualified tribal members to occupy positions at all levels within the Agency, including those that develop policy at its highest levels.

Q. 45: Isn't it both reasonable and necessary to have one of the ten Assistant Secretaries called for by this bill to be responsible solely for environmental policies and programs affecting Indian tribes and lands?

A. 45: The EPA Indian Program is an important function that cuts across all of the Agency's major programs to help protect human health and the environment. If the Agency is elevated to Department status, it will review its current structure and the legislative mandates of both its program-specific and cross-cutting functions to determine how to most effectively employ its human and financial resources to meet its statutory obligations.

Q. 46: The issue of what the economic costs and impacts of environmental regulations on the public and businesses is being increasingly debated. Can you inform us how you will act to see that these concerns are properly evaluated by senior policy makers at a new Department of the Environment? Is this an issue of great importance to you?

A. 46: The issue is indeed of great importance to me and EPA. Since the passage of the Clean Air and Water Acts in the early 1970's, EPA has issued periodic reports on the economic costs of air and water pollution control expenditures. The most recent of these reports, entitled Environmental Investments: The Cost of a Clean Environment, was issued in late 1990, and updates are planned for future years. This report summarizes the pollution control costs in all media for which EPA has responsibility for both the public and private sectors. Since the 1970s, EPA has also prepared comprehensive economic cost and impact studies on each major regulation, as have most other Federal regulatory agencies. These reports are used by the Agency and other Federal agencies in evaluating most major proposed regulations before they are issued.

These efforts will be intensified under the new proposed Department of the Environment so as to assure that the costs and impacts of new proposed regulations are given the attention they deserve both before and after regulations are issued. I also plan to insist that these reports, once prepared, be given careful attention by senior Departmental policy makers to the extent allowed by law.

Although environmental pollution control regulations cannot be made costless, I can and will insist that the costs be held to the lowest levels consistent with the laws under which we operate and the protection of the environment. By preparing and using these reports at both the regulation level and the program level, I believe that the environment can be improved while not increasing the costs of environmental protection beyond the capability of our economy to pay them.

Q. 47: One area I believe you will need to watch very carefully is the environmental problems that exist at military bases in the U.S. that will be converted for civilian purposes. Do you have a plan to work with the Department of Defense to address environmental problems for the large number of military bases that will be closed in the next four years?

A. 47: Yes, EPA has a plan to work with DoD to address environmental problems at closing military bases. The plan is to: 1) define the Agency's mission relative to base closure; 2) define and build the type of organization/infrastructure to carry out the Agency's mission; 3) secure the resources to build the program; and 4) address environmental issues associated with base closure. This response focuses on the mission and some of the steps taken to address the many issues associated with base closure.

The mission of EPA's base closure program was defined in 1991: to protect human health and the environment and return closing bases to safe and productive use as soon as possible. Fundamentally, most of the issues associated with accomplishing the mission can be distilled into two overriding interrelated problems: expediting property transfer and accelerating site cleanup. The following are only several of many actions that have been taken to address these issues:

EPA and DoD co-sponsored a series of conferences entitled, "Military Base Closure: Accelerating Environmental Restoration." The conferences served as forums for improving communication between DoD, EPA, states, local communities, and other interested parties to facilitate cleanup and redevelopment of closing bases and help resolve issues affecting the base closure process. Conference participants met to discuss acceleration initiatives, risk management, real estate and redevelopment, remediation technologies, and the development of standardized techniques relative to hazardous waste cleanups at closing military bases. The team approach, i.e., the close working relationship among the regulators and the installation project manager, was stressed throughout the conferences. The conferences demonstrated that by investing in a team approach, EPA, DoD, and the states can streamline and accelerate cleanup at closing bases.

EPA has also worked closely with DoD to develop procedures for identifying uncontaminated parcels at closing bases so that the parcels can be made available for reuse as quickly as possible. EPA is also working with DoD to establish procedures for the transfer of remediated parcels and leasing of contaminated parcels.

Finally, pursuant to the National Environmental Policy Act (NEPA) and Section 309 of the Clean Air Act, EPA reviews NEPA documents and provides comments to the Armed Service branches regarding the environmental affects associated with proposed base reuse and disposal.

Q. 48: President Clinton has promised a reduction of 100,000 jobs and a 14% cut in Administrative costs of Federal Departments and agencies. Can you comment on how you will achieve these reductions without compromising the integrity of environmental protection programs?

A. 48: The Clinton Administration's deficit reduction strategy is a long-term plan which will be implemented over a five year period, from FY 1993-1998. In the short-term, EPA has taken its share of reductions equally across the board. In FY 1994, EPA has limited spending in some areas, while focusing valuable resources toward critical environmental programs. Through these efforts, EPA will be able to attain the savings necessary for sound economic growth while securing a safe and healthy environment for future generations. In addition, EPA is currently in the early stages of planning a base program review of EPA activities. This review will help us compare resource expenditures with national environmental priorities, as a basis for future budgeting efforts.

STATUS REPORT

SEPTEMBER 21, 1993

DEPARTMENT OF THE ENVIRONMENT ACT OF 1993
(EPA Cabinet Level Elevation)

* As of May 4, 1993, this act (S. 171) passed in the Senate and was sent to the House (H.R. 109) for deliberation. Since then there have been no listings of significant testimony or actions taken to further its passage in the House.

LEGI-SLATE Report for the 103rd Congress Tue, September 21, 1993 10:41am (EDT)

QUICK REPORT:
S. 171 by Sen. John H. Glenn, Jr. (D-OH)
Department of the Environment Act of 1993

Major Actions on Bill:

01/21/93 -- In The SENATE
Introduced by GLENN (D-OH)
Referred to Senate Committee on Governmental Affairs

02/18/93 -- In The SENATE
Public hearing held by Senate Committee on Governmental Affairs
Hearings recessed by Senate Committee on Governmental Affairs subject to the call of the Chair

03/24/93 -- In The SENATE
Public mark-up held by Senate Committee on Governmental Affairs
Ordered reported with an amendment in the nature of a substitute by Senate Committee on Governmental Affairs (by Voice Vote)

03/31/93 -- In The SENATE
Sequential referral to Senate Committee on Environment and Public Works of Section 112 of the measure, under the order of Tuesday, March 30, 1993

04/01/93 -- In The SENATE
Public hearing held by Senate Committee on Environment and Public Works
Hearings adjourned by Senate Committee on Environment and Public Works

04/02/93 -- In The SENATE
Public mark-up held by Senate Committee on Environment and Public Works
Ordered reported by Senate Committee on Environment and Public Works (by Voice Vote) Section 112

04/15/93 -- In The SENATE
Report filed by Senate Committee on Governmental Affairs (S.Rept. 103-38)
Report filed by Senate Committee on Environment and Public Works (S.Rept. 103-39)

04/22/93 -- In The SENATE
Considered (debated) in the Senate under the unanimous consent agreement of Wednesday, April 21, 1993 (CR Page S-4809)

04/27/93 -- In The SENATE
Considered (debated) in the Senate under the unanimous consent agreement of Thursday, April 22, 1993 (CR Page S-4880)

04/28/93 -- In The SENATE
Considered (debated) in the Senate under the unanimous consent agreement of Tuesday, April 27, 1993 (CR Page S-4996)
Text from another measure offered as an amendment by SPECTER (R-PA) and failed (S.631, Amendment 325)

04/29/93 -- In The SENATE

Considered (debated) in the Senate under the uninimous consent agreement of Wednesday, April 28, 1993 (CR Page S-5108)
Text from another measure offered as an amendment by NICKLES, DON (R-OK) and failed (S. 81, Amendment 329)

05/04/93 -- In The SENATE
Considered (debated) in the Senate under the unanimous consent agreement of Thursday, April 29, 1993 (CR Page S-5315)
Parts of a different measure incorporated into this measure as amendment by Senator Bond (S. 824, Amendment 340, subsequently amended)
Passed (agreed to), as amended (Vote No. 1114: 79-15)
Full text of measure printed in "Congressional Record" (CR Page S-5357)

05/05/93 -- In The HOUSE
Received in the House, after passage in the Senate

CQ Weekly Report Articles:

02/13/93 -- (Page 314) Environment - White House Pushes Senate Bill Lifting EPA to Cabinet Level
03/27/93 -- (Page 746) Government Operations - Bill Elevating EPA to Cabinet Worries Environmentalists
04/03/93 -- (Page 837) Government Operations - Senate Panel Votes To End Environment Council
04/24/93 -- (Page 1018) Environment - First Debate Volleys Fly on Elevating the EPA
05/01/93 -- (Page 1077) Environment - Mitchell's Pact Assures Vote on Cabinet Status for EPA
05/08/93 -- (Page 1140) Environment - Senate OKs Elevation of EPA; Hurdles Await in the House
08/21/93 -- (Page 2257) Environment - Poor, Minorities Want Voice in Environmental Choices
09/04/93 -- (Page 2314) Government & Commerce - Issue: Elevating EPA to Cabinet Level

Counterpart or Companion Bills:

H.R. 109 by Rep. Sherwood L. Boehlert (R-NY) -- Department of the Environment Act of 1993

Combinations with Other Bills

04/28/93 -- In The SENATE
Text from another measure offered as an amendment by SPECTER (R-PA) and failed (S.631, Amendment 325)

04/29/93 -- In The SENATE
Text from another measure offered as an amendment by NICKLES, DON (R-OK) and failed (S. 81, Amendment 329)

05/04/93 -- In The SENATE
Parts of a different measure incorporated into this measure as amendment by Senator Bond (S. 824, Amendment 340, subsequently amended)

:

LEGI-SLATE Report for the 103rd Congress Tue, September 21, 1993 10:43am (EDT)

QUICK REPORT:
H.R. 109 by Rep. Sherwood L. Boehlert (R-NY)
Department of the Environment Act of 1993

Major Actions on Bill:

01/05/93 -- In The HOUSE
Introduced by BOEHLERT (R-NY)
Joint referral to House Committee on Government Operations
Joint referral to House Committee on Foreign Affairs

CQ Weekly Report Articles:

03/27/93 -- (Page 746) Government Operations - Bill Elevating EPA to Cabinet Worries Environmentalists
05/01/93 -- (Page 1077) Environment - Mitchell's Pact Assures Vote on Cabinet Status for EPA
05/08/93 -- (Page 1140) Environment - Senate OKs Elevation of EPA; Hurdles Await in the House
09/04/93 -- (Page 2314) Government & Commerce - Issue: Elevating EPA to Cabinet Level

FAX 17 pgs

URGENT

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

May 5, 1993

LEGISLATIVE REFERRAL MEMORANDUM

LRM #M-245

TO: Legislative Liaison Officer -

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FROM: RONALD K. PETERSON (for) Ronald K. Peterson
Assistant Director for Legislative Reference

OMB CONTACT: Holly FITTER (395-3233)
Secretary's line (for simple responses): 395-6194
Richard MERTENS (395-6931)

SUBJECT: EPA Proposed Testimony on EPA Cabinet Legislation

DEADLINE: 3:00 PM May 5, 1993

COMMENTS: This testimony is similar to testimony given before the Senate Governmental Affairs Committee on February 18, 1993, but includes new sections addressing environmental equity, public access, and EPA contracting issues.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
M. Foley
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K. McGinty
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C. Vallina/B. Coleman
J. Breul/N. Shapiro
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S. Neuwirth

DRAFT

#045

STATEMENT OF

CAROL M. BROWNER

ADMINISTRATOR

U.S. ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE

GOVERNMENT OPERATIONS COMMITTEE

UNITED STATES HOUSE OF REPRESENTATIVES

MAY 6, 1993

I am honored to testify before you today in support of creating a Cabinet Department of the environment, and to affirm this Administration's commitment to improving environmental quality. I commend the leadership that this Committee has demonstrated in pursuing this matter. The Administration supports elevation of EPA to a Cabinet Department and will provide our comments to Chairman Conyers' legislation once it is introduced.

We all share a strong commitment to the environment. Environmental quality is inextricably linked to our Nation's and the world's hopes for a better quality of life. However, without an adequate institutional framework, even principled commitment can be rendered abstract. The question is not whether to create a Department on the environment, but when. The answer is now, at the beginning of this nation's third decade of Federal environmental protection--a decade in which we will move from command and control, media-specific regulation to alternative approaches oriented toward pollution prevention, ecosystem protection, and

Kate, Penny

incentive-based policies. It is time for a Department of the environment to function as a permanent and equal partner in the President's Cabinet, integral to any equation of Federal decision-making.

In the past twenty years, this country created most of its existing environmental infrastructure and body of law. To be sure, the national debate among Federal, State, Local and Tribal governments, industry, and the public on environmental matters has not always been successful. Nevertheless, significant progress has been achieved. The air, water, and land are demonstrably cleaner as a result of our joint efforts. Our "command and control" approach has worked well, but has tended to focus on a relatively small number of large point sources of pollution. In addition, its limited scope ignores creative opportunities for pollution prevention and ecosystem approaches.

The facts show that we have had tangible successes in some areas, that we are learning to better anticipate and meet new challenges, and that our successes depend very much on cooperation among the parties: governments, business, and the public. Yet our many environmental successes sometimes seem dwarfed by the growing agenda of environmental challenges, both domestic and international.

1993 is a pivotal point in time. We have the opportunity now to establish an environmental infrastructure ready to meet the challenges of the 21st century. We understand that we live in an enormously complex global ecosystem: "solving" one environmental

problem can create a new one. Clean-up of surface water has contaminated ground water, and solutions to ground pollution have polluted the air. Actions taken by one country can affect the health of the citizens of another, thousands of miles away, and for generations to come.

We also know that assessment of environmental achievement is a relative measure: our "successes" are meaningful only in terms of reducing overall risk. We have learned that we must not limit ourselves to clean-up, but must also seek to prevent pollution at the source. We must adopt a comprehensive and understanding approach that avoids unintended consequences of our actions and decisions. We must force ourselves to address long-term and not just short-term consequences. We must move "upstream" and examine individual pollution sources as elements of larger systems. Preventing pollution by elimination or reduction of waste at the source is key to this Administration's commitment to providing a healthy economy that meets our needs today, while preserving the environment for our children and future generations to enjoy.

A Cabinet Department of the environment will be well-positioned to accelerate efforts to integrate pollution prevention and multi-media decision-making into regulatory and compliance programs Government-wide, to promote the use of incentive-based policies, to improve technical assistance to small businesses and communities, and to encourage corporate commitment to clean manufacturing processes and green products through innovative programs. A Cabinet that includes an environment Department will

ensure that the environment is fully engaged and integrated into the President's examination of, and decisions on, national and international issues.

In 1993, concern for the environment affects individual, corporate, and governmental behavior. The nation's environmental ethic has evolved and is taken seriously across economic, cultural, geographic, and governmental sectors. Just as civil rights issues gripped our nation in the 60's, and nuclear/cold war concerns dominated the 70's and 80's, integration of economic and environmental policy has seized the public's attention in the 90's. A 1992 Roper/Johnson poll on environmental behavior indicated that 60% of the population of North America is concerned about the environment.

We meet today at a unique time in history--a time when modern concerns about environmental degradation are coming face-to-face with age-old concerns about racial and economic discrimination. Today, we realize that these historically separated issues interrelate. Environmental degradation and discrimination combine as a fundamental issue: "environmental ~~equity and~~ justice".

At the beginning of the environmental movement in this country, the concept of environmental justice was rarely discussed. It was widely presumed that environmental risk was blind, that it posed similar problems to all people, regardless of their racial or economic differences. There is no longer any doubt that as we undertake programs to reduce risks, we must explicitly recognize the ethnic, economic, and cultural makeup of the people we are

trying to protect. We now believe that people of color and low income are disproportionately affected by some environmental risks--the risk of living near landfills, incinerators, or hazardous waste sites; the risks posed by lead or asbestos in old, poorly maintained housing; the risk of exposure to pesticides in farm fields; and the risk of eating contaminated fish when fish is a mainstay of their diet.

We already have begun to address these issues. Over the past three years, EPA has established an Office of Environmental Equity; we have expanded our education and outreach programs to communities of color and those of low income; and we have increased technical and financial assistance to communities with special environmental concerns. But we must do more.

I have made environmental justice one of the four key policy themes of my Administration. [CB Decision: state intention to redefine an Office of Environmental Justice??] Environmental justice must be woven into all aspects of EPA operations: rulemaking, permitting, enforcement, education, and outreach. Our program offices are expanding their data collection efforts in communities located near large sources of pollution in order to help us assess health impacts. The President's FY-94 budget includes $15 million to address lead paint contamination in urban cities. We are looking at new ways to target inspections, enforcement, compliance monitoring, and pollution prevention projects in these communities. Environmental justice must be considered a shared responsibility in the actions of all Federal

hiring

agencies and ultimately at the state, local, and Tribal government level. To this end, we have acted to implement the President's Earth Day announcement by establishing an interagency group to address environmental justice issues across all Federal agencies. We have recently finalized an interagency agreement with the Department of Commerce, the Department of Housing and Urban Development, and the District of Columbia government to create entrepreneurial and job opportunities to build and sustain a "green movement" throughout the inner city. On another front, we are working with Federal health agencies including.... to strengthen the scientific and health effects data related to communities of color and those of low income.

We have initiated three environmental justice projects with the Department of Justice. First, we are working with the Civil Rights Division using its computerized database to identify and evaluate low income and communities of color. We are working with the Environmental Division to identify ongoing litigation in which environmental justice goals can be implemented. We also are exploring a possible agreement with the Department of Justice Community Relations Service to provide outreach, mediation and conciliation to communities affected by sources of pollution or contamination where racial or ethnic concerns are involved. We hope to make the EPA/DOJ relationship a model for working with other Federal agencies, collectively drawing upon our individual areas of expertise to address the spectrum of challenges presented by environmental justice needs.

In this review, we will be looking at regulations and enforcement actions that affect low income and communities of color, to properly collect data on actions that disproportionally affect those communities.

Finally, I am committed to making EPA's workforce more culturally and racially diverse. If EPA is expected to be sensitive to the environmental risks facing all races in this country, then EPA's workforce must reflect the cultural diversity of the nation as a whole. President Clinton, myself, and this Administration share a deep and enduring commitment to fairness and environmental equity and justice.

Public access to information and environmental education are linchpins to making environmental equity, pollution prevention, and waste reduction work. EPA long has been a proponent of public access, and has been a leader in the Federal government in this area. Public access to environmental information is fundamental to increasing environmental awareness, and spurring the public and the regulated community to greater environmental responsibility. The Toxics Release Inventory created by Title III of SARA clearly demonstrates how periodically reported information builds individual and corporate responsibility across this country.

Experience has shown that sharing information with the public advances the mission of the Agency by leveraging additional environmental protection efforts at the grass roots level. This contributes significantly to the public's understanding of our programs, and builds support for our decisions. So many of our personal choices--what we buy, how we transport ourselves, how we dispose of our waste--affect the environment, our health, and our economy.

EPA has made substantial progress in making its information available to the public--despite a myriad of legislative mandates and strained resources. I am committed to expanding EPA's efforts in information integration and making our information more easily accessible by the public.

The Department must also serve as a model for responsible fiscal practices and responsive, accountable management. Financial integrity and sound resources management are critical to fulfilling our environmental mission and to safeguarding the taxpayer's dollar. The EPA of today is a highly leveraged Agency, focused increasingly on complex, cross-cutting health and environmental issues. I have made a commitment that resources management will be a cornerstone of my Administration. Our financial systems and processes must be designed to meet the highest standards of effectiveness, to satisfy identified customer requirements, and to support program needs. In testifying on this issue in March, I outlined three major themes to integrate management with mission at EPA: we will develop an overall management scheme and measures for success, construct a rigorous system of accountability, and establish clear standards of discipline. I have already begun several initiatives to make these themes a reality, including focusing the highest levels of the Agency on all aspects of managing financial resources. I want to instill an Agency culture that supports both the letter and the spirit of the acquisition rules and regulations; I want to develop prevention-based

approaches; and I want to make financial integrity an integral part of our everyday work ethic.

I support efforts to reform contracts management, particularly in the area of large umbrella contracts and the use of subcontractors. Reforms should limit "contract shopping" in the Agency, and eliminate the improper practice of directed subcontracting. In addition, I support the efforts of the Congress to address inherently governmental functions and to define restrictions on allowable costs on a Governmentwide basis as a matter of good government. I am committed to moving the Agency forward to safeguarding our environmental programs, achieving our mission goals, and upholding the public trust.

In the same spirit of improving our financial management, I believe that a Commission that would address organizational, efficiency, and cross-media issues could play a useful role in enhancing coordination of the Department's efforts to protect public health and the environment. I look forward to Commission recommendations on management improvements and efficiencies among the Department's programs.

EPA increasingly is called upon to focus its attention on international environmental issues. EPA's international environmental programs provide cooperation with and technical expertise to developing and newly democratic countries and our industrialized partners. Cabinet status will be important to make the head of EPA a peer with Cabinet colleagues in foreign environment ministries and promoting international cooperation on

the environment. It will also make EPA a more effective collaborator with other Cabinet Departments involved in international environmental activities, including UNCED follow-up, programs in Central and Eastern Europe and the former Soviet Union, and environmental cooperation with Mexico.

Environmental protection is not a mere footnote, but encompasses all of the Earth's resources and human activity. Its front-page, banner-headline news is woven throughout newspapers, scientific and medical journals, and business and law publications. It shapes our daily thinking, strategies, and budgets in every conceivable issue area. We are moving beyond thinking of environmental quality as a luxury or as a hindrance to economic growth. The growth of our economy depends on the availability of a clean, safe environment and the long-term availability of natural resources. We can best join the need for balancing growth and the environment by unleashing American ingenuity and creativity to revive our economy and create a new generation of environmental technology--which will make us more competitive in a fast-growing international marketplace.

I strongly believe that environmental protection and economic growth are not incompatible. Environmental opportunities can be economic opportunities. The Roper Organization's 1992 Green Gauge Poll showed that a strong majority (63%) of Americans believe economic development and environmental protection go hand-in-hand. The 80's have shown us that environmental action or inaction has economic consequences, in turn affecting our environmental and

business choices in a never-ending cycle of cause-and-effect. Money spent by companies to comply with environmental laws and regulations translates into revenues and jobs for other American businesses. For example, the Clean Air Act Amendments are the latest example of how Congressional and EPA action can drive major economic growth in the pollution control sector.

Our experience over the last few months in fashioning the President's economic plan is illustrative of the role that environmental considerations should play in our Federal decision-making process. As the numerous options for energy taxes were explored, environmental concerns and impacts were analyzed in a matrix alongside energy, economic, social, and trade considerations. This Administration is committed to identifying the dynamic relationship between economic and environmental needs and to ensuring that environmental assets are reflected in our accounting of national well-being.

Any student of democracy and public policy must acknowledge a missing building block in the list of structures in the top tier of the Federal government. Currently, EPA sits in the Cabinet room at the President's invitation, but President Clinton agrees that we should validate its presence as a statutory matter, regardless of who sits in the White House Oval Office. It is time for a permanent chair at the table, institutionalizing the environment as a critical ingredient in the mix of any Federal decision-making.

EPA as an institution is grappling with today's challenges, but the EPA created by Reorganization Plan Number 3 in 1970 is

positioned now to function as more than a regulatory agency. This Administration embraces successful new approaches and the essential dynamic of environmental management handled in partnership across Department and governmental lines. An environment Department will work closely with both its Cabinet counterparts and its State, local, Tribal, and other government partners, and remain responsive to the individual citizen. We must rely carefully on sound science and research to better understand environmental issues such as biodiversity, global climate change, environmental equity, risk, and persistent toxic chemicals, and to better develop policy and solutions. An environment Department must be a model environmental steward both domestically and internationally.

Both our national environmental ethic and the nature of the ecosystem itself tell us that the President's Cabinet currently is incomplete. In today's world, a successful strategy for any public policy issue requires a comprehensive perspective that crosses traditional Departmental boundaries. There is virtually no such thing as a policy or problem that does not have environmental aspects or that is simply "environmental". A sound approach to the environment is essential to the success and sustainability of our Nation's economic, social, and trade policies. The President's Cabinet must be able to function as a collaborative and interdependent mechanism, integrating the best public policy thinking across Department lines. It is not enough that environmental considerations be part of Cabinet discussions: the

environment must be there in its own right as an equal priority and member.

Public concern about the environment drives our need to consider how all of our policies affect quality of life for ourselves and our children. A 1992 survey conducted for the World Wildlife Fund by Peter D. Hart Research Associates found that America's youth are among the most environmentally conscious and concerned segment of our population. As our children, pre-kindergarten through college, study the structures that define our democracy and government, I want to make sure that an environment Department is part of their original understanding of what makes our Nation strong. In addition to our children, students of democracy everywhere in the world should comprehend that an environment Department is key to America's identity. The United States should join the majority of our major partners who count an environment minister as an equal among the top government tier. Not to do so sends the wrong message about our government's priorities here at home; it also prevents us from asserting the kind of leadership that the rest of the world is looking to us to provide on environmental problems affecting the entire planet.

In conclusion, I assure you that the creation of an environment Cabinet Department means more than a new chair. As public officials we must judge ourselves not only by what we accomplish today, but by the legacy we create for tomorrow. Joining the Cabinet ensures direct access to the President, and consequently, a voice on behalf of citizens concerned about the

environment their children will inherit and industry seeking to mesh environmental and business concerns. An environment Department's involvement in the Federal government's domestic and international agenda will improve the quality and efficiency of Federal decision-making as the Cabinet addresses all of the Nation's challenges. Creation of an environment Department signals at home and abroad the highest commitment of the United States to environmental stewardship. (Close with quote from President Clinton's Earth Day speech?)

Challenges Ahead for the U.S. Environmental Protection Agency in the 21st Century

Final Report of the "Megatrends" Project

Prepared by the World Resources Institute
in cooperation with
the U.S. Environmental Protection Agency

December 1, 1992

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Challenges Ahead

for the U.S. Environmental Protection Agency in the 21st Century

Final Report of the "Megatrends" Project

Part I: Executive Summary

If the U.S. Environmental Protection Agency (EPA) is to play a leadership role in protecting the environment in the 21st century, the Agency must fundamentally reevaluate and redefine its identity and mission. Regulation of specific environmental media, a principal focus in the past, will not be sufficient in the future. The Agency can make its greatest contribution by seeking to improve the nation's stewardship of natural resources and seeking to build a more efficient and environmentally sustainable economy.

In practical terms, a focus on stewardship and sustainability implies a fundamental reorientation and reorganization of the Agency. The Agency must position itself to help set, not merely react to, the national environmental agenda. Policy innovation, education and public outreach, and science and technology must become central activities. It must increasingly work closely with, coordinate, and support the environmental and natural resource activities of other federal agencies. The Agency also must broaden its vision internationally. These new institutional imperatives are summarized in this report in terms of seven critical, interrelated challenges the Agency will face as it prepares itself for the next millenium.

LEADERSHIP AND VISION

Challenge 1: To create a national vision of an environmentally sustainable future

Challenge 2: To exercise a leadership role in environmental education for all segments of society

BEYOND REGULATION

Challenge 3: To move beyond the current regulatory approach, characterized by command-and-control and defect-finding, with pro-active policies such as market-based incentives and voluntary programs that encourage the pursuit of excellence

Challenge 4: To broaden the Agency's mandate, goals, and orientation to include not only pollution control and prevention but also resource protection, preservation, and sustainability

INTERNAL MANAGEMENT

Challenge 5: To create of a world-class scientific capacity within EPA in order to give the Agency the ability to develop and utilize new knowledge and to serve as a catalyst for technology innovation critical to achieving the nation's environmental objectives

Challenge 6: To play an expanded leadership role in the international arena

Challenge 7: To become a more responsive, efficient, and innovative organization through changes in internal structure and improvements in management, in order to be able to meet the challenges ahead

Meeting these seven challenges will be difficult. In part, EPA's success will depend on factors external to the Agency, including actions taken by the President and the Congress. Yet much depends on the leadership exercised by the Agency itself. Avoiding the hard decisions necessary will ultimately cost the nation and the world dearly in environmental quality.

The world is now at a critical environmental juncture. Many existing environmental problems remain unresolved. Economic hardships here and abroad could weaken support for environmental protection. Rising consumption, burgeoning populations coupled with poverty, and unwise patterns of industrial development could still further degrade natural resources and the global environment. New environmental problems and concerns are likely to emerge.

At the same time, there are unparalleled opportunities for progress. Public interest in environmental issues has never been higher. Scientific understanding of environmental problems is growing and a wide range of promising new technologies are under development. Innovative new policies are being proposed and tried. There is increasing awareness that long-term economic success and environmental sustainability are closely coupled.

Ultimately, protection of the planet will require strong leadership, wise policies, and a lasting commitment. The Environmental Protection Agency can, and must, be a source of all three.

PART II: Project Rationale and Strategic Themes

The "Megatrends" Project was a collaborative effort between the World Resources Institute (WRI) and the U.S. Environmental Protection Agency (EPA), undertaken at the request of EPA. This study, conducted over an eight-month period from May-December 1992, was designed to address two overall questions:

> "What major forces, trends, events, uncertainties, and/or surprises will have significant impacts—positive or negative—on the quality of the global environment, or on our ability to protect the environment, over the next 30 years?"
>
> "What are the strategic implications of these trends and forces for the U.S. Environmental Protection Agency?"

EPA's interest in the "Megatrends" questions pertains to the future institutional environment in which the Agency will be required to function and how it can play a more effective, pro-active role. WRI has a long-standing interest in the planet's environmental future and a specific research interest in factors affecting environmental sustainability.

This report is based on information obtained during a series of one-day workshops which brought together experts from across the country. The topics of these "Megatrends" workshops were:

- water, including marine and coastal zone resources
- urbanization, including transportation and land use
- innovative technologies
- energy and the environment, including climate resources
- institutions
- biodiversity
- synthesis

The first six workshops were for primarily fact-finding. Summary reports were combined into a package which highlights recurring themes and strategic issues. The task of a final Synthesis Workshop was to organize and integrate the fact-finding package into a coherent vision of the future and to identify the strategic implications for EPA. Attendance at all workshops was by invitation, with each participant selected for his or her unique expertise and experience.

The goal of the "Megatrends" Project was to provide a basis for discussion and analysis by EPA of its future role. The fact-finding effort relied on expert opinion, not on an extensive literature search or detailed policy analysis. Accordingly, the findings are preliminary and should be viewed not as an end in itself but as input into an ongoing process of institutional reevaluation and renewal. It is hoped that a close examination of the challenges raised by this report will help EPA to become more informed, realistic, and introspective in its pursuit of environmental quality and a sustainable, high quality of life.

While the content of this report reflects the accumulated knowledge and experience of the experts who participated in the "Megatrends" workshop series, final responsibility for the report rests with WRI and EPA.

The challenges ahead for EPA that are identified in this report relate to both the Agency's internal and external functioning. These challenges are driven by trends and forces likely to shape the future environment. The key trends identified by the workshops include population growth coupled with poverty, economic development coupled with rising consumption, technological change, and shifting social and leadership patterns.

Four recurring, strategic themes concerning the future of the environment emerged during the course of the Project—themes that are pertinent to EPA and on which the Agency needs to reflect.

1. Economic growth and environmental quality are complementary goals. Economic growth, if properly managed, has positive implications for the environment. For example, on the supply side, it enables the replacement of old plants, processes, and machinery with environmentally-friendly capital stock. On the demand side, economic growth makes possible the higher disposable incomes and prior fulfillment of basic human needs that are usually necessary before societal preferences for environmental quality are expressed.

Despite trends that are beginning to decouple economic growth and environmental degradation in the developed world, the economic-growth versus environmental-quality battle continues to be waged in the United States. Resolution of this battle will entail the design of long-term approaches that can reasonably accommodate the legitimate needs of all stakeholders. Without resolution, there is likely to be an increasing politicization of environmental issues and more deadlock.

2. Solving environmental problems involves more than "technology fixes" and ultimately will require broad-based participation by many segments of society. Technological innovations have an important role to play in enabling a sustainable environmental future. To be most effective, however, technological innovations must be supported by managerial, educational, and economic initiatives, particularly the decision-making processes in both government and private firms.

Building consensus is critical, yet the success of consensus-building efforts depends on many factors including the informed participation of a broad cross section of society, the accurate and realistic portrayal of options and tradeoffs, and recognition by all parties of the potential for mutually beneficial outcomes.

3. The locus of power for environmental decision making is shifting. Many environmental responsibilities that historically fell under the purview of the federal government are increasingly being assumed by state and local governments and private institutions at the local, regional, and international levels (e.g., by grassroots organizations, NGOs, and corporations). In part, this shift is the result of institutional rigidities at the national public-sector level, cynicism towards public sector management, and the growing number and effectiveness of other institutions. The coordination of local concerns and the broader institutional context requires a concerted, flexible response from a variety of institutions operating at different levels.

4. Attitudinal issues—concerning human nature, values, and culture—will likely pose the most difficult challenges for environmental protection over the long term. Many environmental challenges tend to reflect broader social and political issues. Often at the core of these challenges is a need to show all parties that they have a stake in, and responsibility for, environmental quality. In particular, the United States as a nation must recognize that it has a stake in the environmental conditions of other nations. Individuals, too, must come to realize that they are accountable, i.e., that there is a direct connection between environmental quality and the choices they make daily in their personal lives.

Part III: The Challenges

LEADERSHIP AND VISION

Challenge 1: To create a national vision of an environmentally sustainable future

In the 1970s, the United States found itself faced with a legacy of waste from years of rapid industrialization. In response, the federal government created EPA and charged the Agency with identifying and disposing of hazardous wastes once these hazards—threats to human health—were discovered.

Worldwide, a fundamental shift in environmental protection strategies is now underway, as the previous era of pollution control gives way to an era of sustainability and stewardship. No longer can society's needs and aspirations be met by resource-intensive methods that result in high environmental penalties. In general, resource- and pollution-intensive lifestyles are not possible for either the developed world to maintain or the developing world to achieve.

The shift to stewardship gives rise to a new set of environmental problems and issues that cannot be adequately addressed through the Agency's traditional waste-oriented, reactive approach. A new, long-term national vision of environmental quality is necessary. Moreover, such a vision must be pursued with consistency, persistence, and commitment if it is to set an effective course for environmental policy and programs over the long term. Importantly, it can no longer presume a human right to dominion over nature. Rather, the vision must create an environmental ethic that improves the relationship between people and nature, recognizes the finiteness of natural resources, instills a sense of society-wide responsibility for the common good, and emphasizes resilience and adaptiveness in the face of ongoing change.

As one of the nation's principal environmental stewards, EPA would be in a position to explore how to complete the transition to a new, environmentally sustainable economy that can fulfill the needs and aspirations of this and future generations. Moreover, knowledge gained about this new economy could be made available to developing nations in hopes that they might avoid duplicating the wasteful, resource- and pollution-intensive period that developed countries have experienced.

The goal of economic activities is to enhance the quality of life by providing society with certain amenities such as shelter, food, security, communication, education, health care, mobility, culture, and entertainment. Society, aided by technology and wisdom, is finding new and better ways to provide these amenities with fewer resources. People have a right to expect more affordable and less resource-intensive lifestyles in the future. But people also must be persuaded that the economic-environment connection can lead to something better; they will not demand what they do not know is possible.

Leadership is critical for the development of an environmentally sustainable vision of the future. EPA could take the lead in articulating this vision and, towards that end, facilitate consensus and coordinate national activities. The Agency might work with companies, states, and the public to set an agenda for change; review existing laws and regulations to set priorities for change and make a case for such change to the President and Congress; help agencies and departments of the Executive Branch to establish a basis for judging their decisions in environmental terms; and foster a national long-term perspective on environmental issues.

Creating a new national vision will take effort. But its importance cannot be underestimated as a guiding principle for resource use and environmental protection into the next century. It provides the means for judging the merit among alternative ways of supplying amenities, internalizing the full costs of natural resource use, designing new incentive structures, developing coherent and integrated environmental strategies for different levels of government, and gauging progress. Furthermore, a national vision can serve as the basis for formulating achievable environmental goals and policies for specific economic sectors.

There are hopeful trends that favor the creation of a new national vision. For example, some progress has been made to decouple GNP growth from resource inputs in the economy, to rely on market forces to value resources, and to increase resource efficiency through recycling and reuse. Efforts to create a vision also could capitalize on the increasing numbers of Americans who today recognize the benefits of a sustainable environmental future.

Challenge 2: To exercise a leadership role in environmental education for all segments of society

The success or failure of attempts to accommodate human activities within the natural environment will depend in large part on the ethical underpinnings and value structure of society. The value structure of society must be influenced in a way that leads people in all segments of society to make wise environmental choices. Environmental education in the broadest sense—of the public, students at all levels, consumers, business people, environmental professionals, and governmental leaders—could be one of the most important strategies for protecting the environment over the long term, especially if educational activities are designed to nurture the values that are the foundation of stewardship.

The need for a better informed population is reflected throughout society. If the Agency is to foster stewardship of the nation's natural heritage, it will need to play a far greater role in education. While it already has statutory primacy in the federal government for environmental education, the Agency must expand its efforts to give Americans a direct sense of connection between environmental quality and their personal activities. Opportunities include curriculum development (starting in the earliest grades), training (e.g., teacher training and management training), outreach, and development and improvement of publications and other educational materials.

EPA also could assume a more active responsibility for raising the level of public debate about the environment. For example, the Agency could help to develop public discourse capabilities (e.g., by encouraging the cross-fertilization of ideas, promoting public dialogue, and building consensus) and increase access to the information and knowledge that can empower citizens to participate more actively and constructively in local decisions and programs.

One pressing need that EPA could fill is to document and disseminate information about successful or interesting environmental case studies. There is much for the federal government to learn from the experiences of other nations as well as from states, regions, and localities. Moreover, EPA could enhance its role as an information clearinghouse for the states, which would be consistent with the trend among states to assume increasing responsibilities for environmental decisions.

Information is a powerful lever for change. In general, EPA could facilitate learning about specific environmental topics by collecting, synthesizing, and disseminating information. For example, it could disclose

information on emissions (e.g., under Title III), accounting procedures, and environmental discrepancies in daily personal choices. Ways of better harnessing the power of the media might be explored. Not only could the Agency make the information it has already collected more accessible to the general public, but it also could better tailor this information into forms more relevant to decision making. By re-casting its materials in this way, EPA could help both the public and policy makers develop more realistic expectations about the environmental risks, tradeoffs, and improvements implied by various decisions.

Americans have had a deep-seated frontier ethic—a value system based on the notion that resources are infinite and there is an ever-new place to which they can move. In order to create an ethical system that is consistent with sustainability, EPA could help increase the public's awareness of alternative perspectives. For example, the traditional values of Native Americans revolve around an intricate web of dependent relationships among the land, water, sky, and creatures. The Amish concept of land ownership is that land is only held in trust by the current generation for the benefit of future generations.

The younger generation is showing signs of great sensitivity to environmental issues. For example, children are increasingly aware of the need for recycling and of their power as consumers in the marketplace (e.g., they realize that boycotting certain goods can be a vote against environmentally "bad" products). These attitudinal changes are encouraging, but they are still only a beginning. Education in the broadest sense has proven to be an effective and relatively inexpensive way to increase environmental awareness, influence values, and motivate change, and it holds great promise as a centerpiece for a renewed EPA.

BEYOND REGULATION

Challenge 3: To move beyond the current regulatory approach, characterized by command-and-control and defect-finding, with pro-active policies such as market-based incentives and voluntary programs that encourage the pursuit of excellence

During its formative years, EPA assumed the role of regulator, setting forth rules (in the form of prohibitions) and prosecuting those who violated the rules. This approach, characterized by "command-and-control" and "defect-finding" that focused on specific media, resulted in a model of environmental excellence based on actions to avoid. In the process, EPA developed an adversarial image as "watchdog" and "cop" that plagues the Agency today.

Command-and-control is in striking contrast to the quality assurance approach now pursued by many successful firms and agencies. Underlying quality assurance is a vision of continuous improvement and rising standards. The operative language is "even better," not "good enough." Firms and government agencies alike have discovered that a floor on performance (as embodied in standards) effectively acts as a ceiling to further improvement. In general, command-and-control stifles innovation and creativity, erects barriers to entry, and hinders competitiveness.

Importantly, the command-and-control approach poses environmental decisions as choices between what a firm would like to do in order to make profits and what it would not like to do but might be forced into doing. Environmental protection thus is cast as a minefield of troubles rather than as opportunities to excel. Furthermore, the implication is that there is necessarily a tradeoff between environmental and economic benefits, an implication that is contradicted by overwhelming evidence. That so many people believe there is a tradeoff between the environment and economic benefits is one of the most costly consequences of the traditional regulatory/enforcement paradigm.

Moreover, EPA likely will not have the resources to fully implement regulatory control. Such control is cumbersome—with too many rules to write, plants to visit, samples to analyze, and lawsuits to settle—and may eventually crumble under its own weight. EPA might consider shifting regulatory functions both to state, regional, and international bodies, as is consistent with the changing locus of decision-making power, and laterally to other federal agencies if appropriate. The

Agency also could better capitalize on the innovative approaches now being pursued in the private sector.

By freeing resources that are now required for regulatory activities, EPA could devote more attention to developing a new model of leadership featuring market-based incentives and voluntary programs. As part of this new leadership approach, the Agency could promote the building of a pro-environmental culture within firms and agencies. Such a culture would be motivated by both environmental protection and profits rather than threats of punishment and the minimum performance that can be "gotten away with."

In addition, the Agency could assume the role of a trustworthy and fair process-engineering consultant, a role that has been assumed successfully by environmental agencies in many European countries. Positive consultancy role models also exist in the United States. For example, a small group of environmental regulators in New York State have started to teach local governments how to build and operate sewage treatment plants and water systems, and performance has improved to levels that far surpass those achieved with the previous system of fines and compliance orders.

Characterizing environmental responsibility as an accelerated pursuit of excellence would generate a variety of new policy options for Agency consideration. While some regulation may still be necessary, it becomes only one of many instruments from which to choose. In particular, market incentives and financial engineering (e.g., emissions trading, revised accounting standards and practices) are likely to play greater roles as forms of control. The elimination of environmentally damaging subsidies is already underway in the United States and needs to continue. Privatization is a trend that is stimulating competition and resource efficiency elsewhere in the world in some sectors (e.g., water) and, if pursued more actively in the United States, could profoundly change the regulatory climate. Another option might, arguably, be moral suasion.

Importantly, less emphasis on regulation could promote more industrial experimentation and variation which, in turn, could be treated as valuable sources of learning rather than as signs of trouble. The competition to excel, catalyzed by positive incentives and rewards for performance, would replace compliance as the prime motivator. Public information could further highlight the competitive performance of firms. Information also could be collected on interesting state and local experiments with alternatives to regulation, and the demonstrated effectiveness of these alternatives could be documented and publicized.

Experiments with alternatives to command-and-control have proven to be effective. Examples include emissions-data publication under Title III and the nonregulatory anti-smoking campaign. Demand management also offers hopeful opportunities (e.g., if it could reduce the need for travel rather than aim to reduce emissions from cars). Voluntary programs, in particular, are appropriate for government sponsorship and have been well-received; the innovative voluntary programs pioneered by EPA (e.g., the "Green Lights" program) should be continued and expanded. Overall, alternatives to command-and-control should be designed to encourage innovation—now stifled by defect-finding, blame assignment, and coercion towards a single standard—in an atmosphere of continuing improvement.

Moving beyond compliance does have risks. For example, command-and-control involves a degree of certainty and predictability of outcome to which both Congress and the public have become accustomed; steps will be required to build a constituency for change. In addition, undoing some regulatory knots (e.g., permitting procedures), addressing controversial features of the liability system (e.g., joint and several liability), and resolving questions of business ethics (e.g., many firms now view making profits on the environment as "unsavory") may prove to be institutional hurdles. In general, EPA needs to examine carefully the full range of implications if the nation's protection against pollution were to depend on the will and intentions of people rather than on the fear of a "cop" or lawsuit. On balance, the potential gains from positive, pro-active policies would seem to outweigh the risks.

Challenge 4: To broaden the Agency's mandate, goals, and orientation to include not only pollution control and prevention but also resource protection, preservation, and sustainability

The cutting edge of environmental issues and the institutional climate in which EPA operates are radically different today from those that prevailed when the Agency was created. With respect to water resources, for example, the focus of attention is shifting from point-source pollution problems caused by industrial or municipal facilities to diffuse pollution sources such as agricultural run-off and to watershed management issues. In energy, the focus of attention is moving from the environmental problems of supply such as Clean Air Act enforcement to the opportunities for demand management through more efficient use and incentive policies; there is also a shift in concern from local and regional to global impacts of energy use that has broad implications for future energy strategies. A focus on the protection of endangered species is rapidly being replaced by a broader concern for preserving habitats and ecosystems, with profound implications for the management of forests, rangelands, and other natural resources. Urban environmental problems are increasingly viewed as closely linked to land use, transportation, and infrastructure policies.

All of these trends involve areas that exceed EPA's present jurisdiction. In part, changing environmental issues reflect the Agency's past success in dealing with straightforward pollution problems. In part, it also reflects growing sophistication about the ultimate causes and consequences of pollution and environmental degradation and what must be done to prevent them. (See box, below, on URBANIZATION). What is clear, however, is that EPA's traditional mandate—to regulate environmental pollution—is inadequate to address the stewardship of natural resources and the environmental sustainability of economic systems.

The EPA thus has a clear strategic choice: The Agency must either successfully seek a broader mandate and orientation or risk a future of increasing irrelevance. It must develop new partnerships and new mechanisms of cooperation with other federal agencies. It must lead by identifying and framing issues rather than merely reacting, by helping to set the national agenda, by policy research and innovation. The EPA must make the case that a lead federal agency is essential on coupled environmental/economic, environmental/infrastructure, or environmental/natural resource issues and seek to be that lead agency where appropriate. It may be significant that there appears to be support for the renewal and elevation of EPA to cabinet-level status.

A broader mandate, goals, and orientation may be difficult for EPA to manage if it remains preoccupied with regulatory tasks and issues. One option worth careful examination is for the Agency to increasingly seek to delegate much of its regulatory tasks to state and local authorities, continuing a trend already underway, or to replace the need to regulate with incentive or cooperative approaches that engage industry, NGOs, and other institutions as the main actors in the system. Making the case for such changes to the President and to the Congress will be essential, but so will demonstrating EPA's capacity to fulfill a broader mandate, through innovative policy proposals, non-regulatory initiatives, and articulateness about the new environmental challenges that the nation faces.

Comprehensive, multidisciplinary, and integrated solutions will be necessary to future environmental problems. Fundamental reorganization of the Agency may be desirable, perhaps by sector or by function; statutory reform may be called for. Integrating EPA's perspective into the mainstream of economic activities will be critical.

URBANIZATION

Community settlement patterns have profound and long-term effects on air and water quality and biodiverity. The lack of integrated land-use, transportation, and urban policies in the United States is now resulting in urban environmental conditions that are, in many respects, more comparable to those of developing than to Organisation for Economic Co-operation and Development (OECD) countries. The most likely future for urbanization in the United States over the next 30 years, in the absence of fundamental institutional change, is further deterioration of environmental conditions.

The legal and institutional processes that guide community building in America today were conceived by the Hoover Commission in the 1920s. According to the Hoover Commission model, the federal government was to play no part in how cities, suburbs, and countryside were shaped. In addition, by 1940, virtually every state had adopted major features of the U.S. Department of Commerce's *Standard Zoning Enabling Act* of 1926 and the *Standard Planning Enabling Act* of 1928. In adopting these planning and zoning statutes, the states had effectively relinquished their authority over community building by giving cities, towns, and counties the power to prepare plans and manage change through the adoption of zoning, subdivision regulations, and other related measures. These measures often have been adopted and enforced without accountability to, or oversight by, any regional, state, or federal authority. Moreover, environmental impacts from local land-use practices often spill over local boundaries.

Some state and federal agencies are beginning to understand the importance of having a state or national strategy for community growth and change. For example, 10 states have replaced their old planning statutes with new systems that hold different levels of government both vertically and laterally accountable. At the federal level, the relationship between land use, transportation, and air quality has become a key component of the Intermodal Surface Transportation Efficiency Act (ISTEA). In addition, the amendments to the Clean Air Act have sought to deal with municipal spillover and cumulative environmental impacts by addressing air quality from a regional perspective. Thus, while an increase in regional governance over large metropolitan areas, at least for some functions (e.g., air quality, transportation), seems likely, still much remains to be done.

If EPA becomes focused on stewardship and sustainability, it cannot overlook its stake in the built environment. Working with other federal agencies, and with states and NGOs, the Agency has the opportunity to help incorporate environmental safeguards and mitigation measures into the community planning and land-use management process. Creation of a national strategy for community growth and change is essential for avoiding future, costly environmental degradation.

INTERNAL MANAGEMENT

Challenge 5: To create a world-class scientific capacity within EPA in order to give the Agency the ability to develop and utilize new knowledge and to serve as a catalyst for technology innovation critical to achieving the nation's environmental objectives

Many federal agencies are involved in environmental research and environmentally-related technology development. As part of these activities, EPA could provide leadership in two broad areas: (i) research that relates to the Agency's stewardship functions including regulatory activities, and (ii) technology innovation that responds to the nation's long-term, strategic environmental and sustainability goals. Overall, this role would represent a philosophical shift for the Agency towards experimentation and environmental risk management.

Several alternative models for organizing a scientific capacity should be explored including the ones used by the National Institutes of Health (NIH) in support of health-related research and by the Defense Advanced Research Projects Agency (DARPA) in support of defense-related research. In any case, the institutional structure selected must be independent of EPA's regulatory functions, able to operate across the Agency, and able to accommodate both the multiplicity of disciplines involved in environmental issues and the pace of change occurring in still-young environmental fields.

Opportunities exist for EPA to strengthen its collaborative ties with other federal agencies and departments, such as the National Aeronautics and Space Administration (NASA), the National Oceanic and Atmospheric Administration (NOAA), the National Science Foundation (NSF), and the Departments of Interior and Energy, whose missions also pertain to the environment. However, there is a leadership role for EPA to play because it serves more broadly-based public and private sector constituencies. For example, EPA could act as coordinator for the collection and dissemination of scientific information, including environmental statistics, from across government.

In the area of environmental science, key areas for research include monitoring (e.g., of emissions and environmental conditions), simulation and predictive modeling (e.g., to deal with uncertainty and system-wide effects), and the basic science that could lead to new opportunities or

technologies for efficient resource use as well as for pollution prevention, control, and cleanup (e.g., research on microbial contamination and thresholds for ecological impacts). The validation, documentation, and dissemination of research results also are essential; one possible model is the National Library of Medicine's work on information dissemination. Importantly, research must have sufficient quality and credibility (e.g., neutrality) to guide public sector policy decisions, support private sector business decisions, and promote public understanding and education.

EPA also could improve the public process both for the deliberation, acceptance, and integration into policy of research results and for the setting of wise research policies. Such a process is essential if results from environmental research are to have their greatest impact on decision making. Opportunities exist for EPA to assist in incorporating environmental and social concerns into national research agendas; enhancing cooperation within the environmental research community; and improving public understanding of uncertainty and risk.

With respect to technology innovation, EPA, in collaboration with other federal agencies, could take the lead in designing, implementing, and managing an ongoing program to stimulate the development of new technologies on behalf of the nation's long-term environmental goals. One task of the program would be to design positive competitive incentives so that industry will seek to innovate in support of these long-term goals. In addition, regulatory measures, if properly managed, also can spur innovation as has been demonstrated in Germany and France. And with the increased international recognition of environmental issues, there is an opportunity to stimulate broad sectors of U.S. industry to take the lead in world markets with environmentally-related goods and services.

The scope of a technology innovation program might encompass: (i) technologies related to monitoring, instrumentation, and lowering the cost of implementing regulations, (ii) technologies that stimulate long-term industrial competitiveness taking into account environmental considerations, and (iii) the development, demonstration, and assessment of high-risk technologies that could offer cost-effective, order-of-magnitude environmental improvements in multiple sectors. To support such innovations, EPA also might consider activities to provide broad-based technical advice.

Importantly, any program should catalyze, not subsidize, the development of new technologies. This implies investing at the margin to foster advancements in critical areas. The program also should be managed by an organizational structure that is accountable for the overall return on investment in the long term but that has sufficient independence to sustain

a vision, tolerate risk, and handle occasional failure. In general, EPA needs to improve its understanding of the innovative process as it relates to environmental technologies. Management principles to be considered relate to: investing directly at the sources of innovation and at the focal points for adoption and letting the rest follow; providing regulatory flexibility for experimentation and innovation (e.g., to ensure that regulations do not lock-in particular processes or create barriers to entry); and supporting cooperative efforts such as consortia when specific, identified pre-competitive technology goals and broad-based industry action are required.

Success of the program will depend critically on the creation of an enabling regulatory, legal, and financial environment for long-term innovation and risk taking. This environment could be improved in the United States, for example, by improving the functioning of legal systems that determine liability and protect intellectual property rights. Financial accounting systems also do not fully value long-term environmental investments.

Science and technology alone cannot solve environmental problems. But science and technology can improve environmental quality in many instances. Positive advances already are evident, and some future breakthroughs could be especially significant for the environment (e.g., in photovoltaics). Importantly, science and technology will be most effective if coupled with appropriate managerial, political, and economic initiatives. Research in the social sciences, too, will be required; for example, there is a general need to improve understanding of public values and perceptions concerning environmental matters. Because of its unique position, EPA has tremendous leverage in helping both to link science and technology policy to long-term societal goals and to create a policy climate in which science and technology can flourish.

Challenge 6: To play an expanded leadership role in the international arena

Threats to the environment are of growing global concern. For example, environmental problems are increasingly transnational in character. The environmental prognosis for developing countries is generally pessimistic, in large part because greater numbers of people live in poverty. There are widening economic disparities among nations along with more social strife, factionalization of nation states, and heightened concerns about international security. The globalization of markets and industries also is complicating the regulation of potential multinational polluters.

No one country can solve the environmental problems that affect the planet, and all countries have a stake in the environmental conditions of other countries. The trend is towards increasing global governance—including of the environment—in the form of treaties, conventions, and trade agreements. The United States will be increasingly called upon and expected to play its part as a responsible global citizen.

As a result, EPA will be drawn into the realm of international diplomacy and will need to develop a coherent international strategy. As it works towards international solutions, the Agency's comparative advantage lies not only in areas it has traditionally addressed, namely information transfer and capacity building, but also in the areas of international negotiations and trade.

Building on EPA's current activities, the Agency could take a more active role in assembling, synthesizing, and disseminating information on a global scale. This information could include data on the creative experiences that are being amassed worldwide on environmental conditions and management including the approaches that work or do not work; a vast knowledge base about U.S. experiences already resides within EPA. Broad access to, and the interpretation of, these data will influence perceptions about not only the nature of global problems but also the amenability of these problems to solution. For example, EPA could make information on special topics (e.g., testing the emissions of motor vehicles) available upon request to interested countries as well as to multilateral development banks. The United States, too, has much to learn from other nations.

With respect to capacity building, many countries lack the institutions, infrastructure, and personnel to tackle their environmental problems. The expertise EPA has gained in such areas as CFC alternatives, marine pollution, and energy efficiency could be increasingly important to

these countries. Assistance from EPA need not be limited to governmental agencies; EPA also could help to increase the capability of NGOs and other local organizations. Similarly, EPA has an opportunity to assist newly-formed international institutions that are charged with addressing global environmental problems (e.g., the Global Environmental Facility and the United Nations Commission on Sustainable Development). In general, capacity-building expertise could be transmitted in several ways, through training and technology transfer among others. Capacity-building efforts, of course, must be responsive to national differences and needs.

The areas where EPA may have the greatest opportunities to expand its international role are negotiations related to international agreements and trade. Environmental concerns are becoming more prominent in both these areas, and a strong, substantive involvement of the Agency could prove to be vital. For example, EPA could provide the expertise to help formulate and oversee environmental safeguards in trade dealings. Free trade also is relevant to the Agency because it serves as a powerful vehicle for environmental progress both by raising productivity and income and by providing a channel for diffusing clean, efficient technology. However, EPA needs to exercise special caution if it promotes U.S. environmental goods and services, or it could risk losing credibility to carry out other important activities in the international arena.

Challenge 7: To become a more responsive, efficient, and innovative organization through changes in internal structure and improvements in management, in order to be able to meet the challenges ahead.

If EPA is to meet the previous six challenges outlined in this report, the Agency will need to improve its internal performance. A strategic realignment will be required that is aimed at the organizational structure of the Agency and related administrative support systems. Importantly, such a realignment does not imply modest change, but rather a complete redirecting of the Agency's intellectual, creative, and financial resources. The result should be a vastly different organization than now exists.

The case is made in this report that the mission of EPA needs to be re-cast. It is incumbent upon Agency management to clearly articulate this re-cast mission and to identify an organizational strategy to carry it out. In addition, qualitative and quantitative measures of performance, which have critical impacts on operations and on the evaluation of Agency success, need to be specified. A clear public statement of mission and performance measures also will help the public better understand, assess, and build confidence in the Agency.

In seeking strategic realignment, the EPA will need to assess its current organizational capabilities. On the basis of this capabilities assessment, the Agency could identify the new organizational capabilities it must develop as well as the existing capabilities it must shed in order to fulfill its new mission. For example, if the Agency exercises a leadership role in environmental education (Challenge 2), it will likely require personnel with professional skills different from those currently within the Agency. Replacing command-and-control with more proactive policy approaches (Challenge 3) will likely necessitate different communications skills, review procedures, and geographic deployment of personnel than now in place. If the Agency gains a broadened mandate and shifts its orientation to include sustainability issues (Challenge 4), it will likely need to alter its planning horizons and use professional skills not now available.

The capabilities assessment thus can help the Agency formulate programs to redeploy existing resources and personnel and to educate, retrain, and motivate existing staff. Hiring practices may have to be examined and modified to attract and reward a new mix of professionals.

The capabilities assessment also should give rise to action-oriented performance measures, i.e., measures that reveal to management both how

well the Agency is performing and what to do differently when performance is inadequate. These measures can serve to eliminate sources of mistrust of the Agency and barriers to achieving public accountability. For example, performance measures that are disconnected from desired outcomes (e.g., that only measure environmental quality in terms of enforceable actions) should be replaced. Some measures might require the Agency to better organize and keep track of its activities and improve its ability to communicate and market what it is doing. EPA should better publicize its current efforts to broaden its view of the environment, reevaluate its future role, and implement innovative programs (e.g., "Green Lights").

Furthermore, innovative performance measures need to be developed to replace strict adherence to economic and quantitative analysis as the basis for decision making. Quality of life—and environmental quality—is about preserving and respecting people and places, which cannot be captured by efficiency measures alone.

In short, EPA must ensure that its organizational structure and related administrative support systems are capable of meeting the critical challenges the Agency faces. Only then will it maximize its chances of becoming more responsive, efficient, and innovative. If it can become more of a risk taker, allow for more variation in its programs, and be more willing to learn by doing, it will be better able to handle change. Through strategic realignment, EPA can expect to meet its environmental challenges while achieving the level of public support and accountability its mission requires.

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David D. Doniger
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Personal: 41 years old, married, 3 children.

Education: B.A., 1973, Yale College. J.D. and M.C.P. (Masters of City Planning), 1977, University of California, Berkeley.

Employment:* Senior Attorney, Natural Resources Defense Council, Air and Energy Program. 1978-present. Focus on Clean Air Act legislation and implementation, domestic and international processes for protecting the ozone layer and curbing global warming.

Staff Attorney, Environmental Law Institute, 1978.

Special experience and skills: Strong expertise in the nation's air quality program, especially concerning toxic and smog-forming emissions from factories and vehicles. Drafted and secured adoption of 1990 Clean Air Act Amendments on toxic air pollutants and ozone depletion.

Made first proposal in 1986 for phase-out of CFCs and other ozone-depleting chemicals. Played key role in forming the U.S. policy in ozone treaty (Montreal Protocol) negotiations in 1987, 1990, and 1992. Played similar role in EPA's domestic regulatory decisions on CFCs.

Represented NRDC in international negotiations on climate change treaty, 1991-92.

Handled more than a dozen major Clean Air Act cases in courts of appeals and district courts. Argued one Supreme Court case (Chevron v. NRDC).

Strong negotiating skills. Led negotiating teams of environmentalists, state and local government, and labor in five successful 'regulatory negotiations' involving big industries such as steel, oil, chemicals, and autos, as well as small woodstove manufacturers. The agreements secured large pollution reductions while giving industry greater certainty and flexibility.

Able to work well with people from government, business, and labor sectors.

Committees: National Academy of Sciences, Committee on Air Pollution Risk Assessment, now preparing report on risk assessment required by Clean Air Act.

EPA, Clean Air Act Advisory Committee and Stratospheric Ozone Protection Advisory Committee.

Recognition and awards: EPA Stratospheric Ozone Protection Award, 1991.
Profiled in Wall Street Journal (1990) and National Journal (1989).

Interests: Soccer, piano.

* Since April 1993, Associate Director, White House Office on Environmental Policy

Kurt D. Zwally, Special Assistant.

Mr. Zwally graduated from the University of Massachusetts, Amherst with a B.A. in Social Thought and Political Economy (STPEC) including studies in environmental economics. STPEC is an interdisciplinary major which focuses on issues of race, class and gender within the fields of economics and sociology. While attending UMASS Amherst, he competed on the University's NCAA Division II Ski team and was active as a leader in the Zeta Psi Fraternity. His employment includes work as a paralegal of the National Institutes of Health, Patent Branch. Mr. Zwally served as an intern in Senator Gore's office in 1992 for Ms. McGinty, and before coming to the OEP he was a member of the Vice President's scheduling staff.

Mr. Zwally serves as an executive assistant to Ms. McGinty and Ms. Zoi, coordinates administrative matters, and works with senior staff on special projects.

April 27, 1993

TO OEP STAFF

FROM PAM

Please review the enclosed bio statement to be released by the press office. If you have changes or additions, please get them to me by 2:00 on Wednesday. Especially on some of your duties I had to wing it so please edit carefully. Some of you do not have bios (DAVID AND KURT) so please get me one asap.

THANKS!

OFFICE ON ENVIRONMENTAL POLICY
STAFF BIOGRAPHIES

KATHLEEN A. MCGINTY, Deputy Assistant to the President and Director.

Ms. McGinty was appointed by President Clinton on February 16, 1993 to be Deputy Assistant to the President and Director, White House Office on Environmental Policy. Prior to her appointment in the Clinton Administration, McGinty served as Senator Albert Gore's Senior Legislative Assistant for Energy and Environmental Policy. In this capacity, she was instrumental in drafting the Clean Air Act, as well as legislation involving international environmental policy. McGinty served as Congressional Staff Coordinator for the Senate Delegation to the United Nations' Conference on Environment and Development held in June 1992 in Rio de Janeiro, as well as an Official Member of U.S. Delegation to Negotiations on the Framework Convention on Climate Change and the Antarctic Protocol. McGinty was awarded an American Chemical Society Congressional Fellowship. She served on Gore's Senate staff for one year as a Congressional Fellow, working on environmental technology, and science policy.

McGinty received her J.D. from Columbia School of Law in 1988. Throughout law school, McGinty worked for various law firms in New York and Philadelphia, including Thelen, Marrin, johnson & Bridges; Skaden, Arps, Slate, Meagher & Flom; Morgan, Lewis & Bockius; and Cooper, Dunham & Morgan. McGinty studied for her B.S. degree at St. Joseph's University in Philadelphia. She graduated summa cum laude in 1985 with a degree in Chemistry. McGinty spent the summers of her undergraduate career as a laboratory assistant for the Atlantic Richfield Company.

Ms. McGinty directs the Office on Environmental Policy and advises the President on all matters of international and domestic environmental policy.

CATHERINE R. ZOI, Chief of Staff and Deputy to the Director.

Prior to her work in the Office on Environmental Policy, Ms. Zoi was head of the Energy Productivity and Pollution Prevention Branch of the Global Change Division at the Environmental Protection Agency. She oversaw development and implementation of a variety of "Green Programs" including EPA's Energy Star Computers initiative and the "Green Buildings" effort. Cathy was also responsible writing the Clean Air Act rules associated with conservation and renewable energy. Ms. Zoi was the recipient of the Administrator's Gold Medal for Exceptional Service for negotiation the framework convention on climate change for the 1993 Earth Summit. Before her work at EPA, Cathy was a consultant with ICF Incorporated where she performed a wide variety of energy analyses, and she sent two years in San Francisco working for Pacific Gas and Electric Co in the corporate planning department. Cathy also held brief stints at

the United Nations Industrial Development Organization in Vienna and National public Radio in Wisconsin. She holds a B.S. in Geology from Duke University and a M.S. in Resource Systems from the Thayer School of Engineering at Dartmouth College.

Ms. Zoi's duties as Chief of Staff include managing the Office on Environmental policy, conducting personnel reviews, and directing the staff of 11. She also is assisting with policy directives, action plans, and project timelines. She serves as a liaison with other White House and Executive Agency staff and represents the Office on Environmental Policy at the deputies level.

DANIEL P. BLANK, Associate Director for International Trade and Development.

Mr. Blank formerly served as a Special Assistant to the Director of EPA's Office of Atmospheric Programs where he led initiatives and managed crosscutting issues on stratospheric ozone protection, global climate changes, and acid rain. He also served as a Program Analyst in EPA's Global Change Division, where he wrote two proposed regulations under Title VI of the Clean Air Act and supported ongoing negotiation of the Montreal Protocol. He has also been an Assistant Editor of International Barometer, and an intern in the Natural Hazards Prevention Project the Organization of American States. He received his BA in Regional Development magna cum laude from the University of Michigan.

Mr. Blank is currently responsible for following and developing policy on international issues that include trade and foreign assistance to promote sustainable development, international forestry issues, desertification, population and the UN Commission on Sustainable Development. He works closely with the Senior Director for Global Environmental Affairs on the National Security Council.

MARC W. CHUPKA, Chief Economist.

Mr. Chupka formerly was a staff economist with the Joint Economic Committee of the U.S. Congress, working primarily with Senator Gore on the economic aspects of environmental policy. Prior to that, Mr. Chupka was a consultant at ICF Incorporated where he conducted research for EPA primarily on the economic and environmental benefits of renewable energy technology. He also served for five years at the Congressional Budget Office where he analyzed the economic impacts of acid rain control legislation, fossil fuel taxes, pollution abatement technology, and federal budget policy. He is the author of several publication on carbon taxes, acid rain, and the electric utility industry. Mr. Chupka received his B.A. in economics from Yale College, and his M.A. and M. Phil. in economics from Yale University.

Mr. Chupka will review economic analysis of Office issues,

and will commission and coordinate environmental economic research relevant to Administration policy. He has coordinated work on the economic aspects of a Pacific Northwest Forest Management Plan, and will work extensively on a Climate Action plan.

DAVID COTTINGHAM, Associate Director for Natural Resources.

Mr. Cottingham is on detail from the National Oceanic and Atmospheric Administration, where he is the Director of the Ecology and Conservation Office in the Office of the Chief Scientist. He has been with NOAA since 1981. His responsibilities at NOAA included coordinating NOAA's compliance with the National Environmental Policy Act, OCS Lands Act and other statutes. During his tenure at NOAA, Mr. Cottingham co-chaired the Aquatic Nuisance Species Task Fore, represented Administrator Knauss on Endangered Species Committee review of the northern spotted owl, coordinated NOAA's involvement in the U.N. Conference on Environment and Development and was a member of the US delegation to the Conference, and chaired the interagency task force on plastic marine debris. Prior to his work at NOAA, Mr. Cottingham was a resource policy analyst at the Center for Natural Areas, where he managed contracts with the U.S. Forest Service and the National Park Service, and was an aquatic ecologist for Duke Power Company. He received a B.A. in biology at the University of North Carolina at Chapel Hill and a M.~~E.~~S from the Duke University School of Forestry and Environmental Science.

Mr. Cottingham's duties at the Office on Environmental Policy include coordinating policy on all natural resource issues, including public lands, endangered species, marine resources, clean water and ecosystems management. Mr. Cottingham has been leading the Office's efforts to ~~create~~ formulate a Forest Management Plan for the Pacific Northwest ~~in response to litigation over the northern spotted owl.~~

DAVID DONIGER, Associate Director for Global Environment.

DAVID -- I need a bio!!

Mr. Doniger is responsible for coordinating policy initiatives and interagency reviews for a portfolio of international issues that include climate change, the multilateral development banks, biodiversity, oceans, nuclear issues, the National Environmental Policy Act, and Arctic/Antarctic issues.

JOHN SHAFER, Associate Director for Sustainable Development.

Mr. Shafer joins the Office from Arkla, Inc., where he was the Vice President for Environmental Affairs. He was responsible for the overall environmental and safety affairs of the Arkla Pipeline groups, and coordinated the environmental compliance activities for all other business units within Arkla, Inc. He

spent 16 years working in Rate, Regulatory, Environmental and Pipeline Operation areas for Arkla, winning numerous environmental awards including the citations from the Arkansas Archaeological Society, the Nature Conservancy, and the National Wildlife Federation. He received the first "Corporate Wildlife Stewardship Award" from the Fish and Wildlife Service and the 1990 Conservationist of the Year from the Oklahoma chapter of the Nature Conservancy. Mr. Shafer served on the President's Council on Environmental Quality, on the advisory board of the Louisiana Nature Conservancy and on the environmental committee of the Interstate Natural Gas Association of America, and was a member of the Arkansas Federation of Air and Water Users, the Oklahoma Wildlife Federation, the Arkansas Archaeological Society, the Texas Wildlife Federation, and the Louisiana Wildlife Federation. He received a B.A. from Northwestern State University and Baptist Christian College, and an M.B.A from the Baptist Christian University.

At the Office on Environmental Policy, Mr. Shafer is responsible for coordinating regulatory and sustainable development issues. He has been formulating work on a commission on sustainable development and serves as a liaison with the business community.

PAMELA D. MCELWEE, Special Assistant for Legislative and Public Affairs.

Ms. McElwee was formerly a Legislative Correspondent for Senator Al Gore, working on environmental issues. She also served as a Special Assistant to Ms. McGinty, working on research projects and tracking environmental legislation. She has also been a Special Assistant at the EPA's Gulf Task Force, working on congressional and public outreach, and office management. She has also worked for several environmental organizations as a researcher and writer. Pam was graduated with highest distinction from the University of Kansas with a B.A. in Political Science and Environmental Studies, where she was the first dual recipient of federal Truman and Goldwater Scholarships. She is also a 1992 Rhodes Scholar and plans to receive a M.Sc in Forestry from Oxford in 1994.

Ms. McElwee plans congressional outreach, tracks bills and testimony, responds to legislative inquiries and coordinates the Office's legislative initiatives, and serves as a liaison to public interest groups. She also handles the issues of pesticides, environmental justice, children's issues, and national service.

ARNOLD V. LINDSETH, Special Assistant for Correspondence

Mr. Lindseth graduated magna cum laude from Vanderbilt University in 1992 with a B.A. in Mathematics. He was a member of Gamma Beta Phi and Phi Beta Kappa scholarship societies, and sent his third year at the University of Regenburg, Germany. He

has worked for the Clerk and Master's Office of the Chancery Court of Shelby County, Tennessee, at the Monotage Corporation of Memphis and for the Memphis Pink Palace Museum. Mr. Lindseth served as an intern in Senator Gore's office in 1992 working for Ms. McGinty.

Mr. Lindseth responds to all environmental correspondence, directs agency responses to correspondence, and works with senior staff on special projects.

CHRISTIAN MARSH, Special Assistant for Scheduling

Mr. Marsh is a graduate of the University of California, Santa Cruz, where he received his B.A. in economic and politics. While attending UC Santa Cruz, he worked at various law firms dealing with land use and endangered species issues.

Mr. Marsh handles all scheduling for the Office on Environmental Policy, coordinates adminstrative matters, and serves as an executive assistant to Ms. McGinty.

KURT ZWALLY, Special Assistant

KURT - I need a bio!

United States
Environmental Protection
Agency

Food and Drug
Administration

United States
Department of
Agriculture

TUESDAY, SEPTEMBER 21, 1993

CLINTON ADMINISTRATION PROPOSES STRENGTHENING THE NATION'S PESTICIDE AND FOOD SAFETY LAWS

EPA - Al Heier (202)260-4374
USDA - Tom Amontree (202)720-4623
FDA - Brad Stone (202)205-4144

The Clinton Administration today proposed comprehensive reforms of the nation's pesticide and food safety laws to reduce the risks pesticides pose to Americans, especially infants and children. The reforms were presented at a joint House and Senate committee hearing by the Environmental Protection Agency, the United States Department of Agriculture and the Food and Drug Administration.

The reform package represents the first significant, realistic attempt to improve and update the nation's food safety and pesticides laws in the last 20 years. It stems from the three agencies' joint commitment earlier this year to seek the reforms, which contain specific provisions to protect infants and children, as well as incentives to achieve a real reduction in the use of pesticides in the United States.

The Administration's reform package will:

- Extend the strict FDA health-based standard of a "reasonable certainty of no harm" for food safety across the board for all pesticide treated foods, including raw fruit and vegetables.
- Initiate a USDA-EPA one year project to establish commodity specific pesticide use reduction goals to be met by 2000.
- Require that most high risk pesticides meet the safety standard within three years and all other pesticides meet the standard within seven years.

- Eliminate the consideration of economic benefits in the pesticide review and approval process, except in exceptional cases involving significant disruption of the food supply and even then the benefit consideration would be limited to only five years.

- Mandate that EPA issue specific findings that a tolerance is safe for infants and children.

- Make it easier to remove from the market pesticides suspected of posing a risk to health and the environment and make lower-risk pesticides a top priority in the approval process.

- Significantly enhance the enforcement provisions of existing laws for violations of statutes and regulations.

- Establish a national goal for use of Integrated Pest Management (IPM).

- Prohibit the export of pesticides that have been banned or voluntarily withdrawn in the United States because of health concerns.

- Protect farm workers from the hazards of working with pesticides.

"Today's proposal is a giant step toward protecting all Americans--especially our children--from the risks of harmful pesticides on the foods we eat," said Carol M. Browner, EPA Administrator. "For the first time ever, the federal government is breaking the logjam of competing and vested interests to ensure that Americans will be able to rely on a single, rigorous standard for food safety."

Secretary of Agriculture Mike Espy said, "This proposal for meaningful pesticide reform is another good example of the interagency cooperation under the Clinton Administration. It is a significant step forward as we continue our effort to make the world's safest food supply even safer. The agreement also protects the environment and public health, while maintaining the economic viability of the American farmer."

"The time has come to streamline and modernize our pesticide laws," said FDA Commissioner David A. Kessler, M.D. "The shift we have proposed to a strict health-based standard for all pesticide residues represents real food safety reform."

Under this proposal, EPA for the first time must identify--within six months--all pesticide-residue levels on foods that may exceed the safety standard. Within three years, regulatory action

must be taken against the highest risk pesticides. Within seven years, EPA must officially have reviewed all pesticide-residue levels, or tolerances, to ensure that all foods are safe from unacceptable risks from pesticides.

The legislative proposals call for setting tolerances or allowable pesticide residues at levels that ensure a "reasonable certainty of no harm to consumers of food," the same strict standard FDA applies to food additives today and the same standard recommended by the National Academy of Sciences. The proposal also calls for a seven year phase-out of all pesticides that do not meet the "no harm" standard. If the pesticide is a potential carcinogen, the residue can pose no more than a negligible risk.

Currently the negligible risk standard is interpreted to mean that the increase in risk above the background cancer risk is no greater than one in one million persons exposed over a 70 year lifetime. Because of the conservative nature of risk assessment, in reality this means the risk consumers actually face will likely be far less. Only in exceptional cases involving indispensable consumer benefits would EPA have the authority to set time-limited tolerances (up to five years) that exceed negligible risk.

The Administration called for reducing the use of high-risk pesticides, particularly through increased use of IPM techniques, which utilize a combination of agricultural practices such as crop rotation, cultivation of predator insects, biological pesticides, and other practices, together with judicious and limited chemical pesticide use. By the year 2000, the Administration's goal is that 75% of all farms will use integrated pest management (IPM) techniques that reduce pesticide use.

The Administration's proposals recognize that infants and children may receive greater exposure to pesticide residues because they consume more food for their size than adults. Other provisions call for more comprehensive surveys of food consumed by children of all ages, races and geographic areas. Under the proposals, EPA and USDA would more accurately identify the foods children eat in large quantities and to focus on child safety when setting tolerances for these foods.

Some of the other major proposals include:

-provisions for giving greater priority to safer and reduced-risk pesticides;

-a requirement to "sunset" all pesticide registrations every 15 years to ensure they either meet the public health standards or are automatically cancelled;

-a phase down and phase out of those pesticide uses which credible science indicates may pose a significant risk to the public or the environment;

-authority to suspend the immediate use of a pesticide in the face of significant potential risks without also having to simultaneously take a time-consuming cancellation action;

-incentives to the pesticide industry to support the continued registration of lower-risk pesticides for use on minor crops; and

-expedited cancellation procedures, which currently can take up to five or more years to remove a pesticide from the market.

The three agencies presented their testimony before a joint hearing of the Senate Committee on Labor and Human Resources and the House Subcommittee on Health and the Environment.

# # #

United States Environmental Protection Agency

Food and Drug Administration

United States Department of Agriculture

ADMINISTRATION PESTICIDE/FOOD SAFETY LEGISLATIVE REFORMS: EXECUTIVE SUMMARY OF TESTIMONY

Last June, the Administration announced its commitment to reducing pesticide use and promoting sustainable agriculture through the development of legislative, regulatory, and administrative initiatives. Today, we are pleased to have the opportunity to present the results of our efforts to date.

The Administration's initiatives are designed to maintain and enhance food safety for all Americans, to address recommendations of a 1993 National Academy of Sciences (NAS) report on ways to improve pesticide regulation to better assure that children are fully protected from pesticide risks, and to strengthen regulatory agencies' ability to make and enforce sound, timely, science-based decisions to protect public health and the environment.

The Administration's pesticide/food safety reform package includes changes to both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The heart of the proposal is the establishment of a strong, health-based standard that would apply to all pesticide residues in food. Existing residue tolerances would have to be reviewed and brought into conformity with the new safety standard within fixed time frames. The proposals allow for a transition period under carefully prescribed conditions that will help avoid undue dislocations in agricultural production but still ensure an absolute deadline for all tolerances to meet the new standard.

The principles that guided our work in developing legislative and regulatory proposals included:

- a firm commitment to reducing risks to people and the environment that may be associated with pesticides, and especially to providing greater assurance of protection for children, while ensuring the availability of cost-effective pest management techniques;

- recognition of the need to work with American farmers to develop and implement improved means of pest control, to reduce use of higher-risk pesticides and promote greater use of integrated pest management (IPM) techniques, including biological and cultural pest control systems and other sustainable agricultural practices;

- implementation of regulatory reforms and incentives for the development of pesticides that will eliminate or reduce risks.

Building on the recommendations of the NAS report and the input we have received from representatives of all interests concerned about pesticide use and regulation, we have developed a comprehensive set of legislative reforms we believe will allow us to make real progress in enhancing public health and environmental protection. Consistent with the approach of the National Performance Review, these changes will make government work better, and establish a more credible pesticide regulatory system that is based on sound science and is capable of acting promptly to reduce pesticide risks whenever they are identified.

The major elements of our reforms are outlined briefly below. Our formal testimony provides more detail on how these provisions would work and the benefits we expect from their implementation. In addition, the testimony gives an update on our progress in addressing the NAS report recommendations and developing pesticide use reduction strategies.

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) PROPOSALS

- **TOLERANCE SETTING**

  Tolerances for pesticide residues in all types of food would be based on a strong, health-based standard, defined as "a reasonable certainty of no harm" to consumers of the food. For carcinogens this standard represents an upper-bound risk of 1 in one million over a lifetime, calculated using conservative risk assessment methods.

  The statute would mandate use of the best available science and information in decision-making. In the absence of reliable information that could refine residue level estimates or other assumptions used in risk assessment, however, conservative or "worst case" default assumptions would be required.

  The statute would also specify criteria for the types of factors EPA should consider in assessing pesticide risks as part of the tolerance setting process, including, for example, risks to potentially sensitive subpopulations.

- **SPECIAL PROVISIONS FOR INFANTS AND CHILDREN**

  Our proposals for tolerance setting are directly responsive to the NAS recommendations that EPA consider unique aspects of children's diets and other sources of pesticide exposure. EPA would be required to issue specific findings that a tolerance is safe for infants and children.

EPA would also follow the NAS recommendations of looking at multiple exposures when establishing a tolerance and vigorously pursuing more accurate data on children's consumption habits. FDA would prioritize monitoring of residues on the foods children eat most.

- **REVIEW OF EXISTING TOLERANCES**

EPA would be required to review all existing tolerances and ensure that they meet the new standard within seven years of enactment.

Special fast track provisions would require priority review of pesticides which, based on currently available data, appear not to meet the safety standard. EPA would have to identify these pesticides within 180 days of enactment. The review of 75% of these tolerances will be complete within three years, and the review of all these tolerances will be completed no later than four years after enactment.

- **TIME-LIMITED TRANSITIONAL TOLERANCES**

In exceptional cases, EPA could grant time-limited transitional tolerances of no more than five years for a pesticide identified during the tolerance review process as not meeting the safety standard, if the loss of the pesticide would result in significant disruption in the food supply.

Under no circumstances would such time-limited tolerances be granted for pesticide risks that exceed ten times negligible risk. The total time tolerances for such pesticides could remain in effect could not exceed 10 years after enactment. The burden would be on the tolerance sponsor to make the showing needed to support a time-limited tolerance, and to report biannually to EPA on efforts to reduce risks to negligible and the continuing existence of the effects that warranted the initial extension of the tolerance.

A greater than a time-limited tolerance extended under these provisions could only be renewed if Congress enacted a statutory exemption.

Both the tolerance review and transitional, time-limited tolerance provisions are responsive to NAS recommendations that tolerance setting be health-based, and that risk assessments incorporate improved toxicology and exposure data.

IMPROVED REGULATORY COORDINATION AND NEW ENFORCEMENT TOOLS

Both FIFRA and FFDCA should explicitly recognize and require that changes made to one statute should be reconciled with complimentary action under the other statute for issues relating to pesticide use on food. Additionally, FDA should have enhanced enforcement authorities to recall and embargo violative foods as well as to levy civil penalties, and have access to certain pesticide-related records.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) PROPOSALS

- **REGISTRATION "SUNSET"**

  Pesticide registrations and tolerances must be renewed every 15 years to ensure they are in conformity with health standards. This will apply unless a new application meeting current scientific standards is received by year 12 after registration and approved by EPA.

- **PHASE-OUT/PHASE-DOWN**

  Whenever credible scientific evidence indicates that a pesticide is reasonably likely to pose a significant risk to humans or the environment, EPA could by rule-making take steps to limit the potential risk by requiring the phase-out or phase-down of the pesticide's use, for example by imposing production caps or eliminating uses. EPA would consult with USDA in establishing phase-out requirements.

- **STREAMLINING LABEL CHANGES AND ESTABLISHING A SINGLE, UNIFORM LABEL COMPLIANCE DATE ("LABEL CALL-IN")**
  Modeled on the existing "data call-in" provisions of FIFRA Section 3(c)(2)(B), this authority would establish a streamlined process for achieving relatively small changes in the conditions of registration (e.g. label changes that reduce pesticide risks but do not affect the availability of a pesticide for use on any particular site).

  An annual uniform labeling effective date would be established, and registrants would be able to make label changes in a predictable, orderly fashion.

- **INCENTIVES FOR DEVELOPMENT OF REDUCED RISK PESTICIDES**
  EPA would establish criteria for designation of reduced risk pesticides. Registration applications that appear to meet the criteria would qualify for priority review, and, if approved, would be accorded two additional years of exclusive data use, beyond the ten years now provided in FIFRA.

Also, EPA would be authorized to grant special time-limited conditional registrations for biologically-based pesticides posing low potential risks.

- **PESTICIDE RISK AND USE REDUCTION AND SUPPORT FOR INTEGRATED PEST MANAGEMENT**
  The Administration is calling for a joint EPA-USDA chaired effort to, within one year, develop commodity-specific pesticide use reduction goals.

  The statute would state a clear policy goal favoring reduced use and direct federal agencies to take a leadership role in promoting use reduction and IPM in their programs.

  The statute would authorize regional ecosystem-based reduced use pilot projects and set a goal for development of IPM programs and implementation strategies for 75% of acreage within 7 years of enactment. EPA and USDA would be mandated to work together to identify the research, education and extension activities that are most promising in terms of opportunities for reducing dependence on pesticide use, in particular targeting pesticides that raise risk concerns.

  The current prohibition on requiring IPM training as part of certification and training programs would be repealed.

  EPA would be authorized to establish criteria for "prescription use" of pesticides. Such authority could permit retention of pesticides critical to IPM and pesticide resistance management programs.

- **IMPROVED PESTICIDE DATA COLLECTION**
  Following the model of the 1990 Farm Bill provisions, which requires record keeping for restricted use pesticides, the Administration calls for record-keeping on all pesticide uses.

  EPA and HHS will continue to pursue better incident monitoring and surveillance systems.

- **PESTICIDE MINOR USES**
  Incentives for registering minor uses would include priority review and extended exclusive data use rights. In reregistration, unsupported minor uses lacking only residue chemistry data could continue until the last study for the pesticide is due, and registrants would have until that date to supply data for the minor use.

  EPA, HHS/PHS, and USDA would collaborate to identify critical public health minor uses that might otherwise be lost, and to arrange for necessary data support, with

HHS/PHS playing a role analogous to that of USDA in the IR-4 program for agricultural minor uses.

- **CANCELLATION, SUSPENSION, AND TOLERANCE REVOCATION PROCEDURES**

  Cancellation and tolerance revocation procedures would be amended to replace formal, trial-type ALJ proceedings with a notice-and-comment cancellation process. Suspensions would be decoupled from cancellation procedures, and the time-consuming and cumbersome ALJ process for challenging suspensions would be replaced by a petition procedure and prompt judicial review.

- **ENFORCEMENT AUTHORITIES**

  Improvements in enforcement authorities would include enhanced inspection, record keeping and lab audit authorities; "whistle blower" and citizen suit provisions; and significant increases in penalties for FIFRA violations, commensurate with the nature of the offense. All regulations under FIFRA would be fully enforceable.

- **PREVENTING EXPORT OF PESTICIDES BANNED BY EPA**
  Export of any pesticide to a country that has decided that it does not want to receive shipments under the terms of the international system of "Prior Informed Consent" (PIC) would be prohibited, as would export of any pesticide that has been denied registration or administratively or voluntarily canceled for all or virtually all uses in the U.S. based on health concerns or those pesticides that were voluntarily canceled in U.S. by the manufacturer for health or safety reasons. Never-registered food use pesticides could only be exported if there were a U.S. tolerance for the active ingredient and/or a method capable of detecting residues in food.

- **FEES TO SUPPORT FIFRA '88 REREGISTRATION**
  The proposal would include authority to impose a new one-time supplemental reregistration fee assessed on an active ingredient basis and an individual product reregistration fee. Annual maintenance fees as required under the current reregistration program would continue.

September 21, 1993

LRM #I-1206

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: Holly FITTER
Office of Management and Budget
Fax Number: (202) 395-5691
Analyst/Attorney's Direct Number: (202) 395-3233
Branch-Wide Line (to reach secretary): (202) 395-6194

FROM: 9-16 (Date)
Katie McGinty (Name)
DEP (Agency)
X6224 (Telephone)

SUBJECT: EPA Proposed Testimony RE: S 331, Pesticide Food Safety Act of 1993

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_X_ See proposed edits on pages pg. 6 Executive Summary pg. 33 Testimony

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

- **PREVENTING EXPORT OF PESTICIDES BANNED BY EPA**
  Export of any pesticide to a country that has decided that it does not want to receive shipments under the terms of the international system of "Prior Informed Consent" (PIC) would be prohibited, as would export of any pesticide that has been denied registration or canceled for all or virtually all uses in the U.S. based on health concerns.* Never-registered food use pesticides could only be exported if there were a U.S. tolerance for the active ingredient and/or a method capable of detecting residues in food.

- **FEES TO SUPPORT FIFRA '88 REREGISTRATION**
  The proposal would include authority to impose a new one-time supplemental reregistration fee assessed on an active ingredient basis and an individual product reregistration fee. Annual maintenance fees as required under the current reregistration program would continue.

DRAFT--9/14/93

* or those pesticides that were voluntarily cancelled in US by the manufacturer for health or safety reasons.

citizen suits under FIFRA, with prior notice to responsible regulatory authorities at the state and/or federal level.

We would also propose to expand EPA's record-keeping authorities under FIFRA with respect to commercial applicators, pesticide dealers and laboratories that conduct testing to support pesticide registrations.

Finally, we support FIFRA amendments to make enforceable under U.S. law prohibitions on the export of certain pesticides. The Administration proposes enactment of several legislative changes in this area.

First, FIFRA should prohibit the export of any pesticide to a country that has decided that it does not want to receive shipments under the terms of the international system of "Prior Informed Consent" (PIC) established under the auspices of the UN Food and Agriculture Organization and the UN Environment Programme. The PIC system is designed to cover pesticides that have been prohibited for all or nearly all uses by participating countries, based on human health or environmental risk concerns.

Second, FIFRA should prohibit export of any pesticide that has been cancelled for all or virtually all uses in the U.S. based on health concerns. Approximately 50 pesticides would fall in this category, including pesticides that have been voluntarily cancelled due to risk concerns.

Third, never-registered food use pesticides should only be allowed to be exported if there is a U.S. tolerance for the

→ or those pesticides that were voluntarily cancelled in the U.S. by the manufacturer for health or safety reasons.

WHITE HOUSE OFFICE ON ENVIRONMENTAL POLICY

TO: Pam McElwee

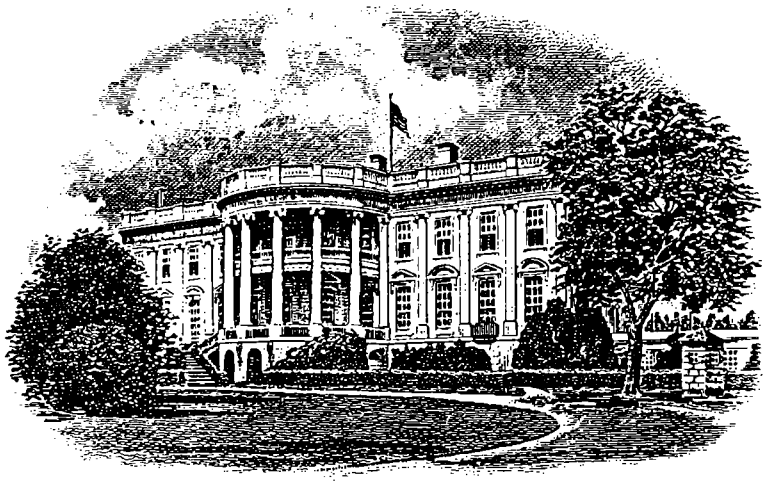
FROM: Trey Leinbach

DATE: 9-16

FAX: 913-864-5317

Number of pages including cover: 8

COMMENTS: Let me know what you think. I need comments back by 5:00 pm TODAY! Thx.



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SPECIAL

September 14, 1993

LEGISLATIVE REFERRAL MEMORANDUM

LRM #I-1206

TO: Legislative Liaison Officer -

AGRIC-CR - Hal Gross (all testimony) - (202)720-7095 - 230
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FROM: RONALD K. PETERSON (for) Ronald K. Peterson
Assistant Director for Legislative Reference

OMB CONTACT: Holly FITTER (395-3233)
Secretary's line (for simple responses): 395-6194
Mark KRAMER (395-3445)

SUBJECT: EPA Proposed Testimony RE: S 331, Pesticide Food Safety Act of 1993

DEADLINE: 5:00 PM September 16, 1993

COMMENTS: This testimony provides the Administration's recommendations for the reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
B. Clendenin
M. Weatherly
T. Hunt/M. Mitchell
B. Damus
B. Galston
H. Paster
K. McGinty

ADMINISTRATION PESTICIDE/FOOD SAFETY LEGISLATIVE REFORMS: EXECUTIVE SUMMARY OF TESTIMONY

Last June, the Administration announced its commitment to reducing pesticide use and promoting sustainable agriculture through the development of legislative, regulatory, and administrative initiatives. Today, we are pleased to have the opportunity to present the results of our efforts to date.

The Administration's initiatives are designed to maintain and enhance food safety for all Americans, to address recommendations of a recent National Academy of Sciences (NAS) report on ways to improve pesticide regulation to better assure that children are fully protected from pesticide risks, and to strengthen regulatory agencies' ability to make and enforce sound, timely, science-based decisions to protect public health and the environment.

The Administration's pesticide/food safety reform package includes changes to both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The heart of the proposal is the establishment of a negligible risk standard that would apply to all pesticide residues in food. Existing residue tolerances that may have been established on a risk/benefit basis would have to be reviewed and brought into conformity with the negligible risk standard within fixed time frames. The proposals allow for a transition period under carefully prescribed conditions that will help avoid undue dislocations in agricultural production but still ensure an absolute deadline for all tolerances to meet the new standard.

The principles that guided our work in developing legislative and regulatory proposals included:

- a firm commitment to reducing risks to people and the environment that may be associated with pesticides, and especially to providing greater assurance of protection for children, while ensuring the availability of cost-effective pest management techniques;

- recognition of the need to work with American farmers to develop and implement improved means of pest control, to reduce use of higher-risk pesticides and promote greater use of integrated pest management (IPM) techniques, including biological and cultural pest control systems and other sustainable agricultural practices;

- implementation of regulatory reforms and incentives for the development of pesticides that will eliminate or reduce risks compared to currently registered pesticides.

Building on the recommendations of the NAS report and the input we have received from representatives of all interests concerned about pesticide use and regulation, we have developed a

comprehensive set of legislative reforms we believe will allow us to make real progress in enhancing public health and environmental protection. Consistent with the approach of the National Performance Review, these changes will make government work better, and establish a more credible pesticide regulatory system that is based on sound science and is capable of acting promptly to reduce pesticide risks whenever they are identified.

The major elements of our reforms are outlined briefly below. Our formal testimony provides more detail on how these provisions would work and the benefits we expect from their implementation. In addition, the testimony gives an update on our progress in addressing the NAS report recommendations and developing pesticide use reduction strategies.

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) PROPOSALS

- **TOLERANCE SETTING**
  Tolerances for pesticide residues in all types of food would be based on a strong, health-based standard of "negligible risk," defined as "a reasonable certainty of no harm" to consumers of the food.

  The statute would mandate use of the best available science and information in decision-making. In the absence of reliable information that could refine residue level estimates or other assumptions used in risk assessment, however, protective, "worst case" default assumptions would be required.

  The statute would also specify criteria for the types of factors EPA should consider in assessing pesticide risks as part of the tolerance setting process, including, for example, risks to potentially sensitive subpopulations.

- **SPECIAL PROVISIONS FOR INFANTS AND CHILDREN**
  Our proposals for tolerance setting are directly responsive to the NAS recommendations that EPA consider unique aspects of children's diets and other sources of pesticide exposure. EPA would be required to make specific safety findings for infants and children in all tolerance decisions.

  A high-level interagency task force would be charged with focusing on the NAS' recommendations to provide a greater level of assurance of protection for children, and reporting back to Congress and the President on implementation.

- **REVIEW OF EXISTING TOLERANCES**
  EPA would be required to review all existing tolerances against the new standard and ensure that risks are brought down to negligible within seven years of enactment.

Special **fast track** provisions would require priority review of pesticides which, based on currently available data, appear to exceed negligible risk. EPA would have to identify these pesticides within 180 days of enactment. To the extent feasible, the review of these tolerances should be complete within three years, and in any event no later than four years after enactment.

- **TIME-LIMITED TRANSITIONAL TOLERANCES**
  In exceptional cases, EPA could grant time-limited transitional tolerances of no more than five years for a chemical identified during the tolerance review process as posing greater than negligible risk, **if** the pesticide provides direct health benefits to consumers or the loss of the pesticide would result in significant disruption in the food supply by substantially decreasing domestic production.

  Under no circumstances would such time-limited tolerances be granted for pesticide risks that exceed ten times negligible risk. The total time tolerances for such pesticides could remain in effect could not exceed 10 years after enactment. The burden would be on the tolerance sponsor to make the showing needed to support a time-limited tolerance, and to report biannually to EPA on efforts to reduce risks to negligible and the continuing existence of the effects that warranted the initial granting of the tolerance.

  A greater than negligible risk tolerance granted under these provisions could only be renewed if Congress enacted a statutory exemption.

  No new transitional tolerances exceeding negligible risk could be granted after enactment unless warranted on the basis of public health benefits. After the seven year tolerance review is complete, existing tolerances that are newly-identified as possibly exceeding the negligible risk standard (e.g. due to new data or changes in risk assessment assumptions) could be granted transitional tolerances of up to 5 years.

  Both the tolerance review and transitional, time-limited tolerance provisions are responsive to NAS recommendations that tolerance setting be health-based, and that risk assessments incorporate improved toxicology and exposure data.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) PROPOSALS

- **REGISTRATION "SUNSET"**
  Pesticide registrations would expire in 15 years unless a new application meeting current scientific standards is

received by year 12 and approved by EPA. In between renewal dates, EPA could also require new data or, if risk concerns warrant, take action to phase-out, cancel, or suspend the pesticide.

- **PHASE-OUT/PHASE-DOWN**
  Whenever credible scientific evidence indicates that a pesticide is reasonably likely to pose a significant risk to humans or the environment, EPA could by rule-making take steps to limit the potential risk by requiring the phase-out or phase-down of the pesticide's use, for example by imposing production caps or eliminating uses. EPA would consult with USDA in establishing phase-out requirements.

- **STREAMLINING LABEL CHANGES AND ESTABLISHING A SINGLE, UNIFORM LABEL COMPLIANCE DATE ("LABEL CALL-IN")**
  Modeled on the existing "data call-in" provisions of FIFRA Section 3(c)(2)(B), this authority would establish a streamlined process for achieving relatively small changes in the conditions of registration (e.g. label changes that reduce pesticide risks but do not affect the availability of a pesticide for use on any particular site).

  An annual uniform labeling effective date would be established, and registrants would be able to make label changes in a predictable, orderly fashion.

- **INCENTIVES FOR DEVELOPMENT OF REDUCED RISK PESTICIDES**
  EPA would establish criteria for designation of reduced risk pesticides. Registration applications that appear to meet the criteria would qualify for priority review, and, if approved, would be accorded two additional years of exclusive data use, beyond the ten years now provided in FIFRA.

  Also, EPA would be authorized to grant special time-limited conditional registrations for biologically-based pesticides posing low potential risks.

- **PESTICIDE USE REDUCTION AND SUPPORT FOR INTEGRATED PEST MANAGEMENT**
  The statute would state a clear policy goal favoring reduced use and direct federal agencies to take a leadership role in promoting use reduction and IPM in their programs.

  The statute would authorize regional ecosystem-based reduced use pilot projects and set a goal for development of IPM programs and implementation strategies for 75% of acreage within 7 years of enactment. EPA and USDA would be mandated to work together to identify the research, education and extension activities that are most promising in terms of

opportunities for reducing dependence on pesticide use, in particular targeting pesticides that raise risk concerns.

The current prohibition on requiring IPM training as part of certification and training programs would be repealed.

EPA would be authorized to establish criteria for "prescription use" of pesticides. Such authority could permit retention of pesticides critical to IPM and pest resistance management programs.

- **IMPROVED PESTICIDE DATA COLLECTION**
  Following the model of the 1990 Farm Bill provisions, which require record keeping for restricted use pesticides, FIFRA would require USDA to establish record keeping requirements for all pesticide use.

  EPA and HHS are also pursuing better incident monitoring and surveillance systems.

- **PESTICIDE MINOR USES**
  Incentives for registering minor uses would include priority review and extended exclusive data use rights. In reregistration, unsupported minor uses lacking only residue chemistry data could continue until the last study for the pesticide is due, and registrants would have until that date to supply data for the minor use.

  EPA and HHS/PHS would collaborate to identify critical public health minor uses that might otherwise be lost, and to arrange for necessary data support, with HHS/PHS playing a role analogous to that of USDA in the IR-4 program for agricultural minor uses.

- **CANCELLATION AND SUSPENSION PROCEDURES**
  Cancellation procedures would be amended to replace formal, trial-type ALJ proceedings with a notice-and-comment cancellation process. Suspensions would be decoupled from cancellation procedures, and the time-consuming and cumbersome ALJ process for challenging suspensions would be replaced by a petition procedure and prompt judicial review.

- **ENFORCEMENT AUTHORITIES**
  Improvements in enforcement authorities would include enhanced inspection, record keeping and lab audit authorities; "whistle blower" and citizen suit provisions; and significant increases in penalties for FIFRA violations, commensurate with the nature of the offense. All regulations under FIFRA would be fully enforceable.

DRAFT--9/14/93

TESTIMONY OF CAROL M. BROWNER, ADMINISTRATOR

U.S. ENVIRONMENTAL PROTECTION AGENCY

AND

RICHARD ROMMINGER, DEPUTY SECRETARY

U.S. DEPARTMENT OF AGRICULTURE

AND

DAVID A. KESSLER, COMMISSIONER

FOOD AND DRUG ADMINISTRATION

BEFORE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

AND

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 21, 1993

I. INTRODUCTION

Good afternoon Senator Kennedy, Congressman Waxman, Senate Committee and House Subcommittee members. We are pleased to appear before you today to present the Administration's views on important issues relating to food safety, pesticide use, and pesticide regulation.

In late June, the Administration announced its commitment to reducing the use of pesticides and promoting sustainable agriculture in this country. We stated our intention to work to reduce risks associated with pesticides for all Americans, and especially, to ensure appropriate protection for children. We also pledged to intensify our efforts to facilitate the availability of alternative and effective pest management tools.

Since that announcement, the Environmental Protection Agency (EPA), U.S. Department of Agriculture (USDA), and Food and Drug Administration (FDA) have been meeting together and with a number of interested parties, including farmers, environmentalists, consumer groups, state agencies, industry, and others to discuss the measures that need to be taken to achieve the goals we set forth in June. We have developed a three part program involving both legislative and administrative initiatives.

First, we want to strengthen existing legislative authorities governing pesticides. Second, we pledge to upgrade the science related to pesticides and food safety, especially as it applies to children. We are addressing the recommendations put forth in the National Academy of Sciences (NAS) report, "Pesticides in the Diets of Infants and Children." Third, we are

reorienting our efforts to focus on preventing problems at the source, through appropriate reduction of pesticide use. History teaches us that in all aspects of life, prevention saves time, energy, and resources. By stressing prevention, we not only safeguard today's children, we look beyond to protect the health and environment of future generations.

II. PESTICIDE/FOOD SAFETY LEGISLATIVE REFORMS

Soon after the inauguration, the Administration began focusing on pesticide matters. Earlier this year, key members of Congress turned to the Administration for leadership in resolving the very complex administrative and legislative issues posed by current agricultural, public health, and environmental laws and policies. Under the auspices of the White House Domestic Policy Council, representatives of EPA, USDA, the Department of Health and Human Services (HHS) and its FDA have worked closely together over the last seven months to develop a comprehensive set of reforms that can provide a new direction and depolarize much of the debate about pesticide/food safety legislation that has too long prevented enactment of meaningful legislative change in this area. The progress we have made is significant, and we are pleased to have the opportunity to present our views to you today.

It is important to acknowledge at the outset that the issues we will be discussing today, and that have been debated in the halls of Congress and elsewhere for several years, are

exceedingly difficult and complex. Many stake holders are involved: individual citizens concerned about the potential effects of pesticide use on their health and the environment; the public health, environmental and consumer communities; the agricultural production, pesticide manufacture, and food processing and distribution industries; scientists; and officials at all levels of government who are charged with developing and implementing our pesticide and food safety laws. The scientific and technical considerations are complicated and evolving, and require dealing with uncertainties. This is why it has been so difficult in the past to achieve broad consensus on the reforms that will best reflect sound science and our common goals of environmental and public health protection within a growing economy.

The proposals we are presenting today would change how pesticides are used and regulated in this country, and offer the promise of far-reaching public health and environmental benefits. They will complement and help ensure the success of our ongoing administrative initiatives to reduce pesticide use, encourage the development and use of safer alternatives, respond to the recommendations of the NAS report on how to improve our assurance that children are protected from potential pesticide risks, and streamline regulatory programs to improve our ability to act promptly and effectively.

Our proposals require amendment of both major pesticide regulatory laws: the Federal Food, Drug, and Cosmetic Act

(FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Only by reforming both statutes can we achieve our food safety, health and environmental protection goals and establish a consistent framework for timely regulatory decision-making.

Clearly, we will need to work closely with all four Congressional committees who have jurisdiction over these statutes in order to ensure passage of sound legislation. Interagency deliberations are ongoing, and we welcome the opportunity to work with you, our sister regulatory agencies in the states, and others in the public health, environmental, consumer, agricultural, and food marketing and processing communities to refine our proposals in the coming weeks and months.

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) PROPOSALS

The Administration's key proposals for amendments to the Federal Food, Drug, and Cosmetic Act are central to our goal of maintaining and enhancing the safety of our food supply from pesticide risks, with particular emphasis on ensuring that our children are protected. We will achieve these objectives by (1) establishing a strong, protective and science-based safety standard for pesticide residues in all types of food, (2) providing for a timely review of all existing tolerances to ensure they meet that standard, and (3) strengthening the

authorities of our food safety regulatory agencies to carry out their responsibilities under the law.

TOLERANCE SETTING

The standards for tolerance setting under FFDCA need to be reformed and updated in order to allow EPA to use the best, state-of-the-art science in establishing and reassessing tolerances for pesticide residues in food that will fully protect public health. This can best be achieved by amending the law to require EPA to set tolerances based on a strong, health-based standard of "negligible risk." We believe the safety standard generally applied to food additives is appropriate: pesticide residue tolerances should be set at levels that ensure "a reasonable certainty of no harm" to consumers of the food.

The new standard should replace the conflicting standards that now apply to pesticides found in raw and processed food, including the Delaney clause which governs residues of pesticides that concentrate in processed food or are added in food processing. The Delaney standard may have been appropriate when first enacted over 30 years ago, when our abilities to quantify potential risks and detect minute residue levels in food were far less sophisticated than they are now. The consensus among authorities today, however, including the National Academy of Sciences and many other food safety experts, is that Delaney should be replaced. For example, in its 1987 report on pesticide regulation, the NAS recommended "a negligible risk standard for

carcinogens in food, applied consistently to all pesticides in all forms of food" as an effective means to reduce risk. Legislation introduced in recent Congresses, including the two bills pending before your committees this session, further demonstrate the consensus on the need to replace this out-dated provision with a science-based negligible risk standard.

We believe the statute should enable EPA to change procedures as science advances. Therefore, we propose a narrative negligible risk standard rather than a numerical one. To prescribe current standards in statute may inhibit further scientific progress. We do support, however, clear report language and legislative history indicating how the negligible risk standard is intended to be interpreted and implemented, given the current state of the science. For potential carcinogens for which mainstream scientists believe it is appropriate to estimate a probability of risk, we believe the reasonable certainty of no harm/negligible risk standard means an upper bound risk in the range of one in one million (10^{-6}) over a lifetime or lower. In evaluating threshold effects, defined as effects that are not expected to occur below certain exposure levels, the agency would generally use the equivalent of a 100-fold uncertainty or "safety" factor, applied to the No Observed Effect Level (NOEL) derived from animal studies, unless the available data supported using a different factor for a particular chemical or until improved methods of quantifying threshold risks are developed. Any future modifications in

EPA's implementation of the negligible risk standard would have to be based on sound science and provide assurance of the same, or greater, level of protection as these current approaches.

In order to ensure that future EPA decisions and risk assessments will reflect the best of evolving science, the statute itself should not prescribe the risk assessment assumptions and methodology that the agency should use in evaluating whether a pesticide meets the negligible risk standard. Rather, the agency should have a mandate to use the best available information in its decision-making. In the absence of reliable information that could refine residue level estimates or other assumptions used in risk assessment, the law should require EPA to make "worst case" default assumptions: e.g., that residues are present at tolerance levels and 100% of the crop is treated. Thus, in the absence of adequate data and information, the agency would make protective assumptions that would tend to overstate potential risks.

The statute should also specify criteria for the types of considerations EPA should take into account in assessing pesticide risks as part of the tolerance setting process. For example, EPA should consider other potential routes of exposure to the same or related chemicals, through drinking water or non-dietary exposures, risks of other chemicals causing the same effect(s) and risk to potentially sensitive subpopulations. Where appropriate, EPA should also consider food distribution patterns in assessing potential exposure.

SPECIAL PROVISIONS FOR INFANTS AND CHILDREN

The Administration is absolutely committed to maintaining and enhancing food safety for infants and children. We would support legislation requiring EPA, as a part of any tolerance evaluation, to take into account the potential risks to infants and children, who eat relatively larger quantities of food for their size and therefore may have higher exposures on a body weight basis.

Our proposals for tolerance setting are directly responsive to recommendations in the NAS report on "Pesticides in the Diets of Infants and Children" that EPA consider unique aspects of children's diets and nondietary sources of pesticide exposure. They would also ensure implementation of NAS recommendations that tolerances be based on health considerations and that risk assessments incorporate use of improved toxicology and exposure data, consistent with evolving science. By requiring protective default assumptions and consideration of multiple exposures, as well as mandating the use of the best available data and information, the statutory scheme will work to provide the necessary margin of safety for our children.

To further ensure that children receive appropriate attention, we would support provisions requiring EPA to make specific safety findings for infants and children whenever the agency sets or reviews tolerances. While we do not believe implementation of this provision would need to be delayed pending the development of new data, we support additional funding for

USDA to collect improved food consumption data to support better identification of foods consumed by children.

As you know, we are also working administratively to address the recommendations of the NAS report. A detailed description of our current progress is provided later in this testimony. We believe it would be appropriate to include in legislation a mandate for a high-level interagency task force charged with focusing on the NAS recommendations and reporting back to Congress and the President on the progress of implementation and the improvements we will be making in order to provide a greater level of assurance of protection for children.

Finally, we are committed to improving the openness and accessibility of our regulatory decision-making. The bases for all our tolerance decisions should be clearly documented and open to public scrutiny. If EPA, on the basis of sound information and data, refines the assumptions made in risk assessments to more closely approximate actual exposure, rather than assuming that 100% of the food contains residues at the tolerance level, that should be clearly laid out for public notice and comment as part of the tolerance decision. We would also support provisions authorizing EPA to reexamine such tolerances periodically, to ensure that the refined assumptions remain valid, and providing authority for the agency to require tolerance sponsors to generate additional data when needed as part of the re-examination or to assure EPA that the major factors impacting exposure (and therefore risk) are still valid.

TIMELY REVIEW AND ACTION ON EXISTING TOLERANCES TO ENSURE COMPLIANCE WITH THE NEGLIGIBLE RISK STANDARD

FFDCA reform legislation should provide for the review of all currently established tolerances and elimination of tolerances that do not meet the new statutory standard within a fixed time frame. The Administration proposes that all tolerances be reviewed within seven years after enactment of a legislative reform package, and that pesticide tolerances that now appear to exceed negligible risk be subject to special "fast track" review procedures.

Under our proposal, EPA would be required to complete review of all existing tolerances to ensure that they meet the negligible risk standard within seven years of enactment. The burden is on the tolerance sponsor to show that the statutory standard is met. If the agency determines that this burden has not been met, the tolerances would expire and complementary FIFRA cancellations would be triggered without further analysis or proceedings. In some cases, a "pipeline" period may be permitted for legally treated food to clear the channels of commerce or for unavoidably persistent residues to dissipate. EPA's determinations would be judicially reviewable if challenged within 60 days, but the revocations and cancellations would take effect unless a court orders otherwise.

If EPA failed to complete the tolerance reviews within the seven-year time frame, the Administrator would have the authority to extend tolerances for up to two additional years to allow

completion of review and a determination by the agency whether the standards are met. This extension could only be granted if the Administrator makes a finding that tolerance sponsors have fulfilled their commitment to supply the information required for agency review in a timely fashion.

In summary, this approach ensures re-evaluation of all tolerances within seven years. For pesticides subject to reregistration under amendments to FIFRA enacted in 1988 (FIFRA '88), we expect tolerance review will track reregistration schedules. For newer tolerances established since 1984, EPA will have to develop a schedule to complete review within the seven-year period.

SPECIAL 'FAST TRACK' REVIEW. Special expedited review provisions would apply to pesticides which, based on information available at the time of enactment, appear to exceed negligible risk. Within 180 days of enactment, EPA would identify such potentially higher risk pesticides for priority attention. To the extent feasible, review of these tolerances should be complete within three years, and in any event no later than four years after enactment.

Of course, independent of these new tolerance review and "fast track" provisions and the time-limited transitional tolerance proposal outlined below, EPA would be able to act at any time to revoke or modify tolerances using standard procedures or to parallel action taken to suspend or cancel registrations under FIFRA.

TIME-LIMITED TRANSITIONAL TOLERANCES

Under the reforms we propose, EPA would generally only establish tolerances that pose no more than negligible risk. So long as the negligible risk standard is met, no other factors would be considered in establishing (or reassessing) tolerances.

In exceptional cases, however, we would propose to give EPA the authority to grant non-renewable, time-limited tolerances of no more than five years for a chemical that is identified during the tolerance review period as posing greater than negligible risk, but only if the pesticide provides direct health benefits to consumers or the loss of the pesticide would result in significant disruption in the food supply by substantially decreasing domestic production.

Under no circumstances would such time-limited tolerances be granted for pesticide risks that exceed ten times negligible risk. The total time tolerances for such pesticides could remain in effect could not exceed 10 years after enactment. The burden would be on the tolerance sponsor to make the showing needed to support a time-limited tolerance, and to report biannually to EPA on efforts to reduce risks to a negligible level and the continuing existence of the circumstances that warranted the initial granting of the tolerance.

In the future, after the seven-year tolerance review is complete, EPA may identify additional pesticide tolerances as possibly exceeding negligible risk, either because new data raise risk concerns or because of a change in EPA policy (for

example, the agency could revise its risk assessment assumptions or decide additional uncertainty/safety factors are warranted in some circumstances.) In these cases, non-renewable transitional tolerances could be granted for up to five years. If the risks are not brought down to negligible within the period of the transitional tolerances, they would be revoked.

After enactment, new tolerances would have to meet the negligible risk standard, and transitional tolerances could not be granted except when warranted by public health benefits, which could justify nonrenewable tolerances of up to five years.

If at any time during the period of any time-limited or transitional tolerances the agency concludes that circumstances no longer justify exceeding the negligible risk standard (e.g., if a safer alternative pest control method were developed for some or all uses), EPA would revoke the tolerances before the expiration date. FIFRA product registrations would be automatically cancelled upon the expiration or revocation of the corresponding tolerances.

Tolerances posing greater than negligible risk under any of the transitional tolerance provisions could only be renewed if Congress enacted a statutory exemption.

Both the tolerance review and transitional, time-limited tolerance provisions are responsive to NAS recommendations that tolerances be based on health considerations, and that risk assessments incorporate use of improved toxicology and exposure data. They will ensure that all tolerances meet the new

statutory standard within fixed time-frames, unless Congress intervenes.

PROVIDING REGULATORY AGENCIES WITH IMPROVED TOOLS

In addition to strong new standards for tolerance setting and the tolerance review program, we are proposing additional authorities to improve our agencies' ability to carry out their regulatory responsibilities. For example, we would support a provision in FFDCA analogous to the provision in Section 3(c)(2)(B) of FIFRA that would authorize EPA to require new studies whenever needed to support an existing tolerance, including studies on improved testing procedures and actual residue monitoring data when appropriate. This concept is included in the bills sponsored by Chairmen Kennedy and Waxman. While in most instances EPA can use the "data call-in" authority of FIFRA to require such information, a parallel FFDCA provision could be useful in cases where a pesticide has U.S. tolerances under FFDCA but no U.S. registration under FIFRA.

The interagency group is continuing to review additional proposals to enhance the regulatory and enforcement tools available to EPA and FDA under FFDCA. We look forward to working with Congress in these areas.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) PROPOSALS

The focus of FFDCA reform is on food safety and potential dietary risks. Our proposals for reforming FIFRA would complement FFDCA initiatives and expand on them to enhance our ability to improve pesticide regulation and use across-the-board. The two sets of proposals form a balanced package and in our view are inextricably linked. We must have a consistent, comprehensive scheme for addressing all pesticide risks.

The major goals of our FIFRA reforms are to strengthen our efforts to reduce pesticide use, better enable us to identify and act to reduce or eliminate potential pesticide risks to health or the environment, make development of safer alternatives a clear priority, and provide a broader range of regulatory and enforcement authorities to improve compliance with pesticide regulations. The Administration's proposals would not only improve food safety, they would also enhance our ability to deal with farm worker risks, groundwater contamination, hazards to endangered species, and exposures of children and others to pesticides used for lawn care or residential pest control, or that may in any way affect our daily lives and our environment.

REGISTRATION "SUNSET"

Our policy goal in proposing a "sunset" for pesticide registrations is to ensure that all pesticides are reviewed periodically and are taken off the market if the data supporting their continued registration do not meet up-to-date scientific standards for safety testing.

Currently, pesticide registrations generally have no fixed expiration or renewal dates. Even the massive reregistration program EPA is currently implementing under FIFRA '88, covering all pesticides first registered before November 1984, does not involve any automatic "sunset" or sanction against pesticides that are found ineligible for reregistration. We propose to amend FIFRA to provide for a sunset for all pesticide registrations. Future registrations would expire in 15 years unless a new application meeting the then-current scientific standards is received and approved by EPA.

For existing pesticide registrations subject to FIFRA '88, the 15-year period would begin on the date EPA issues a reregistration eligibility decision, or "RED"; for new pesticides, it would generally begin on the date of initial registration. Applications for renewed registration would be due to EPA in the twelfth year of the 15-year period, to allow time for agency review of the new data submitted.

In order to maximize efficiency, we are considering setting sunset dates on an active ingredient basis. The sunset date for an active ingredient would apply to all products containing that

active ingredient. As a practical matter, this would mean that individual product registrations could have varying terms. For example, if a new producer registers a product containing active ingredient A in 2010, and active ingredient A was initially registered in 2000, the new product's registration would only be good through the 2015 expiration date for the active ingredient. It could be renewed only if an application for renewed registration of the active ingredient were submitted by 2012 and approved by EPA before the expiration date.

This approach will place the burden on registrants to identify and supply all the data needed to keep their registrations up to date with current EPA standards. If they do not submit a new application by year 12, or if the application is deficient, the registrations will simply expire in year 15, without additional time for data development or the need for EPA to initiate cancellation proceedings. Like the FIFRA '88 reregistration program, EPA will need authority to charge fees to help cover the costs of reviewing renewal applications.

Like our proposal for tolerance review, if registrants submit complete, timely applications but EPA does not complete its review and issue a registration renewal decision by year 15, the agency would have the authority to extend the registration for an additional two years, contingent on a finding that the registrant had submitted a complete and technically adequate application on time. Also, at any time before the sunset date,

EPA could initiate action to cancel or suspend the registration, or to require additional data under FIFRA Section 3(c)(2)(B).

PHASE-OUT/PHASE-DOWN

Our phase-out/phase-down proposal would give EPA an important new regulatory tool to begin to reduce potential pesticide risks in the face of uncertainty when new questions arise about safety of registered products. Whenever credible scientific evidence indicates that a pesticide is reasonably likely to pose a significant risk to humans or the environment, EPA could, by rule-making, take steps to limit the potential risk by requiring the phase-out or phase-down of the pesticide's use, for example by imposing declining production caps or elimination of uses. EPA would consult with USDA in establishing phase-out strategies to avoid unnecessary dislocations in agricultural production.

The purpose of this authority is to begin to reduce exposure and potential risks while efforts to resolve the scientific uncertainty proceed. Under current FIFRA, full pesticide production and use often continue for years while data are generated to resolve scientific questions, and the public bears the potential risk.

The phase-out could be complete over time (e.g., production caps down to zero production by year 5 of a five year phase-out rule), or less than complete. If, during the phase-out process, the risk concerns are resolved, phase-out controls would be

removed. Alternatively, at any point during the phase-out, if the data support a cancellation or suspension finding, EPA could invoke those procedures.

Phase-out authority is an intermediate sanction that can provide time for gradual readjustment of pesticide users and for the development of alternatives, easing the transition for users as compared to total cancellation. It allows EPA to act to reduce potential risks while scientific uncertainties are being resolved. We also believe it would increase incentives for prompt data development and voluntary interim risk reduction measures early in the process, once new perceptions of risk were identified.

IMPROVING PESTICIDE LABELS, STREAMLINING LABEL CHANGES, AND ESTABLISHING A SINGLE, UNIFORM LABEL COMPLIANCE DATE

Pesticide labeling plays an important role in ensuring food safety, public health and environmental protection. The label specifies application rates, directions for use, including special steps required for applicator or environmental safety. Currently, EPA lacks a streamlined mechanism to require minor labeling, packaging, or formulation changes and may have to resort to cancellation procedures. EPA has also often been criticized for a lack of uniformity in pesticide labeling. Our proposal would streamline procedures, improve consistency and establish a single annual compliance date for most required changes.

Full cancellation procedures are a wasteful and inappropriate way of achieving relatively small changes in the conditions of registration (i.e., label changes that reduce pesticide risks but do not affect the availability of a pesticide for use on any particular type of crop or site). We expect many such changes to flow from FIFRA '88 reregistration decisions, and registrants may not always agree to make the changes voluntarily. A streamlined mechanism for implementing label changes would help ensure that the benefits of reregistration are realized without undue delay. Examples of the types of changes that could be made through the streamlined process include requirements for protective clothing and equipment, limitations on applications to protect endangered species or groundwater, increases in pre-harvest or worker re-entry intervals, and additional warning statements. Changes that would essentially eliminate the use of the pesticide on any use site could not be implemented through the new process, but would remain subject to cancellation procedures.

Coupled with the streamlined process would be the establishment of a single, uniform effective date each year for all EPA-required labeling changes, except in instances where the agency believes the change is too urgent to delay. This will give registrants ample notice and time to arrange for new labels to be printed in an orderly, predictable fashion.

The process we envision for this streamlined "label call-in" provision would be modeled on EPA's existing data call-in

authority in Section 3(c)(2)(B) of FIFRA. Once EPA has determined that a change is necessary, the agency would notify affected registrants of the new requirement and explain the basis for the agency's determination. Registrants would have 60 days to object to the requirement. The basis for objection could be the registrant's contention that the change essentially eliminates an entire use site and thus requires full cancellation procedures. Alternatively, the registrant could present data and information demonstrating that the change is not necessary or appropriate for the particular product or that another change would be equally or more effective in addressing EPA's concerns.

EPA would then have 90 days to respond to the registrant's submission and state its reasons for continuing, modifying or withdrawing the proposed requirement in light of the arguments made by the registrant. EPA's decision would be judicially reviewable if challenged within 60 days. The basis for review would be the record of written exchanges between the agency and the registrant.

Unless ordered otherwise by a court (or EPA determines that urgency requires more expeditious action to address significant risk concerns), changes will take effect on the next applicable uniform effective date. (At present, we are considering setting effective dates that would provide no less than 12 months notice before the change would be required in the normal course of events.) Failure to make changes would result in suspension, and products without updated labels that enter commerce after the

relevant effective date would be subject to seizure or mandatory recall, and other appropriate enforcement action.

Following the data call-in authority model, the only grounds for challenging enforcement action would be a factual dispute as to whether the required change was made. We would expect judicial review of EPA's final decision to be completed and the issue resolved in time for registrants to meet the uniform compliance effective date.

INCENTIVES FOR DEVELOPMENT OF REDUCED RISK PESTICIDES

The Administration is committed to reducing pesticide risks and encouraging the development of safer alternative means of pest control, including nonchemical control alternatives. A legislative reform package should include provisions to give greater priority to these efforts in both EPA and USDA programs. Just as we need to take expeditious action to remove from the market products that pose unacceptable risks, we must also speed the development and approval of safer substitutes so that pesticide users will have access to the pest control alternatives they need.

Our proposal would direct EPA to establish criteria for designation of reduced risk pesticides. Registration applications that appear to meet the criteria will qualify for priority review, as described further below. Once approved, pesticides meeting the criteria will be accorded two additional years of exclusive data use, beyond the ten years provided in

current FIFRA. EPA would also be authorized to grant time-limited conditional registrations for biologically-based pesticides, if, before a full data set is developed, the agency determines that the pesticide is unlikely to pose a risk of unreasonable adverse effects on health or the environment during the period required for full data development and review.

EPA's registration program review priorities would be set as follows:

(1) FIFRA Section 18 emergency exemption applications

(2) Pesticides that reduce risk compared to currently registered alternatives (e.g., by replacing a pesticide subject to phase-out or cancellation proceedings or that has been identified as posing greater than negligible dietary risk)

(3) Pesticides that meet EPA criteria for designation as "reduced risk"

(4) Minor use registration applications

(5) Other applications

PESTICIDE USE REDUCTION AND SUPPORT FOR INTEGRATED PEST MANAGEMENT

Promoting pesticide use reduction through increased use of Integrated Pest Management (IPM) techniques and expanding sustainable agriculture programs is another goal of our legislative proposals, and of the initiatives we are already pursuing administratively. These initiatives are firmly grounded

in an environmental ethic of pollution prevention, a keystone of Administration policy in all sectors, including agriculture.

Strengthening USDA program mandates to develop, demonstrate and disseminate alternative pest control practices, and eliminating impediments to IPM under FIFRA, should be aimed at effecting changes in agricultural production methods that reduce pesticide use and risk.

The statute should direct federal agencies to take a leadership role and to adopt in their own pest management activities the same risk reduction and IPM approaches that private interests are being encouraged to adopt. EPA and USDA should also be directed to institute a process for coordinating environmental risk reduction efforts with research efforts, through identification of pesticides that raise risk concerns and for which development of safer alternative means of pest control should be high priority for USDA research programs.

The statute should set a goal for USDA, in consultation with EPA, to develop IPM strategies that would cover a certain percentage of total crop acreage by a fixed date; for example, requiring the development of IPM programs and implementation strategies for 75% of acreage within 7 years of enactment. A provision authorizing the establishment of several pilot ecosystem-based reduced use programs, tailored to specific regions and involving all stakeholders (growers, homeowners, government officials, industry and others) could facilitate such efforts as well.

We also support the use of market-based incentives to help achieve environmental progress, and we will explore additional options to bring these incentives to bear as part of our use reduction initiatives.

Two other legislative changes would further our use reduction initiatives. First, FIFRA's current prohibition on requiring IPM training as part of certification and training programs should be repealed. Second, to ensure that adequate tools are available to carry out IPM programs, some pesticides should remain available for use under selective and controlled circumstances. Thus, EPA should have the authority to establish criteria for "prescription use" of pesticides. Such authority could permit retention of pesticides critical to IPM and resistance management programs or otherwise to reduce pesticide risks, and could be modeled on the state management plan approach EPA is currently implementing for groundwater protection. Under this approach, EPA would limit registration of certain pesticides to states which have developed appropriate management plans aimed at ensuring that they are only used in appropriate circumstances, upon "prescription" of qualified pest control advisors.

IMPROVED PESTICIDE USE DATA COLLECTION

Sound pesticide regulation depends on high quality data and information to support decision-making. The changes in the regulatory system we are proposing will create greater incentives for the timely submission of data from registrants. By the same

token, we must also ensure that information collected and used by government agencies is current, complete and reliable.

We propose the following measures to help ensure that data collected and generated by the federal government is comprehensive and valid for use in making decisions about pesticides and their impacts.

- In keeping with the recommendations of the NAS, we plan to enlarge and improve the data base on foods consumed by infants and children. We look forward to working with Congress to find the funding to increase USDA's survey efforts in compiling consumption data, especially for children. This information will help us to fulfill our objective of increasing our assurance that children are protected from pesticide risks.
- The availability of accurate pesticide use information can help refine "default" assumptions and enable EPA to make more realistic exposure estimates in setting tolerances. USDA proposes to expand the scope and detail of its pesticide use surveys to include more crops and more states and, in addition, to conduct a national baseline survey of all pesticide use on a periodic basis. Given the importance of reliable information in making percent-of-crop-treated assessments, we also propose to expand current record-keeping requirements to include all pesticides used in agricultural production. While protecting confidentiality, following the model of the 1990 Farm Bill, this new record-

keeping authority will help ensure the reliability of information used in decision-making. It can also be important in diagnosing and following up on problems and developing targeted risk mitigation strategies for vulnerable areas.

In addition, we want to enlist the support of health professionals and others in identifying risks to health and the environment, particularly with respect to worker exposures. The Administration expressed its commitment to better incident monitoring earlier this year, and EPA has already undertaken efforts to strengthen programs in this area. We want to explore additional avenues for making our systems more useful and effective.

The Administration is also looking into the role of HHS research and surveillance programs related to the health effects of pesticides on farm workers. EPA and HHS need to work closely together to identify and collaborate on the highest priority research needs. Current HHS surveillance activities are focused on the collection, analysis and field investigation of reports of pesticide-related illnesses and injuries. HHS is working with three states testing various approaches, including physician, laboratory, and migrant clinic reporting. Better surveillance data, follow-up, and analysis should help identify pesticides posing the greatest risks to workers. This kind of information is useful in targeting pesticides for further review. It could help guide risk reduction efforts, and be directly relevant to

regulatory decisions, for example, with respect to evaluating application rates and methods, the adequacy of personal protective equipment, and worker re-entry intervals.

PESTICIDE MINOR USES

Generally, pesticide minor uses are considered to be those agricultural or public health uses for which anticipated sales revenues do not justify the expense of registering or reregistering a pesticide product.

The Administration supports the creation of incentives for registration of new pesticides for minor uses by giving applications that include three or more minor uses priority for review and extending exclusive data use rights for two additional years under FIFRA.

Existing minor uses are also at risk for lack of support in reregistration. The best solution to this problem is to ensure that the data needed for reregistration are developed, so that EPA can make timely decisions on these uses as well as on major uses on the basis of sound science and an adequate data base. For this reason, the Administration supports full funding of USDA's cooperative IR-4 program, which has undertaken support of many residue field trial studies needed to support minor agricultural uses. In addition, we would support legislation to give minor uses the maximum time for development of residue chemistry data required under the FIFRA '88 reregistration program (until the last study due date for the chemical) and

allow full time for data development when a minor use waiver request is denied by EPA.

Even with these proposals, some minor uses may be lost. Therefore, we would support legislative changes designed to ease growers' transition to alternatives, by allowing minor crop uses to continue until the due date of the final study required in the reregistration process. This extension would only be permitted if no risk concerns have been raised, other uses of the pesticide are being supported, and only residue chemistry data related to the minor use are lacking support.

Finally, we recognize that some public health uses of pesticides may lack adequate economic incentives for registration and reregistration. We support legislation providing for the Department of Health and Human Services/Public Health Service and EPA to collaborate in identifying critical public health minor uses that might otherwise be lost, and to arrange for necessary data support, with HHS/PHS playing a role analogous to that of USDA in the IR-4 program for agricultural minor uses.

CANCELLATION AND SUSPENSION PROCEDURES

Cancellation procedures under FIFRA should be improved through the adoption of a notice-and-comment type cancellation process, to replace adjudicatory hearings before an Administrative Law Judge (ALJ). Final cancellation orders could be challenged in court, but the pesticide would be off the market unless the court overturned the cancellation.

Trial-type formal ALJ procedures as required under existing law are not the best way to resolve scientific issues. They are cumbersome and extremely time and resource-intensive for all parties. This change, combined with the other regulatory tools outlined above, will enable EPA to implement the benefits of reregistration review more effectively and expeditiously. In addition, a notice and comment procedure will be more open to public participation and will be more accessible to all interested groups, such as agricultural producers who may have an interest in the issue but not be prepared to participate in a formal hearing.

While we are not advocating a change in the standards for suspension under FIFRA, we would propose that EPA's authority to issue suspensions in cases of "imminent hazard" be decoupled from cancellation procedures. Under current law, suspension orders must be issued at the same time as, or be preceded by, a proposed cancellation. We believe EPA should be able to issue the suspension in the absence of a proposed cancellation, provided that the cancellation proposal is issued within six months of the suspension. Failure to issue the proposed cancellation within the six-month period would result in automatic termination of the suspension.

We would also replace the time-consuming and cumbersome ALJ process with a petition procedure for challenging suspensions, with prompt judicial review. Petitions could be filed within 30 days by anyone who would be adversely affected by the suspension,

and EPA would have to respond within 120 days. If EPA failed to respond within that time period, the suspension would be invalidated automatically. Any petitioner who is dissatisfied with EPA's response could seek judicial review. Alternatively, adversely affected persons could go directly to court for review of the suspension within 10 days, bypassing the petition procedure. We believe these expedited procedures are appropriate when EPA has determined that an imminent hazard exists.

ENFORCEMENT AUTHORITIES AND PREVENTING THE EXPORT OF PESTICIDES BANNED BY EPA

Any legislative reform package must include major improvements in enforcement authorities and a strengthened penalty structure under FIFRA. Among the key provisions should be improved inspection and lab audit authorities and significant increases in penalties for FIFRA violations, commensurate with the nature of the offense. All regulations promulgated under FIFRA should be fully enforceable. Farmers or private applicators should in most cases still receive warning letters for first violations, unless there is a knowing violation.

The Administration supports "whistle blower" provisions to help ensure that employees who report potential violations do not suffer recriminations from their employers. In addition, compliance with our pesticide laws and regulations would be enhanced by inclusion of a carefully-crafted provision for

active ingredient and/or if there is a method determined by EPA to be capable of detecting residues in food.

FEES TO SUPPORT FIFRA '88 REREGISTRATION

Timely completion of EPA's FIFRA '88 reregistration review program is a critical component of all our efforts to make certain that pesticide risks are fully assessed and appropriate regulatory action taken. It is now clear that additional resources will be required for this program. An immediate $20 million shortfall has been projected through the end of 1997.

To meet these program needs, the Administration supports enactment of a one-time supplemental reregistration fee assessed on an active ingredient basis, calculated on average market share over the three year period of FY 1990 - FY 1992, an individual product reregistration fee, and continuation of annual maintenance fees.

Provision of these fees will enable EPA to reduce its dependence upon outside contractors for science data reviews, to maintain in-house expertise during the critical decision-making years of the reregistration program, and to respond effectively to the new requirements of this legislation.

NATIONAL PESTICIDE ADVISORY COMMITTEE

The Administration also supports the creation in statute of a National Pesticide Advisory Committee. This should be a broadly representative committee comprised of 15 members serving

three year staggered terms. The Committee should meet at least twice a year to review progress in carrying out our pesticide laws and policies.

III. NAS CHILDREN'S STUDY FOLLOW-UP INITIATIVE

We would now like to turn to a discussion of the administrative initiatives that are underway to address the recommendations of the recent NAS report, "Pesticides in the Diets of Infants and Children."

The NAS report recommended a number of changes in the regulation of food-use pesticides to provide a greater level of assurance that our children are protected from pesticide risks. Commissioned by EPA and Congress in 1988, the report examines how EPA regulates pesticides in foods, with special emphasis on the foods regularly eaten by infants and children. The recommendations cover all three of the basic elements of our traditional approach to evaluating food safety: toxicity testing, or the identification of the potential to cause harm; exposure analysis, or the determination of how much of a pesticide residue we are exposed to when we eat; and risk assessment, or the ways we combine and interpret the toxicity and exposure data to determine whether our foods are safe.

Not surprisingly, the Academy confirmed that there are age-related variations in susceptibility to the toxicity of environmental agents such as pesticides. For example, both anatomical and physiological differences are the basis for different rates of metabolism, respiration and growth. Anyone who holds a sleeping child notices that the child is breathing faster than an adult would, just as anyone who has lunch with an average pre-schooler knows how much food a child can consume and

still be hungry two hours later. Because of these and other differences, the Academy recommended modifying current reproductive, developmental, and carcinogenicity testing protocols and adding studies to test for pesticide neurotoxicity, immunotoxicity, and hormonal effects.

The Academy reaffirmed age-related differences in the amount of exposure to pesticide residues for infants and children. For their size, children consume more food than adults do, eat fewer types of foods, and drink more water. To address these differences, the Academy recommended more and better food consumption data targeting specific age groups from infancy through adolescence, more and better pesticide residue data on basic foods (raw agricultural commodities) and processed foods, standardized methods for reporting residue monitoring and maintaining residue data bases, and characterization of exposure from nondietary sources in assessing tolerances under FFDCA.

To better characterize exposure and risk, the Academy recommended use of a statistical procedure for determining potential distributions or ranges of pesticide exposure based on limited actual exposure data. This procedure, if supported by sufficient "real" data, could allow better assessment of subpopulations which may be at greater risk than is possible with current methods. The Academy also recommended considering all routes of exposure to a pesticide in assessing risk, combining exposure through the diet with environmental sources such as air, indoor surfaces, lawns, and pets, as well as combining exposures

to pesticides with common toxic effects. Finally, where toxicity data are incomplete or there is evidence of frank developmental toxicity in animal studies, the Academy recommended use of an additional uncertainty, or "safety" factor when defining acceptable exposure limits.

These recommendations, taken as a whole, present a great challenge in terms of higher standards for the quality, quantity, sensitivity, and scope of the data we use for evaluating risk. This is a challenge we are prepared to meet. We want to ensure that the decision making process for setting tolerances is based on health considerations, incorporating improved exposure estimates and better hazard characterization. We must not overlook the fact, however, that demands for more and better data development will also have important resource implications, for government agencies and the private sector. We must work to effect needed changes efficiently to minimize these burdens, while assuring that protective standards are maintained and enforced.

Efforts are well underway to assess and implement the Academy's recommendations where appropriate. We are ready to tackle the numerous issues. We have already accomplished a number of key tasks, and we will be initiating others in the near future.

Organization

The Office of Pesticide Programs (OPP) within EPA has the lead in organizing this initiative, with very significant participation from USDA and FDA. In addition, OPP has an array of outside participation in our NAS study work groups, including representatives of other HHS offices, Department of Commerce, Department of Defense, state regulatory agencies, and the U.S. Census Bureau. It is evident from the sheer size of our task that we will need to elicit the help and cooperation of a wide variety of outside groups, and we have already met with organizations who have offered their support and assistance, particularly in the area of pesticide use reduction.

Progress

EPA, FDA, and USDA are committed to making real progress and expect to achieve tangible results within the coming year. While this initiative represents a new frontier for the federal government, we began work even in advance of the NAS report, with the goals of improving the science base for pesticide decisions very much in mind. The impetus of the NAS report and the Administration's commitment to reducing pesticide use imparted increased energy, tenacity, and enthusiasm to our efforts. Some of the relevant programs that are now in place, our actual accomplishments, short-term plans, and near-term goals are described below.

Toxicology

As part of the registration or reregistration of a pesticide, EPA requires a battery of toxicological tests to be performed. Registrants must submit a number of studies including acute, subchronic, and chronic toxicity studies; carcinogenicity (cancer or tumor causing effects), developmental toxicity (e.g., birth defects), and mutagenicity (genetic effects) studies; and reproductive effects and metabolism studies. We also require data on environmental fate and ecological effects.

The NAS report recommended expanding the scope of this testing. Several of the recommendations in the report for additional or modified study requirements are in their final stages of development, while a few will require further work. EPA is reviewing and researching each new study suggestion. While it may be ideal to have as much data as possible from a purely scientific standpoint, we realize that in a regulatory setting, decisions must be made in a timely fashion based on the best available scientific information. Our decisions on new testing requirements will be subject to scientific peer review and open to comment by the general public.

Immune Function Testing. The NAS committee considered the human immune system to be among the more robust of systems in terms of resistance to pesticides or other chemical toxicity. In general, NAS concluded that EPA's current approach is sufficient. If abnormalities are found during histopoathologic examination of the spleen, lymph nodes, thymus, and bone marrow, they suggest

that more detailed and specific studies should be conducted on a case-by-case basis relevant to the types of effects initially seen in immune system tests.

EPA agrees with the committee's findings. We have prepared proposed protocols for immune system testing and will present these guidelines to a public meeting of EPA's Scientific Advisory Panel (SAP) this fall. EPA's guidelines are more comprehensive than NAS recommended and consider a variety of endpoints, including changes in cell profile and thymus weights as well as histopathological changes. The guidelines will be finalized following SAP review.

Neurotoxicity Testing. In March 1991, EPA issued new and revised guidelines for conducting studies to determine the effects of pesticides on the nervous system. They include a description of how to assess the effects of pesticides on the developing nervous system both before and after birth. EPA also proposed requiring data for acute and subchronic neurotoxicity testing. Following the issuance of the guidelines, EPA required the development of such data for certain pesticides such as organophosphates and carbamates. Data call-ins (DCIs) were issued beginning in early 1991, and DCIs for over 66 chemicals or chemical cases have gone out to date. The NAS committee encouraged EPA to require neurotoxicity testing for all food-use pesticides as a general data requirement. This question will be presented for public review when we propose revised requirements for all pesticide regulatory testing. Current plans call for

review of this proposed rule by the SAP and publication for public notice and comment in 1994.

Visual System Testing. The NAS committee recommended that a general guideline for visual system toxicity testing be established that can be modified and applied on a case-by-case basis. EPA has been working to design suitable protocols for sensory testing which will reliably predict visual system toxicity and has developed testing guidelines which are in the final stages of internal review. These guidelines will also be presented to EPA's Scientific Advisory Panel in 1994 and finalized following SAP review.

Other NAS recommendations for added or modified toxicological studies will require more investigation into their feasibility and compatibility with our regulatory needs. Age-related physiological studies, pharmacokinetic studies on immature animals, *in utero* exposure studies to assess cancer, and hormonal measurements are very complex and often controversial studies. Adding them to our current battery of routine toxicology testing will require more detailed scrutiny into issues such as degree of difficulty in performing the study and the value added of the data in making risk assessment and management decisions.

Residue Data and Tolerance Setting

Use of Field Trial Data in Exposure Estimation. Results from multiple pesticide field trials are currently used by EPA in

setting tolerances. The tolerance is often used in dietary exposure estimates for acute effects and is also the initial value used in chronic risk assessments. Tolerances facilitate enforcement of the use directions on registered products and will overestimate actual dietary exposure over a lifetime because they are set to cover maximum residue levels found in unpeeled, unwashed, uncooked commodities collected at the farm gate following treatments made at the maximum label rates and harvested at the minimum allowed interval following treatment. On the other hand, the tolerance value may, in some cases, underestimate acute exposure because it is based on composite samples that represent an average value for individual items collected.

The NAS report suggests that data from pesticide field trials be utilized to provide a basis for estimating potential maximum residue levels for acute effects and that more and better data be used for estimating dietary exposure for chronic or long term effects. We agree with these recommendations. EPA already uses field trial data as a basis for estimating maximum residue levels. It has also published for comment draft guidelines for the generation of better residue data to be used in both chronic and acute dietary risk assessments. These new guidelines will complement existing residue field trial guidelines and will document a more formal and uniform approach to assessing both short and long-term dietary health risks. Public comments have

been solicited and EPA will finalize these guidelines in 1994, following SAP review.

Monitoring Pesticide Residues in Foods. The NAS committee emphasized the importance of obtaining more and better monitoring and processing data for use in estimating dietary exposure of children to pesticide residues. The Academy outlined a number of potential areas for improvement, including standardized reporting formats; the establishment of a national monitoring data base; market basket surveys designed around infants and children with an independent validation process; the institution of sampling strategies; and more sensitive analytical methods for detecting residues. Substantial changes in these areas are likely to be costly and will therefore need to be examined carefully for their added value compared to current practices and the many other possible improvements which could be made at increased cost.

Nonetheless, advances have been made in several of these areas. For example, significant progress has been made in recent years to standardize reporting of pesticide residue monitoring data. FDA's monitoring data reporting system has been adopted, to some extent, by many states and by USDA's Agricultural Marketing Service in its Pesticide Data Program. Recording of multiple residues in a single food sample is currently standard operating procedure in the FDA Pesticide Program, the USDA Agricultural Marketing Service's Pesticide Data Program, and the USDA Food Safety and Inspection Service's monitoring of meat and poultry. Since 1986, FDA has had a contract with Mississippi

State University to compile state data into a data base. In 1989, EPA developed the Pesticide Residues Information System, which uses this state monitoring data base, as well as data generated by the National Food Processors Association, Agriculture Canada (now the Department of Agriculture and Food), and Scientific Certification Systems. The data base has been recently updated and is now available to the public.

In October, FDA will implement a statistically designed incidence level monitoring program for apples and rice. Both are listed in the NAS report as high consumption items for children. FDA will ensure that rice destined for baby food is included in this program. Last year's statistically based incidence level program included pears, another food identified by NAS as a high-consumption food for children. Currently, FDA's "Total Diet Study" looks at eight subgroups of the population, including two children's age groups, 6 to 11 months, and 1-2 years. Soon, the study will be expanded to 14 subgroups with more groups for children.

Food Consumption

Dietary Surveys. One elememt of assessing dietary exposure to pesticides is a determination of how much and what types of food are consumed. EPA uses the computerized Dietary Risk Evaluation System (DRES) to estimate the amount of the pesticide in the daily diet, using national food consumption survey data from USDA. DRES allows us to assess the potential risks to a

number of age-based population groups including infants and children; several different ethnic groups; and regional populations.

While DRES represents a significant advance over earlier methods of utilizing food consumption data, we agree with the NAS recommendation that more and better data are needed, especially on children in different age groups. Data in DRES currently are derived from USDA's 1977-78 Nationwide Food Consumption Survey (NFCS). Because of the apparent changes in America's eating habits since that time, and the relatively limited sample sizes for children in the 1977-78 NFCS, we need a more up-to-date data base.

We are evaluating several existing surveys, such as USDA's Continuing Survey of Food Intakes by Individuals (CSFII) and the Department of Health and Human Services' National Health and Nutrition Examination Survey (NHANES), which contains water consumption information. EPA is considering using one of these two surveys in the near term for an interim upgrade of DRES, although there are certain age groups for which sample sizes may not be fully adequate and NHANES excludes infants less than two months of age. USDA and EPA, along with HHS and the Bureau of the Census, are currently designing a special supplemental survey to acquire data adequate for EPA's purposes with respect to understanding the dietary patterns of infants and children. These data would provide better support for special findings with

respect to children as part of the tolerance setting process described in the legislative portion of our testimony.

Additional future surveys will be designed to provide better data, but we need to explore whether a single survey design can simultaneously meet the needs of nutrition and food safety agencies, both of which need well-designed surveys. EPA will be working with USDA, FDA and other federal agencies on the design of future food consumption studies to help make sure that these studies provide the information needed for more precise estimates of risk for the general population, as well as infants and children.

Food Composition. EPA uses DRES to estimate food consumption. The foods reported are evaluated in terms of their individual ingredients. For example, a chocolate chip cookie may be made up of flour, eggs, sugar, vegetable (soybean and/or cottonseed) oil, cocoa, whole milk, corn syrup, and molasses. This breakdown of foods is necessary because the pesticide residues in the foods as they are eaten are the sum total of residues in the individual components of the food. The NAS committee recommends that a simple, uniform method be developed for conversion of a product as consumed to its components in terms of raw agricultural commodities (RACs).

The Human Nutrition Information Service's (HNIS) Food Grouping System, which has been under development for some time, is envisioned as the means of providing a simple, uniform method for converting foods to RACs. This system will allow for

standardized conversion. While HNIS is completing work on the Food Grouping System, EPA is developing an improved list of raw agricultural commodities so that all HNIS recipes can be standardized to the new DRES RAC list.

Risk Assessment

Additional Uncertainty Factor(s). The NAS committee recommended that an additional uncertainty factor of up to 10 be used when there is evidence of developmental toxicity following birth and/or when data from toxicity testing relative to children are incomplete.

Current EPA practice prefers to derive guidelines or benchmarks for chronic exposures from a complete, "ideal" set of toxicology studies. These studies include two or more chronic studies in different species along with one or more acceptable studies which evaluate the potential for reproductive effects and two or more (prenatal) developmental studies in different species. The Agency usually applies the standard 100-fold uncertainty factor to the most appropriate toxicological endpoint identified in these studies. When the existing data base does not include the "ideal" set, EPA uses additional uncertainty factor(s) to accommodate for incomplete knowledge of the pesticide's toxicity potential. Our current methodology provides flexibility for application of uncertainty factors of lesser or greater magnitude, if the data warrant it. We will evaluate

whether our standard practice should be further modified in light of the NAS recommendation.

Other Sources of Exposure. The NAS committee concluded that to properly evaluate potential pesticide risks, other avenues of exposure should be included in an overall risk assessment. Risks from multiple pesticides known to have common mechanisms of action, nondietary exposures, and water consumption should be considered. Many of these recommendations have merit; however, further research and analysis are needed to better characterize certain exposure scenarios and to identify scientifically valid methods for combining multiple exposures. It is clear that people can be, and in fact are, exposed to multiple pesticides and to pesticides by more than one route, depending upon the use pattern of the product. The recommendation to combine exposures across similar chemicals has great appeal, yet is really a very complex issue. Currently EPA's general practice is to evaluate each pesticide and pesticide use separately, with the exception of multiple food uses of a pesticide, where we evaluate the total dietary risk. Changing the current risk management approach from a one-chemical or one-route focus to a multiple-chemical or multiple-route one will require further analysis. In our analysis, we will draw on the California Department of Environmental Regulations' experience in conducting multi-route risk assessments and evaluate their program for applicability to EPA's.

In addition, OPP will be working with EPA's Office of Water, which is developing a policy proposal which attempts to provide a consistent approach toward "allocating" allowable levels of exposure from various sources such as air, water, and food.

Use of the Benchmark Dose. EPA fully accepts the NAS committee's recommendation that we should explore the use of the benchmark dose approach for risk assessment applications involving infants and children. The benchmark dose concept has been developed as an alternative methodology for deriving quantitative measures of hazard and is argued to have several advantages over current methods. Work is underway on the feasibility of the use of benchmark doses as an integrated approach to cancer and noncancer risk assessment, with initial emphasis on the specific definitions, assumptions, decision points, and science policy required for its implementation in noncancer risk assessment. Potential applicability to specific subpopulations such as the young is being considered. EPA, the International Life Sciences Institute, and the American Industrial Health Council are sponsoring a public workshop at which the work done with respect to developmental toxicity will be discussed. In addition, OPP has acquired necessary computer software and will be developing case studies during the next fiscal year.

Use of Probability Distribution Curves. EPA also agrees with the NAS recommendation to use probability distributions based upon actual data rather than simple summary statistics.