

Howard
This is Dr Jenkins
summary of what she will
discuss along with the attached documents
which support it.
Mark

EPA DIOXIN REASSESSMENT
Status as of February, 1993

Cate Jenkins, Ph.D.¹
U.S. EPA

1st 2 pages
SUMMARIZED.
- Do you want
the rest
- JGZ thinks you
already have this

The pulp and paper industry, whose effluents are contaminated with dioxin, sought to have EPA downgrade its potency estimate for dioxin. The industry pushed several "scientific theories" it wanted EPA to use. Industry held at least one documented meeting with John Sununu to force EPA to perform this reassessment.

Schedule and milestones: In the fall of 1991, and spring of 1992, EPA held two public meetings for public input into the reassessment. In August, 1992, a *Federal Register* notice announced the availability of nine draft chapters for public comment.² These chapters included human epidemiology, dose-response estimates, immunotoxicity, and reproductive toxicity.

The week of September 21, 1992, a public workshop meeting was held, where the authors of the chapters (outside consultants) and peer reviewers discussed their preliminary conclusions. As a result of this meeting, reporters such as Keith Schneider of the New York Times ran articles saying there was no dioxin threat. On October 19, Erich Bretthauer, EPA's Assistant Administrator for Research and Development, wrote a memo to dispel these misrepresentations in the press (see below).

The current schedule is to release a new set of draft chapters for public review this spring, incorporating comments on the first drafts. New expert panels of different scientists (but including the same chapter authors) will again be convened. Another public meeting with the new expert panels will be held.

A committee of the authors of the individual chapter will also be preparing an additional chapter, which characterizes the overall risk of dioxin.

A package of all the individual chapters, and the umbrella chapter on the overall risk assessment, will then be sent to EPA's Science Advisory Board (SAB) in July or August. (These dates have slipped in the past, and will probably slip again.) The SAB will then issue drafts and hold public meetings before making a final recommendation regarding dioxin to the EPA Administrator (Carol M. Browner).

Three written statements regarding dioxin from EPA are useful. The first comes from slides prepared for a February 14, 1992 (originally scheduled for January 27, 1992) briefing to EPA Administrator Wm. Reilly:

Dioxin does cause cancer in humans.

Cancer may not be the most sensitive toxic response resulting from dioxin exposure. Immunotoxicity and reproductive effects appear to occur at body burdens that are approximately 100 times lower than those associated with cancer.

Recent data indicate that there may not be a threshold for certain responses to dioxin.

¹ Opinions expressed herein are those of the author, and do not necessarily reflect those of the U.S. Environmental Protection Agency

² Copies of the draft chapters are available from the EPA ORD Publications Center, CERL-FRM US EPA, 26 W. Martin Luther King Drive, Cincinnati, OH 45268; (513) 569-7562; fax (513) 569-7566. Copies of the draft chapters (and future drafts) are also available from the EPA contractor Eastern Research Group (Helen Murray); (617) 674-7307. Comments for the record should be addressed to the Office of Health and Environmental Assessment (RD 689), EPA, 401 M Street, SW, Washington, DC 20460, Attention: Dioxin Reassessment.

EPA also prepared a briefing booklet for Clinton's transition team which contained the following brief paragraph on dioxin:

Dioxin Reassessment. ORD is completing a scientific reassessment of dioxin which will be released in early 1993. This is likely to be an extremely controversial document as there are new findings indicating adverse reproductive effects at existing environmental levels.

Another statement is a memorandum from Erich Bretthauer, Assistant Administrator, to the EPA Administrator, dated October 19, 1992:

Certain non-cancer effects, including changes in endocrine function associated with reproductive function in animals and humans, behavioral effects in offspring of exposed animals, and changes in immune function in animals have been demonstrated. Some data suggest that these effects may be occurring in people at body burden levels that can result from exposures at, or near, current background.

Cancer: A The draft chapter for dioxin potency released to the public August, 1992 calculated cancer potency from tissue levels of dioxins found in two human studies, one by NIOSH and the other by a German manufacturer (BASF) on its employees. This human potency value was then compared to the Dow/Kociba rat data which has historically been the basis for EPA's dioxin potency level. The levels were similar.

The August, 1992 human epidemiology chapter stated that the CDC study on Vietnam veterans was "uninformative" since it lacked exposure information. The Ranch Hand studies were mentioned as being credible, but no Ranch Hand findings were included in the chapter..

Immunotoxicity: During the spring, 1992 public meeting, EPA made statements of how it intended to handle the immunological data, which indicated *immunological changes* in humans would occur before cancer. Chuck Elkins, EPA Associate General Counsel for the Cross-Media Analysis and Review Division announced that a policy team would decide how to handle the issue, since EPA thought merely showing a *change* in the immune system did not necessarily prove an *adverse effect*. A compromise of the immune system not shown to be as massive as seen in AIDS or other diseases was not being equated by EPA as an *adverse effect*. The important thing to note is that EPA was stating that immunotoxic effects were predicted to occur at lower doses than cancer..

The August 1992 draft chapter on dose-response relationships fails to give any dose level of concern for immunotoxic effects, thus avoiding the issue. The draft chapter stated that more research would need to be performed to enable calculating levels causing changes and/or adverse effects.

Reproductive effects: The draft chapter on reproductive effects released in August discussed in detail the mechanisms by which dioxin caused reproductive abnormalities in male and female animals, but did not address the question of the concentrations predicted to cause these effects in humans. The chapter yet to be written on the overall risk assessment of dioxin probably will contain a dose level predicted to cause reproductive abnormalities in humans.

The briefing book prepared by EPA for President Clinton's transition team (quoted at the beginning) referred to background concentrations causing reproductive effects in humans. Presumably, this refers to the animal studies demonstrating that *in utero* exposures of male fetuses caused life-long feminization, studies showing infant primates exposed to dioxin through their mothers exhibiting behavioral changes, and studies on humans demonstrating decreased sperm counts and lower testosterone levels.

TABLE OF CONTENTS

	<u>Page</u>
Section I. Introduction	1
Section II. Agency Overview	3
Section III. Priority Policy Areas	6
Section IV. Observations/Areas of Concern	18
Section V. Long-Term Goals	29
Section VI. Near Term Contacts	31
Section VII. Personnel Selection/Organization	32
Section VIII. Budget/Procurement Information	37
Section IX. Key Programs	52
Appendices	

Section I. Introduction

This briefing book was prepared by the EPA Transition Team during December 1992 to assist the incoming leadership and presents an overview of the Agency's history, current budget, personnel, and major issues. The insights and analysis presented reflect interviews with EPA staff and extensive communications from state and local agencies, industry, and the environmental community.

We wish to highlight a central, immediate challenge faced by the new Administrator: how to begin work now on critical changes for the long-term while also handling a daunting range of pressing short-term dictates, budget and personnel decisions, and demands from Congress and other key constituencies.

The new Administrator has an exciting opportunity to free EPA from the cocoon of a regulatory agency of the 1970s and give it a more cooperative, catalytic, and educational role. This does not mean the Administrator can or should discard the body of laws that drive programs for health and environmental protection. But it does mean that the Administrator can adopt, with broad support, some basic principles to guide the agency into the 21st century. These include:

- Much greater reliance on economic incentives and other market-based approaches to environmental protection;
- Use of voluntary programs like "Green Lights" that reward good behavior as a complement to mandates that rely only on sanctions and aggressive enforcement;
- Examinations of multi-media, sectoral, and geographic based strategies as alternatives to narrowly-defined media programs;
- A continued "internationalization" of the Agency's mission and organization reflecting new understanding of the global nature of environmental problems;
- A commitment to play a leadership role in supporting environmental research and education; and
- Building trust and cooperation with the Agency's key constituencies, including other federal agencies and Congress.

The opportunity to initiate these steps is likely to be greatest in the early days of the new Administration.

A lengthy agenda of pressing short-term issues also needs attention. These include responding to a perceived budgetary crisis that allegedly means cuts of a third or more in some areas, major criticisms of the way EPA manages a \$1.4 billion a year in contracts, lack of trust among key constituencies, and the question of a new headquarters building and other morale issues.

The remainder of this report is organized in eight sections. Section II presents an overview of EPA's history and structure; Section III introduces priority policy areas; Section IV provides observations on major areas of concern; Section V identifies basic goals of the Clinton/Gore Administration that involve the Agency; Section VI lists the committees and outside constituencies most important to EPA; Section VII describes the senior managerial positions and organization of personnel; Section VIII presents an overview of budget issues; and Section IX

reviews key Agency programs. Additional background materials are presented in separate appendices.

DRAFT

Section III. Priority Policy Areas

Section III covers a large number of important policy issues that are likely to arise early in the new Administration and is organized primarily by major program areas. However, some items are so critical that they are likely to demand the Administrator's immediate direct attention. These "high-level" issues are discussed in Subsection A.

A. High-Level Consideration

1. **Budget Issues.** EPA faces a number of serious, short-term budget issues, as a result of the current appropriation for fiscal 1993 and the development of a budget request for fiscal 1994. The budget constraints raise serious questions about EPA's ability to fulfill its responsibilities. The budget issue is intimately related to perceived contract management weaknesses in the Agency. These areas are discussed in more detail in Section VII.

2. **Legislative Activities.** Congress, interest groups and the regulated community will press for early signals from the Administration regarding its position on major environmental legislation, including the elevation of EPA to Cabinet status; environmental justice legislation; reauthorization of the Superfund law, the Resource Conservation and Recovery Act, and the Clean Water Act; and implementation legislation for the Basel Convention on waste exports. Top career officials in the Agency recommend early creation of a comprehensive legislative strategy. This strategy could include decisions to use the Agency's existing authority to solve legislative issues by administrative means.

- **Cabinet Status Legislation.** The 102nd Congress proposed, but failed to enact, legislation elevating EPA to Cabinet rank. The 103rd Congress is likely to examine Cabinet status and will want to know EPA's views on such things as: clarification of EPA's mission; structural changes (e.g. from independent bureau of environmental statistics, the relationship between headquarters and the regional offices); and transfer to the Agency of environmental programs from other agencies (e.g., the National Oceanic and Atmospheric Administration).
- **Environmental Justice.** Widespread concerns about the disproportionate environmental burdens experienced by minority and low-income populations due to major pollution sources and corresponding enforcement actions may be reflected in early legislative activity. The new Administrator's plan of action for addressing this pervasive concern and her position on legislation is likely to receive early and significant attention.
- **Superfund Reauthorization.** In 1990, the Superfund law's program authority was extended until September 30, 1994, and the current taxing authority until December 31, 1995. Many interest groups, other than the environmental community, are seeking a comprehensive reauthorization of the statute (Comprehensive Environmental Response, Compensation and Liability Act). The two issues which received the most political attention in the 102nd Congress were relaxation of liability for certain municipalities and for banks and other lenders. EPA published an interpretive rule pertaining to lender liability in 1992 and unsuccessfully attempted to promulgate a model allocation formula for generators and transporters of municipal solid waste in 1992. Expect these issues to

DRAFT

re-emerge during the Senate confirmation process. Absent any signal from the Administration, multiple Superfund hearings are likely in February/March 1993 timeframe. Affected interests will raise other concerns about the law's liability standards, and about clean-up standards.

- *RCRA Reauthorization.* RCRA reauthorization stalled in the 102nd Congress due to Bush Administration and environmentalist opposition, albeit for different reasons. State and local authority to ban, restrict or impose fees on importation of municipal solid waste and local authority to exercise flow control of the waste stream are the driving political issues behind reauthorization. Cities are seeking federal assistance in creating markets for recyclables. Hazardous waste issues are also bound to arise in a RCRA debate. These issues include corrective action, industrial non-hazardous waste regulation, and regulation of the toxic content of products.
- *Clean Water Act Reauthorization.* The Clean Water Act, which expired in 1990, is likely to come up for hearings and mark-up in the Senate Environment Committee in early spring. There are a number of controversial issues identified by Congress, municipalities and interest groups. The Democratic caucus is deeply divided over the scope of the wetlands regulatory program. Stringency of regulations and affordability of controlling combined sewer overflows is of intense concern to municipalities. Other major issues include non-point source pollution and controlling contaminated sediments.
- *Basel Convention.* Legislation necessary for ratification and implementation of the Basel Convention on the Transboundary Movement of Hazardous Waste is likely to be considered in 1993. The Convention was signed in 1989 with U.S. support and has been adopted by thirty-three countries. However, the 102nd Congress did not ratify the agreement because the Administration linked implementing legislation with RCRA reauthorization. EPA staff have done most of the substantive work in Convention negotiations and believe that U.S. ratification is essential, if the agreement is to be effective. They also argue that ratification furthers our interest in retaining a leadership role in international waste issues, and a vote on issues that will likely affect future trade in recyclables. Key legislative issues are the definition of "environmentally sound management" in connection with setting standards for countries receiving hazardous wastes and the treatment of wastes bound for recycling.

3. **Regulatory Activities.** Many regulatory activities will face the new Administrator early in her term including :

- *Clean Air.* Implementing and enforcing the Clean Air Act Amendments of 1990 is already and will continue to be one of EPA's most controversial policy issues. EPA already has issued more than 100 required rules, and is developing another 100 or so. More than 50 of those rules are to be proposed or finalized in the first 120 days of the new Administration. EPA already has been sued for failing to meet statutory rulemaking deadlines and on substantive grounds.

DRAFT

Clean air implementation will involve major decisions affecting the federal/state partnership. Conflicts among the regulated community, public interest community, and all levels of government will continue to be sharp.

- **"Third-third" Land Ban Rule.** The United States Circuit Court for the District of Columbia this year overturned key portions of EPA's land disposal regulations for characteristically hazardous wastes under RCRA. Industries that dispose of these affected wastes are concerned that the court decision will shut them down. The RCRA office anticipates that it will be required to address this situation by promulgating new regulations on a fast-track basis.
- **Alaska Wetlands.** The day before the election, EPA proposed rules to exempt development activities in Alaskan wetlands from permit conditions that require consideration of less environmentally damaging alternatives or mitigation if harm is unavoidable. The exemption would apply until 1 percent of Alaska's wetlands, or 1.7 million acres, were lost. The Agency received more than 2,000 comments on the proposal. The comment period closes on December 21, but EPA is unlikely to issue a final rule before Inauguration Day. Environmentalists strenuously oppose the proposal, while it is supported by the Alaska Governor and congressional delegation, and oil and natural gas interests.
- **Delaney Clause Litigation.** The U.S. Ninth Circuit Court of Appeals has ruled that the Delaney Clause in the Federal Food, Drug, and Cosmetic Act (FFDCA) bars issuance of tolerances permitting residues of carcinogenic pesticides in processed food. The Court's mandate is scheduled to be issued on December 24. In the event that EPA's general authority on processed food tolerances is revoked, grocery shelves could be swept clean of a wide variety of products. (The mandate may be delayed if the Supreme Court acts on a petition for certiorari that has been filed by the National Agricultural Chemicals Association). Key members of Congress have expressed interest in crafting a balanced legislative solution to the problem, and are seeking an early signal from the Administration on this.
- **Oil Pollution Act.** Onshore facilities handling oil and petroleum products cannot operate after February 1993 if they do not have oil spill contingency plans under the Oil Pollution Act of 1990. Plans cannot be written absent EPA guidance, which is currently stalled at OMB. If the guidance is not released by January 20, the new Administration probably will need to give immediate attention to this issue.

The rest of this discussion addresses, by major program area, other policy issues that are important to note for action in the first 90 to 120 days of the new Administration.

B. Office of Air and Radiation (OAR)

The major task of OAR is implementation of the Clean Air Act Amendments of 1990. EPA already has been sued for failing to meet statutory rulemaking deadlines, meaning that the Agency's regulatory agenda is increasingly driven by court-ordered deadlines.

DRAFT

- *Air Toxics.* EPA will promulgate several important rulemakings in the first six months of 1993 regarding clean-up of toxic air pollution, including final action on controls for chemical plants. The new Clean Air Act completely revamped the national program for air toxics control, shifting the initial emphasis from a risk-based to a technology approach. This decision raises important new issues for EPA, including how much risk assessment to conduct before issuing technology standards, as well as important resource decisions. Industries are arguing for extensive risk assessment before technology rules are issued, while environmentalists are opposed to such an approach.
 - *Clean Air and Transportation.* Under the Clean Air Act, state and local government spending for transportation projects is required to "conform" with the Clean Air Act's requirement to clean up polluted areas. EPA's conformity rules have been sent to OMB and await decision. EPA expects to issue this rule in February 1993. Any proposal on this subject is controversial, as it affects billions of dollars of transportation spending. If President-elect Clinton decides to move forward with accelerated transportation spending as a part of an economic recovery package, this rule is even more significant.
 - *Waste Isolation Pilot Plant (WIPP) Standards.* This rulemaking is not a clean air issue, but rather the result of legislation enacted in 1992. Under the new law, EPA must issue by April 1993 standards for disposal of extremely dangerous nuclear weapons waste at WIPP. The Senate Energy Committee, the New Mexico delegation, and other states with waste problems want this project to move forward quickly. Some in New Mexico and the House Government Operations Committee are not sure adequate rules can be written.
 - *Clean Air Sanctions.* EPA failed to issue required guidance for preparation of revised state implementation plans (SIPs) under the 1990 Clean Air Act Amendments. States therefore could not submit, as required by law, complete SIP revisions by the required November 15, 1992 compliance date. EPA now has plans to send letters to the governors of affected states on January 15, 1993, to initiate the process for imposing sanctions for lack of complete SIP submittals. Sanctions can include things like bans on new road construction. Expect to hear from affected governors shortly after Inauguration Day.
2. Legislative Deadlines Within 180 Days. See discussion on litigation.
3. Major Pending Litigation.
- *Deadline Suits.* Rep. Henry Waxman (D-CA) and environmental organizations have sued the Administration for its failure to meet statutory deadlines for rules under the 1990 Clean Air Act Amendments. The rules affect every aspect of the law, including issues affecting international agreements. All parties have reached settlement on the first set of suits, which have established court-ordered deadlines to issue regulations. Rep. Waxman has recently notified the Agency of his intent to file a second suit.

D. Office of Research and Development (ORD)

[NOTE: The functions of ORD do not lend themselves to the format prescribed for the briefing book. Consequently, a different approach has been taken.]

The Office of Research and Development serves as the principal EPA science and technology office for environmental research, environmental monitoring, environmental and health assessment, technology development and evaluation and quality assurance. There are a number of important issues that will have to be addressed in the first 90-180 days:

1. **Dioxin Reassessment.** ORD is completing a scientific reassessment of dioxin which will be released in early 1993. This is likely to be an extremely controversial document as there are new findings indicating adverse reproductive effects at existing environmental levels.
2. **Ozone Control Strategies.** ORD is involved in an evaluation, required by the Clean Air Act, of the proper role of nitrogen oxides emissions control versus volatile organics emissions control in attaining the national ambient air quality standards for ozone. The evaluation, due in January 1993, could result in strategies to emphasize more VOC controls. The result could be major disruptions in the '97 ozone nonattainment areas requiring implementation plans.
3. **Appropriations Committee Report.** Congress, in the fiscal 1993 appropriations for EPA, told ORD to reexamine its organization with special attention to the role of applied versus basic research. The report is due to the Appropriations committees in mid-February 1993.
4. **Feasibility Study/Air Force Base.** ORD is required to complete a feasibility study of converting an air force base in Maine into an environmental training center and report to Congress in February 1993.

E. Office of Prevention, Pesticides and Toxic Substances (OPPTS)

OPPTS administers the federal pesticides law (FIFRA), the Toxic Substances Control Act, pollution release and prevention reporting by industry, and lead control provisions of federal housing law.

1. Significant Legislative/Regulatory Initiatives.

- **Lead Abatement.** Under recently enacted amendments to federal housing law, OPPTS received new responsibility over lead abatement in the areas of public information, training, and lead limits in drinking water, soil, and air. Intense public interest will be focused early on OPPTS actions to carry out the requirements. In addition, Congress will be looking for signals from the new Administration on expected legislation to further regulate lead in drinking water and new uses of lead in products.

- *Farm Worker Protection.* EPA recognized as early as 1979 that federal regulations were needed to protect farm workers from pesticide poisoning. No regulations were issued until August 1992. Now that they are in place, EPA has substantial work before it on implementation and compliance. Some terms, such as "clean drinking water," need further definition.
- *Pesticides in the Diets of Infants and Children.* The National Academy of Sciences will issue a report in spring 1993 on the effects of pesticide residues in the food of infants and children. It may conclude that children are far more sensitive than adults and will be highly publicized. OPPTS may feel pressure to incorporate the report's conclusions through regulatory action.

2. Legislative Deadlines within 180 Days. None.

3. Major Pending Litigation. (See III. 3 above for discussion of Delaney Clause litigation.)

4. Major Enforcement Actions. None.

F. Office of Solid Waste and Emergency Response (OSWER)

OSWER ensures compliance with federal hazardous and solid waste law (RCRA), conducts and manages clean-ups under the Superfund law (CERCLA), and regulates on-shore facilities subject to the Oil Pollution Act.

1. Significant Legislative/Regulatory Initiatives. OSWER has a number of significant near term legislative and regulatory initiatives, including:

- *Hazardous Waste Identification Rule (HWIR).* When a federal court earlier this year struck down rules regulating wastes derived from or mixed with listed hazardous wastes, EPA filled an enormous regulatory gap by reissuing the rules in interim final form. The Agency is now under a congressionally mandated deadline to replace the interim rules with a new hazardous waste identification rule between October 31, 1993, and October 31, 1994. The highly controversial rules are sweeping in their scope and will be watched with intense interest by the states, environmental groups and the regulated community. OSWER staff say that EPA must make a regulatory proposal in April-May 1993 if it is to meet the 1994 deadline.
- *National Environmental Emergencies (Chemical Releases).* The Clean Air Act requires the establishment of a Chemical Safety and Hazard Investigation Board, administered by OSWER, to investigate chemical accidents and make recommendations for attendant regulations. The Bush Administration never made its appointments to the Board. A major emergency could focus attention on the need to establish and fill the board.
- *Contractor Indemnification Under Superfund.* Under the Superfund statute, EPA may provide indemnification protection to contractors cleaning up Superfund waste

sites. Guidelines mandated by the 1986 Superfund amendments have never been issued and are pending at OMB. As a result, the Departments of Defense and Energy have proposed their own policies on contractor indemnification. The issue is controversial within the Executive Branch and Congress.

- *Site-Specific Clean-up, Enforcement and Permitting Issues.*

- a. **Waste Technologies Industry incinerator permit:** The proposed hazardous waste incinerator in East Liverpool, Ohio, has stimulated extensive citizen opposition. The facility has completed construction and hopes soon to begin conducting a trial burn.

- b. **Kennecott Corporation negotiations:** A \$1 billion copper smelter may not be built in Utah if the site for the smelter is listed on the Superfund National Priorities List. Kennecott is negotiating to avoid an NPL listing by promising an expedited clean-up.

2. **Legislative Deadlines Within 180 Days:** None

3. **Major Pending Litigation:** See above for discussion of the "third-third" litigation.

4. **Major Enforcement Actions:** With the passage of the Federal Facility Compliance Act in October 1992, federal facilities are now subject to EPA and state fines and penalties for violations of hazardous waste laws and regulations. Determining and securing additional staff and financial resources to meet these challenges and developing implementation policies and guidance will be major issues for the OSWER's federal facilities enforcement program in the coming year, particularly when coupled with EPA's federal facilities oversight authorities under Superfund and military base closure requirements. EPA's decision will have major budget implications for the Departments of Energy and Defense.

G. Office of Water

This Office is responsible for drinking water, municipal wastewater, water quality, groundwater, wetlands and marine and estuarine protection programs.

1. Significant Legislative/Regulatory Initiatives

- **No Net Loss of Wetlands.** In addition to action on the proposed Alaska wetlands rule (see above), EPA is under close scrutiny on how it will proceed with wetlands protection and fulfillment of President-elect Clinton's "no net loss" pledge. An early decision to consider is whether EPA should continue use of the 1989 Wetlands Delineation Manual or conform with the Army Corps of Engineers, which is under statutory direction to use the 1987 manual. The 1987 manual is less specific in its delineations and is thought to cover fewer wetland acres. The fiscal 1993 EPA appropriations law mandates a study by the National Academy of Sciences, due in October 1993, on a scientific definition of wetlands. This study could be the basis of joint Agency and Army Corps action on a new delineation manual or the focal point for Congressional action during reauthorization of the

DRAFT

Clean Water Act. Agricultural interests, the oil and natural gas industry, development interests, governors, scientists and environmentalists have been battling over this issue for the last three years.

- *Safe Drinking Water Act (SDWA) Deadlines and Reauthorization.* SDWA regulates more than 200,000 public drinking water systems, requiring them to meet national standards for more than 70 contaminants. Eighty percent of the facilities are financially strapped small plants that serve roughly 10 percent of the total population hooked up to public systems. Many systems appear unable to pay for standards compliance.

The affordability issue is putting pressure on Congress to amend the law to allow more time for compliance. Amendments added to the latest EPA appropriations compel the Agency to deliver studies in June 1993 to Congress on the costs and benefits of current regulations, consequent recommendations for amendments, and the scientific basis for regulating radon in drinking water. More than half of all public systems are likely to fail the radon standard. Once the Office of Water submits the reports, legislative action is likely to ensue.

In the meantime, as a result of a December court decision, EPA may no longer allow states to have primary enforcement authority of drinking water if the program is inadequate. The first consequence of this decision is expected in January when five to nine states may have missed the deadline for adopting certain drinking water standards and could no longer meet primary enforcement responsibilities. In addition, another set of states is threatening to return the program to the agency because they do not have sufficient funding.

- *Clean Water Act Deadlines.* The 1987 amendments to the Clean Water Act set out a number of program requirements and subsequent litigation has resulted in additional consent and court ordered deadlines.
 - a. Uncontrolled discharges from abandoned mines, landfills, and oil and gas operations that adversely affect water quality were required to be regulated by October 1992. More than a million such discharges exist. The Agency is in the first stages of developing a series of general permits for these facilities. Land managers, most of them federal agencies, are vulnerable to citizen suits because they are not in compliance with Clean Water Act permit requirements.
 - b. Under a consent order resulting from a challenge to EPA's implementation of the act, the Office of Water is promulgating effluent guidelines for ~~some~~ industrial categories. One, effluent guidelines for the offshore oil and gas industry, is required by court order to be published by January 15, 1993, with no extension to be granted. Both industry and environmentalists are likely to sue the Agency. A final rule on organic chemicals is required by May 1993. Budget cuts are likely to delay the start of promulgation of additional three industrial categories, putting EPA out of compliance with the consent order.

DRAFT

- c. A separate court order requires the Agency by May 1993 to submit a list of sludge pollutants from sewage treatment plants and a schedule for regulating those pollutants.

2. **Legislative Deadlines** within 180 days. See discussion above of mandated drinking water studies due by July 1993.

3. **Major Pending Litigation.**

- Great Lakes Water Quality Guidance was required by law in 1991. The Agency has been sued to force issuance of the guidance and the court probably will decide the case by mid-December, likely forcing Agency action in 1993.
- A final rule setting of toxic water quality standards under the Clean Water Act for 12 states which had failed to adopt their own standards was released in December. Governors have 30 days to accept or reject the standard and set their own. Environmentalists are likely to sue.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 27 1992

OCT -9 1992

TO: DR. EKSILVER423
ALAN MCELWIN
TOM WEBSTER

FROM: PETER DSHUR

202/387-3500

MEMORANDUM

SUBJECT: Update on Dioxin Reassessment Activities

FROM: Reich W. Bretthauer
Assistant Administrator
for Research and Development (RD-672)

TO: The Administrator (A-100)

The Office of Research and Development (ORD) has recently completed several critical steps in its reassessment of dioxin and related compounds. I would like provide you with an overview/perspective on their outcome.

During August and September we achieved our goal of releasing draft versions of both the exposure document and the eight chapters which will eventually comprise the bulk of the overall health assessment for dioxin and related compounds. As planned, these documents were made available to two peer review panels and the interested public for review and comment.

The public peer panel meetings provided an excellent forum for discussion of the many complex issues related to dioxin. Over 70 members of the public participated in the exposure meeting which was held September 10-11, 1992, and more than 130 were present at the health effects meeting on September 22-25. Valuable comments were provided by both panelists and members of the scientific community representing both industry and environmental groups. All comments were made constructively with a perception of participation in "works in process." Because some of the chapters were made available to the public only shortly before the meetings, the comment period was left open for an additional 30 day period. The comments will be summarized and used by our external and internal authors in document revision. All comments that we have received, as well as all the materials that the panels have prepared will become part of the public docket.

The highlight of these recent activities was the preliminary "risk characterization" discussions which occurred on September 24-25. Members of the

OCT-29-1992 14:26 FROM EPA ORD 1094

2588138

panel for the health chapters and the chair person for the exposure panel were asked to discuss and summarize their thoughts on key features of the state-of-the-science, assumptions, and uncertainties which ought to be captured in the Agency's overall risk characterization for dioxin and related compounds. In doing this, they considered the full range of responses seen in human and experimental animals, as well as the sources and levels of dioxin exposure in the general population and in some site-specific situations. A key part of this discussion was the potential for risks to the general population from background levels of this class of chemicals as well as the impacts of incremental exposures to more highly exposed populations or potentially sensitive subgroups. By the end of the meeting the panel members had developed written statements on key issues in risk characterization. These preliminary statements will be turned into a summary report and will be returned to the panel for review, revision, and sign-off. This panel report will then be taken into consideration in Agency efforts to develop a concluding risk characterization chapter for its health effects document.

My interpretation of some salient features of the discussion by the panel members is:

- Risk characterization should encompass the broad range of health effects attributable to dioxin exposure and not focus just on cancer;
- Certain non-cancer effects, including changes in endocrine function associated with reproductive function in animals and humans, behavioral effects in offspring of exposed animals, and changes in immune function in animals have been demonstrated. Some data suggest that these effects may be occurring in people at body burden levels that can result from exposures at, or near, current background.
- While recent epidemiology studies indicate that dioxin and related compounds may be carcinogenic in humans, a focused review of these studies by a panel of epidemiologists is required. The Agency should then reconsider its current classification of dioxin which is based primarily on the results of laboratory animal studies;
- Based on the key role of the Ah receptor in mediating toxic responses to dioxin and related compounds (other dioxins, furans and biphenyls) the full range of compounds which bind to this receptor should be considered in the risk characterization. Additional work will be required to better understand the impact of dioxin-like PCBs;
- Application of biologically based models to predict carcinogenic responses to dioxin and related compounds require additional data. Studies currently underway at NIEHS and EPA may provide the needed data during the next three to five months.

- The available data on early cellular responses are largely consistent with linearity of response at low doses, but the shape of the dose-response for cancer in the low dose region cannot be inferred with certainty; and
- Risks from the ubiquitous background levels of dioxin in the general population need to be carefully considered.

I want to highlight that the above points are our interpretation of the panel's discussions and should not be viewed as final conclusions on the risks of dioxin. These views may be modified as the Panel's summary report is completed over the next few weeks. ORD will now focus its efforts on setting up additional peer review of the epidemiology chapter and responding to the comments and suggestions received in this round of document development, and on working with the external authors to assure that the health chapters are completed in a timely manner. The risk characterization chapter will be developed concurrently.

The open and participatory nature of the process, which marks a significant departure from the way we have conducted risk assessments and prepared risk characterizations in the past, also received overwhelming support by all who participated in, or who observed, the process.

cc H. Habicht, Deputy Administrator