



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

January 24, 1986

Honorable Lee M. Thomas  
Administrator  
U. S. Environmental Protection Agency  
401 M Street, S. W.  
Washington, D. C. 20460

OFFICE OF  
THE ADMINISTRATOR

Dear Mr. Thomas:

The Science Advisory Board's (SAB) Dioxin Research Review Subcommittee has completed its review of the Agency's research program for dioxins. The Subcommittee carried out this review at the request of the Deputy Administrator and the Acting Assistant Administrator for Research and Development. It met in public session in Las Vegas, Nevada on September 4-6, 1985 to discuss ongoing and future research with a number of Agency staff in the research and regulatory offices, as well as staff from other Federal agencies. The Subcommittee's review was enhanced by the preparation of a document entitled "Status of Dioxin Research in the U. S. Environmental Protection Agency" that described the program as of August, 1985.

After reviewing the overall program, the Subcommittee concludes that EPA has made substantial progress in a number of areas in support of the Dioxin Strategy. As in any large research program starting up in a crisis atmosphere, there are parts which, in hindsight, could have been designed better and which could now perhaps be redesigned or dropped, and the funds redirected to more promising research projects.

The current research program is a mixture of short-term fire-fighting and longer-range efforts. The need for action at Superfund sites, particularly in the case of dioxin contamination in Missouri, has brought rapid development and deployment of a mobile incinerator. Conversely, the crisis context within which the total program has had to exist has brought instability. Funding for a number of the projects for FY 1986, for example, was uncertain at the time of the Subcommittee's review.

The Subcommittee concludes that the overall management and direction of the program should be strengthened. We appreciate the difficulties of managing and directing a program that crosses numerous administrative boundaries and involves an array of scientific and engineering disciplines, some of which may be outside the expertise of the Program Director. Even so, a program of this magnitude and complexity requires a high, well-defined level of authority vested in the individual who has the management responsibility. It was not apparent that this was the case.

Also, it was not apparent that communications between project officers and researchers were adequate. For example, some of the project officers presenting the research sponsored by the Agency were not thoroughly familiar with the work conducted. The Subcommittee believes that part of this problem may be due to inadequate technical skills in the in-house staff involved as project officers on these programs.

The Subcommittee believes that not enough is known about the environmental fate of the chlorinated dioxins and dibenzofurans. Without a more complete understanding of this issue, scientifically adequate risk assessments will be difficult to generate or justify. We believe this is particularly true for non-human biological populations where exposure estimates are largely unknown. This may be an area where the Agency could expand its efforts, since it has the requisite expertise.

The Agency needs to more carefully define and articulate its research role and capability with respect to other Federal agencies. This is particularly true with respect to the ongoing work at the National Institutes of Health and the Centers for Disease Control. Research carried out and/or sponsored by these and other agencies may not always adequately fulfill EPA's regulatory information requirements, but EPA should more clearly state what its needs are.

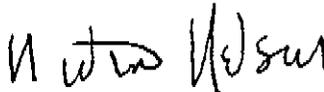
The Subcommittee reviewed the four major components of the dioxin research program--technology assessment, monitoring, environmental effects and health assessment. Technical comments on the strengths and weaknesses of these areas are included in the attached report.

We appreciate the opportunity to work with the Agency in improving the scientific base of knowledge related to dioxins and would welcome any additional requests for SAB participation in the range of dioxin issues facing the EPA. We would appreciate a formal response to the conclusions and recommendations included in this report.

Sincerely,



Robert Huggett, Chairman  
Dioxin Subcommittee



Norton Nelson, Chairman  
Executive Committee

REVIEW OF THE STATUS OF DIOXIN RESEARCH

IN THE

U. S. ENVIRONMENTAL PROTECTION AGENCY

Dioxin Research Review Subcommittee  
Science Advisory Board  
U. S. Environmental Protection Agency

January 1986

## EPA NOTICE

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August 1985

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Appendix A:

Agenda for the September 4-6, 1985 Meeting

## Introduction

At the request of the Deputy Administrator of the Environmental Protection Agency and the Acting Assistant Administrator for Research and Development (ORD), the Science Advisory Board (SAB) agreed to conduct scientific reviews of a number of ORD programs. The purpose of these reviews is to enable recognized, independent scientists and engineers to review ongoing research programs in order to: 1) communicate to the Agency the progress, or lack of progress, made in identifying the research needs and acquiring high quality technical data needed for risk assessment; 2) assess whether EPA has clearly stated the objectives of the program and ensured that individual projects are consistent with these objectives; 3) recommend steps to improve the structure and future direction of the research program. In August, 1985, the staff of the Office of Research and Development prepared a document entitled "Status of Dioxin Research in the U. S. Environmental Protection Agency", which they asked the SAB to review. The Board formed a Dioxin Research Review Subcommittee to evaluate these issues as they relate to dioxin research planned, sponsored or carried out by the Agency.

### A. The Mandate for EPA's Dioxin Research Program

Shortly after its formation in December, 1970, EPA began its dioxin research efforts after 2,3,7,8-tetrachlorodibenzo-p-dioxin was identified as a contaminant of the widely used herbicide 2,4,5-trichlorophenoxy acetic acid. At that time, the research focused on developing a methodology to detect 2,3,7,8-TCDD in environmental samples. With increasing public, scientific and Congressional interest and concern over dioxin contamination, EPA has expanded its research program to include human health and environmental effects, disposal methods and monitoring. The Congress has increased research to the level of \$2.4 million in Fiscal Year (FY) 1984 and \$3.0 million in FY 1985. Additional monies were allocated through the Superfund program for a demonstration of the mobile incinerator. In FY 1986, EPA plans to expend approximately \$3.7 million in dioxin related research. In addition, the Congress has directed EPA to study dioxins and other chlorophenols by monitoring specific dioxin contaminated areas and by performing a national screening study (the "National Dioxin Study") to identify the relative concentrations of dioxin in other areas of the United States.

In parallel with the increased Congressional and public concern over dioxin exposures, EPA formulated a National Dioxin Strategy, published in November, 1983. The Strategy represents an attempt to respond to the Congressional requirements and to integrate the numerous current research and regulatory efforts related to dioxins by assigning responsibilities to various EPA offices. The Strategy is subdivided into seven tiers, identified below by EPA staff in descending order of importance:

- Tier 1 ---- Current and former sites of 2,4,5-trichlorophenol production.
- Tier 2 ---- Current and former sites where 2,4,5-TCP was used as a precursor to develop another chemical product.
- Tier 3 ---- Current and former sites where 2,4,5-TCP and its derivatives were used to develop pesticides.
- Tier 4 ---- Assessment of combustion sources of dioxins.
- Tier 5 ---- Sites where 2,3,7,8-TCDD contaminated pesticides have been or are being used.
- Tier 6 ---- Production of other chemical products lending to the formation of 2,3,7,8-TCDD.
- Tier 7 ---- Control sites to evaluate background dioxin levels.

EPA has also participated in interagency exchanges of dioxin information through the Federal Agent Orange Work Group and in international forums, such as the North Atlantic Treaty Organization's Committee on Challenges to Modern Society.

EPA has completed, or has in progress, various remedial or regulatory actions that it implements through various authorizing statutes. Examples of these activities include:

- o Clean Air Act evaluation of dioxin as a hazardous air pollutant.
- o Banning of dioxin under Resource Conservation and Recovery Act waste stream listings, development of standards and guidance for land disposal and other treatment, storage and disposal techniques and design and operating guidelines for municipal waste incinerators.
- o Data acquisition and reporting requirements under the Toxic Substances Control Act to identify manufactured products that may lead to exposure to polychlorinated dibenzo-p-dioxins and/or polychlorinated dibenzofurans.
- o Remedial actions at hazardous waste sites authorized by the Comprehensive Environmental Response Compensation Liability Act (Superfund).
- o Clean Water Act Section 307 (a)(2) listings of hazardous pollutants in surface waters.
- o Pentachlorophenol Rebuttable Presumption Against Registration (RPAR) actions conducted under the auspices of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

- o Proposed Maximum Contaminant Levels for dioxins in drinking water set under decision criteria established by the Safe Drinking Water Act.

EPA's dioxin research program is designed to satisfy the technical data needs generated by these classes of activity. At present, the program has four major components:

- o Technology assessment--evaluating technologies for their capabilities to control, detoxify or ultimately destroy dioxins.
- o Monitoring--developing analytical techniques and quality assurance procedures to identify and quantify dioxins within biotic and aquatic matrices.
- o Environmental effects--considering the fate, mobility and effects of dioxins in the environment and their uptake and bioavailability in plants and living systems.
- o Health assessment--developing data and methodologies to evaluate human health exposure and risks associated with dioxins to provide the necessary documentation for exposure and risk assessments.

The Subcommittee received budget data for Fiscal Years 1984, 1985, and 1986 for each of these program areas.

#### B. Subcommittee Review Procedures

The Subcommittee met in public session in Las Vegas, Nevada on September 4-6, 1985 to review the dioxin research program. The Office of Research and Development prepared for the Subcommittee a briefing document entitled "Status of Dioxin Research in the U. S. Environmental Protection Agency" that described the program and its components as of August, 1985. The Subcommittee compliments the Agency staff for this useful documentation. Its review could not have proceeded as thoroughly and expeditiously in the absence of such a document. The Subcommittee recommends that the Agency distribute this document in revised form to the public and the Congress to further inform them of the ongoing dioxin research program.

The review meeting proceeded in three phases. EPA officials from various offices discussed the evolution of the dioxin-related activities since the formation of the Agency, the formulation of the National Dioxin Strategy and ongoing regulatory actions and information needs, the activities of various EPA regional offices, the development of the National Dioxin Survey and interagency and international coordination efforts. Second, the Subcommittee listened to in-depth briefings and provided technical comments on the four research program areas. The specific

research topics discussed within these areas are identified in the meeting agenda which is enclosed as Appendix A. Third, the panel held a planning and writing session to draft its key conclusions and recommendations.

### C. Organization of the Subcommittee Report

The Subcommittee presents its technical evaluation of the dioxin research program at three distinct levels. These include:

- o A review of the research program relative to the information needs articulated by the Dioxin Strategy and the regulatory offices, and identifying other technical needs not addressed by these means.
- o An assessment of the quality and direction of individual research program components: technology assessment, monitoring, environmental effects and human health assessment.
- o A critique of the merits of individual research projects encompassed in the dioxin research program.

At each of these levels, the Subcommittee presents its key conclusions and recommends changes in EPA's current and planned research efforts.

### Overview of the Dioxin Research Program

After reviewing the overall program, the Subcommittee concludes that EPA has made substantial progress in a number of areas in support of the Dioxin Strategy. As in any large program starting up in a crisis atmosphere, there are parts which, in hindsight, could have been designed better and which could now perhaps be redesigned or dropped, and the funds redirected to more promising research projects.

The current research program is a mixture of short-term fire-fighting and longer-range efforts. The need for action at Superfund sites, particularly in the case of dioxin contamination in Missouri, has brought rapid development and deployment of a mobile incinerator. Conversely, the crisis context within which the total program has had to exist has brought instability. Funding for a number of the projects for FY 1986, for example, was uncertain at the time of the Subcommittee's review. This has in part led to some unimaginative planning, examples of which are noted in this report.

The Subcommittee concludes that the overall management and direction of the program should be strengthened. We appreciate the difficulties of managing and directing a program that crosses numerous administrative boundaries and involves an array of scientific and engineering disciplines, some of which may be outside the expertise of the Program Director. Even so, a program of this magnitude and complexity requires a high, well-defined level of authority vested in the individual who has the management responsibility. It was not apparent that this was the case. Also, it was not apparent that communications between project officers and

researchers were adequate. For example, some of the project officers presenting the research sponsored by the Agency were not thoroughly familiar with the work conducted. The Subcommittee believes that part of this problem may be due to inadequate technical skills in the in-house staff involved as project officers on these programs.

EPA needs to carefully evaluate the limits of its ability relative to other Federal institutions to conduct human health research. Agencies such as the National Institutes of Health (NIH) and the Centers for Disease Control (CDC) are mandated to carry out these efforts. They are also more experienced in these types of endeavors. The Subcommittee does not imply that the Agency should not maintain a competent staff with an expertise in the human health effects of pollutants. It is essential that such a capability exist in order for EPA to fully evaluate the effects of environmental contaminants. The Subcommittee also recognizes that research carried out by other Federal agencies may not be adequate to fulfill EPA's regulatory information requirements. We recommend that EPA more explicitly state its role as a research agency in relation to these other dioxin related efforts and, in particular, articulate health research needs that are not likely to be addressed by NIH or CDC.

The Subcommittee believes that not enough is known about the environmental fate of the chlorinated dioxins and dibenzofurans. Without a more complete understanding of this issue, scientifically adequate risk assessments will be difficult to generate or justify. We believe this is particularly true for non-human biological populations where exposure estimates are largely unknown. This may be an area where the Agency could expand its efforts, since it has the requisite expertise.

We believe that the Agency's effort to become more involved in the international efforts to study and/or regulate dioxins is commendable, particularly in view of the considerable amount of research being conducted in other countries.

The creation of a dioxins research registry would also be useful for communication and coordination. This registry would contain information on all past and present dioxin projects in this country as well as abroad. It would provide immediate access to needed information by managers, scientists and engineers. The benefits of such a registry could range from better scientific designs for research to avoidance of duplication of effort.

#### Review of Technology Assessment

The options for the control, detoxification or destruction of dioxins are limited. They include storage, preferably by immobilization; chemical detoxification; thermal destruction; and separation from the bulk matrix.

The Agency has partially evaluated these options relative to existing technologies. Research is ongoing, but evaluations are not complete. The Subcommittee offers several comments concerning the appropriateness of available technologies:

- o Storage is only temporary, and a disproportionate use of this option will merely delay the disposal problem until some future time.
- o If proper disposal techniques can be developed, chemical treatment may be the most effective method for detoxifying material containing low dioxin concentrations.
- o Thermal destruction may be quite efficient for the elimination of dioxins in the presence of high concentrations of organic materials such as still bottoms and grossly contaminated soils.
- o Removing dioxins from the soil matrix, followed by their concentration, and thermal destruction may offer a useful compromise.

Future research efforts in this portion of the program should be designed with these points in mind.

#### Comments on Individual Technology Assessment Projects

##### Project I. In-Situ Stabilization

In-situ soil stabilization appeared to present only a temporary measure at best. Possibly it could be used as a holding action awaiting development of a better technology. Concrete, even if it was otherwise suitable, could present a problem if the soil is to be removed later for further treatment. Asphalt would itself be biodegradable in a moderate period of time and, hence, the dioxins would again be available. Plastics, such as epoxy, are susceptible to atmospheric weathering. A more stable product might result from vitrification. However, the merits and demerits of this technique to encapsulate organic components are currently unknown.

This project does not merit further funding.

##### Project II. B. White Rot Fungus

The Subcommittee emphasizes that the dioxin destroying ability of white rot fungus has been demonstrated only in solution under controlled laboratory conditions and, even here, a more rigorous demonstration is needed to confirm that the dioxin and not a chemical contaminant is being degraded. It is essential to determine whether the fungus can function in natural environments where physical obstructions to microbial movement may exist. Secondly, dioxin may not be readily available or it may be too strongly bound to the soil to be easily removed by the fungus.

Finally, the presence of competing microorganisms, predators, and parasites in the natural environment may prove to be detrimental to the effectiveness of this method. The Subcommittee suggests that field research, which is subject to many uncontrolled variables, not be conducted until studies with laboratory soil microcosms are completed and show positive results. Furthermore, such tests should be reviewed by personnel fully familiar with biological studies in soils or soil microcosms.

#### Project III. Shallow Mines as Repositories

If a cost-effective destruction process does not become readily available, storage in mines may be the most expedient short-term compromise. The means of packaging should be examined more carefully in relation to the planned storage life. Corrosion of metal drums and aging of plastic sacks should be taken into consideration. The drawback of this technique is that storage simply passes the problem on to future generations.

#### Project IV. Mobile Incineration

The Subcommittee believes that the Agency performed an excellent engineering job, under severe pressures for rapid completion, during the test burns of dioxin contaminated soil in Missouri. Results should be at least as good as the best of the commercial incinerators. The Subcommittee, however, believes, that for future use of the incinerator, the Agency should also analyze whether it is emitting toxicants not currently measured in the analyses of stack gases. Some Subcommittee members were concerned as to whether it was prudent to permit an operating range of up to 100 parts per million carbon monoxide before sounding the alarm. The Subcommittee suggests that modeling of the control system of the incineration process is desirable.

#### Project V. Chemical Detoxification Using Alkaline Polyethylene Glycol (APEG)

The data generated to date by experiments designed to determine the potential of APEG as a detoxifying agent lead the Subcommittee to believe that a field evaluation experiment is not warranted because it is not yet apparent that the substance has a likelihood of being effective. We recommend that laboratory experiments be designed and conducted to demonstrate its effectiveness under controlled conditions. These include soils of different types and different organic and moisture contents. The results should then be evaluated to determine its potential usefulness in the environment.

#### Review of Monitoring Research

The Agency stated two major goals for this component of the research program: 1) to produce standardized analytical procedures to detect and measure chlorinated dibenzo-p-dioxins in environmental samples, and 2) to establish quality assurance practices to support their routine use.

To achieve these goals, EPA has emphasized the development of well characterized standards of 22 tetra congeners of chlorinated dioxins and plans, in the future, to repeat the approach for the chlorinated dibenzo-furan congeners. The Subcommittee supports the basic approach presented by EPA, but we suggest a broader and more comprehensive program with more explicitly stated objectives. The following discussion, in part, indicates the areas that need expansion.

The Agency should develop a more detailed list of halogenated organics of present and possible future concern for the National Dioxin Strategy. This list should be cross-indexed with known and needed information on toxicity, and transport and fate. In all cases, these needs should be coordinated with other areas of the dioxin program. This listing, at a minimum, should contain all of the congeners of halogenated dibenzo-dioxins and dibenzo-furans. The Agency interest in the products of combustion, both from an industrial pollution as well as from a clean-up perspective, should lead to an immediate expansion of the listing beyond the organic compounds presently mentioned. Based on the preceding, the Agency should prepare a detailed three to five-year plan for synthesizing the necessary organic compounds in appropriate quantities.

The Agency significantly underestimates the present and future need for standard reference materials in a wide variety of matrices. These materials should be produced and documented not only to the specification associated with primary standards but also to mimic environmental matrices. An increased research effort, followed by a production effort, will be necessary to meet this need.

All meaningful environmental data, no matter how elegantly quantitated, are no better than the sampling protocol used. Improved sampling protocols need to be developed, particularly in conjunction with research projects. These improvements can be assisted by at least four approaches:

- o Incorporating well-planned sampling designs as part of the initial research plans. Even with the availability of excellent analytical methods, the data have little value unless they are derived from a program with an adequate and validated sampling design.
- o Recognizing sampling techniques as an important research focus.
- o Adding statisticians as part of the research team.
- o Using analytical methods with rapid screening capability to significantly increase the number of samples that could be processed.

This last point would not only have an effect on research but also on the service component. State public health laboratories have indicated that the development of screening methods in the environmental area is one of their greatest needs.

The development of a highly flexible and responsive analytical chemistry capability (standards, methods, and QC procedures) that is highly coordinated with a reserve service capacity is needed within the Dioxin Strategy in order to cope with emergencies. This capability should be based within EPA. Dioxin-contaminated sites are but one example where chemical emergencies have called for using unique analyses. These development and service demands were not off-the-shelf items. Many times, the issues at stake are of such importance that EPA should not rely only on contract laboratories to document the level of environmental contamination. The Agency should have the capability to conduct very highly sophisticated qualitative and quantitative analyses as part of its research program. Highly trained chemists in a wide variety of disciplines supported by the very latest equipment are necessary to solve these difficult analytical problems.

#### Comments on Individual Monitoring Research Projects

##### Project I. Methods Development for 2,3,7,8--TCDD

The development of a standardized method for measuring of 2,3,7,8-TCDD is of fundamental importance to the dioxin program. The EMSL (Las Vegas) staff clearly demonstrated the analytical expertise necessary to carry out this task by their significant progress in this project. The cooperation that is considered essential by the Subcommittee was shown to be present by the creation and functioning of the TROIKA. Although the laboratories were equipped for this project, there is a need to further modernize the equipment used.

##### Project II. Methods Development--Round Robin Survey

The coordinated use of resources among agencies involved in environmental programs is essential. This project demonstrates the Agency's ability to coordinate the use of in-house and external resources. One of the important objectives that is targeted for increased support in the preceding overview is the need for standard reference materials in a variety of matrices. The strength of this project was the material preparation and the determination of the dioxin concentration. However, increased attention to the complete and formal documentation of such material in the future will demand greater involvement of the research laboratory in the initial phases of such a project. Laboratory resources for this purpose must be maintained and highly coordinated inside EPA.

### Project III. Quality Assurance

The numerous congeners of dioxin increase the complexity of the analysis, making the availability of high quality standards essential to assure specificity. Cooperative programs between EPA and CDC to produce standards for the dioxins and furans is mutually beneficial and will increase cooperation in other areas of both agencies' environmental programs. The unresolved problem of the qualitative and quantitative characterization of the incineration emissions should become a high priority of the quality assurance effort.

### Project IV. GC/MS Methods Development

A more forward looking plan as part of the Dioxin Strategy is needed, and this project begins to address this issue. More staff and increased resources need to be directed beyond just the chlorinated dioxins and furans to other closely related halogenated products of combustion.

### Review of Environmental Effects Research

The development of exposure assessments requires an evaluation of the importance, first qualitatively and then quantitatively, of all likely pathways of contamination. Chemicals bound to soil particles are transported laterally with eroding soil and, thus, they contaminate aquatic sediments where many fish commonly feed. Many chemicals that persist in soil enter the air in significant amounts because of their volatility, and many are subject to aerial dissemination when emitted from municipal and industrial combustion processes. The significance of these modes of transport for dioxin should be established to provide a meaningful basis for evaluating and managing risks.

Since the purpose of this research is to provide an estimation of the critical elements in the exposure assessment models, any future efforts should specifically relate to the priority needs of the model.

EPA assigns low priority to the issue of dioxin transformations in nature. The chemical, for example, may be destroyed by photochemical reactions and, thus, aerial dissemination may not pose a hazard. Other means of transformation in air, water, sediments, and soils seem less likely in view of the apparent persistence of dioxin, but major information gaps may still exist. For example, there exists a slow microbial degradation of the chemical, but the rates of such degradation, the products of the reaction, and the human toxicity of these metabolites are unknown. Studies of these transformations are needed.

A study on transport and fate of dioxin should include at least the following scientific disciplines: chemistry, engineering, soil science, ecology and microbiology. At least one specialist in each of the disciplines must be intimately involved with the study in order to assure that the proper experimental design and subsequent interpretation of results occur.

## Comments on Individual Environmental Effects Research Projects

### Projects I and II. Fate of Dioxins and Sorption/Desorption

The results of two soil studies conducted thus far leave a number of unanswered questions. Except in special circumstances, vertical movement through soil to contaminate ground water does not appear to be a significant route for human exposure. However, movement in soil channels has yet to be evaluated, and its significance should be assessed. Research is required on other aspects of soil-dioxin transport.

Adequate information now exists that dioxin is strongly sorbed by soil constituents, and it is difficult to justify much additional research in this area in comparison to other major data needs. A major exception is the possible transport of dioxin through soil in the presence of organic chemicals in waste disposal sites. With the acknowledged slow mobility of dioxin through soil, shortterm studies with distilled water as the solvent (such as those that have been recently completed) can no longer be scientifically justified since the issue is mobility over long periods with constituents of soil solution or with organic solvents at those sites containing such chemicals. Even in these instances, the organic solvents must have prolonged persistence because their elimination by volatilization or biodegradation would result in an essentially immobile dioxin front.

### Project III. Uptake of Dioxins by Fish

Since a majority of the human exposure to dioxins is probably occurring through the unregulated activity of sportfishing, gathering data on the uptake and bioaccumulation by fish is critical. EPA should consider laboratory experiments utilizing benthic invertebrates that are detritivores, and organically bound dioxins. In general, the EPA scientists assessing dioxin uptake by fish are competent, and this research activity is off to a good start.

### Project IV. Uptake of Dioxins by Plants

The Subcommittee fails to see the significance of growing soybeans in solution culture for assessing the risk of dioxins. First, dioxins are almost entirely bound to soil. Second, the chemicals generally are all near the soil surface. Third, soybeans do not represent the type of plant present in areas where there may be significant soil contamination.

Nevertheless, more work is needed on the uptake of dioxins from contaminated soils, as well as translocation of the chemicals to edible portions of plants from root systems or from the aerial portions of plants likely to be exposed to dioxins from atmospheric fallout. Edible portions in this context refers to parts of the plant directly consumed by humans or entering the human food supply through livestock or other animals.

Some areas of future research on dioxin uptake by plants which may be useful include:

- o The potential relationship among the length of time of exposure of soil to TCDD, the introduction of plants to contaminated soil and the availability of TCDD for plant uptake.
- o The chemistry of TCDD in the soil solution in relation to uptake by terrestrial plants.
- o The possibility of different responses to TCDD by different species or categories of plants.
- o The physiological mechanisms of TCDD uptake and its translocation, fate, toxicity (if any), and/or metabolism (if any) in each plant species evaluated.
- o The effect of phenology on physiological processes involving TCDD activity in each plant species evaluated.

Research designed to add to our understanding of these areas would greatly increase our knowledge about the activity of TCDD and related compounds in both plants and the environment.

#### Projects V and VI. Uptake and Bioavailability of Dioxins by Animals

The study of the partitioning of dioxins to various tissues and organs within a dairy cow is strictly descriptive but still useful. The effects of anaerobic metabolism in the cow's rumen on the metabolism of dioxin should be considered in more detail. The partitioning of daughter products must be considered if metabolism does occur.

The guinea pig study needs a careful evaluation relative to its likelihood of generating data useful to the Agency. Black box experiments utilizing Times Beach and Newark soils leave a lot to be desired. A series of good experiments with controls or quantitative gradients of soil parameters and specific sets of mechanistic hypotheses should be developed.

#### Review of Health Assessment Research

The Subcommittee experienced difficulties in reviewing the Agency's health assessment work, in part because it was not clear how EPA's health research and/or assessment mission should be distinguished from that of other Federal agencies, particularly the Centers for Disease Control. Since EPA's information needs will not be met exclusively through studies conducted by other agencies, the Subcommittee understands the need for an EPA research program. Maintaining such a program will also enhance the Agency's capability to maintain inhouse expertise. The Subcommittee was not impressed with the Agency's efforts to date to define its health research mission for dioxins or to sustain a program that incorporates a critical mass of health effects studies over the long-term.

Comments on Individual Health Assessment Research Projects

Project I. Risk Assessment

A major effort should be made to reduce the various uncertainties in the risk assessments. Agency scientists clearly recognize the imprecision in these assessments, as indicated in part by a recently prepared EPA comparison of the assessment approaches used by EPA, CDC, and the Food and Drug Administration (the Subcommittee did not receive this document until after the Las Vegas meeting, so we did not have a full opportunity to discuss it). These assessments represent both the outcome of the ongoing research program and the feedback for planning future research and development. In the coming months, it will be important to dovetail the EPA laboratories' plans with the conclusions of the Health Assessment Document for Dioxins now being finalized by the Office of Health and Environmental Assessment. This is as much a research management problem as a technical one. The intentions listed in the background document prepared for this review are reasonable. These include updating and broadening the consideration of exposure and bioavailability, and studying such noncarcinogenic health effects as developmental toxicity and immunotoxicity.

Project II. Exposure Assessment.

Most of the exposure-estimation research presented to the Subcommittee has been addressed in other sections of this report. The average steady-state body burden of the general population needs to be analyzed and its implications considered for the regulation of both ambient and episodic environmental exposure to dioxins.

Project III. Pharmacokinetics in Rhesus Monkeys

This study at the University of Wisconsin, despite having gotten off to a weak start and involving only eight animals, is one of the few primate studies of TCDD being conducted anywhere. It holds valuable promise, and EPA should pursue it thoroughly. The pharmacokinetics deserve to be measured on more of the animals than those analyzed to date, especially to confirm the distribution, depuration rate, and intake/burden ratio; this information will be relevant to estimating these values in humans. The general and reproductive toxicology and pathology also need to be pursued.

Project IV. NIOSH Dioxin Registry

This is not fully an EPA research project, even though the Agency is partially funding it. The creation of a dioxins research registry would contain information on all past and present dioxin projects in this country as well as abroad. It would provide immediate access to needed information by managers, scientists and engineers. The benefits of such a registry could range from better scientific designs for research to avoidance of duplication of effort.

Project V. Monoclonal Antibody Assay

The Subcommittee was not impressed with the objectives or promise of this rather nonspecific assay work (conducted primarily by Oak Ridge National Laboratories). The preliminary results presented to us did not indicate that the assays are likely to detect dioxins or furans with

specificity in environmental samples, nor that they are likely to be able to detect these materials in the required parts-per-trillion range.

#### Project VI. Short Term Bioassays for TCDDs

Several approaches for screening environmental samples for dioxins were mentioned, but none was discussed in detail (except for the monoclonal antibody technique, above). We are not able to evaluate these lines of research. It is clear that rapid screening techniques are desirable.

#### Structure-Activity Relationship (SAR) Studies

Although the Subcommittee believes this approach is promising, the rather elaborate SAR project described did not seem to be important for solving the medium-term environmental dioxin problem. The Agency does need to develop experience with these methods, but because of the many dioxin congeners and the lack of correlated biological information it is not clear that the dioxin congeners make a good test case.

#### Marmoset Toxicology

The proposed marmoset research (in Germany) described to the Subcommittee seems interesting, in part because the animals are more tractable than many other primates. But because the reproductive system of female marmosets is very different from that of humans, the relevance for human protection is not direct. The Subcommittee was not convinced that this study is a high-priority research undertaking.

APPENDIX A

AGENDA

SCIENCE ADVISORY BOARD

REVIEW OF DIOXIN RESEARCH IN EPA

September 4-6, 1985

At the Environmental Monitoring and Systems Laboratory

Las Vegas, Nevada

September 4, 1985

8:00 a. m.	Introductory Remarks and Objectives	Erich Bretthauer
8:15 a. m.	SAB Perspective	Terry Yosie Robert Huggett
8:30 a. m.	<u>The Dioxin Problem:</u> An Interagency Perspective	Donald Barnes
9:15 a. m.	Dioxin Strategy and EPA Program Needs	John Milliken
10:00 a. m.	Coffee Break	
10:15 a. m.	<u>Dioxin Activities:</u> A Regional Perspective	Morris Kay Ralph Hazel
10:45 a. m.	<u>Dioxin Research in EPA:</u> Overview	Rizwanul Haque
11:00 a. m.	National Dioxin Survey	Norbert Jaworski
11:15 a. m.	Discussion	
12:00 noon	Lunch	
1:00 p. m.	<u>Review of Technology Assessment</u> <u>Research</u>	
	Introduction	Paul desRosiers
	o <u>In situ</u> Stabilization of Contaminated Soils	Don Sanning
	o Shallow Mines as Repositories	Don Sanning
	o Mobile Incineration	Frank Freestone
	o UV/APEG Detoxification	Charles Rogers
	o White Rot Fungus	Al Klee
	o PCB Transformer/Capacitor Wires	Al Klee
3:30 p. m.	Discussion	
5:30 p. m.	Social Hour	

September 5, 1985

7:30 a. m.	Executive Session Breakfast Meeting	
8:00 a. m.	Tour of the EMSL-Las Vegas Facility	
9:00 a. m.	<u>Review of Monitoring Research</u>	
	Introduction	Michael Dellarco
	o Methods Development for Dioxins	Ron Mitchum/ William Budde
	o Round Robin Survey for Adipose Tissue Analysis	Robert Harless
	o Quality Assurance and Reference Standards	Ron Mitchum
10:45 a. m.	Discussion	
11:15 a. m.	<u>Review of Environmental Effects Research</u>	
	Introduction	Rizwanul Haque
	o Sorption Characteristics of TCDD in Soils	Mike Roulier
	o Mobility of 2,3,7,8-TCDD	Marvin Piwoni
	o Bioavailability to Fish	Philip Cook
	o Bioavailability to Laboratory Animals	Rizwanul Haque
	o Uptake by Plants and Large Animals	Craig McFarlane
12:30 p. m.	Lunch	
1:30 p. m.	Discussion	
2:30 p. m.	<u>Review of Health Assessment Research</u>	
	Introduction	Charles Nauman
	o Risk Assessment for 2,3,7,8-TCDD	Charles Nauman
	o Exposure Assessment Methods	Charles Nauman
	o Pharmacokinetics in Rhesus Monkeys	Peter Voytek
	o Antibody Research	Michael Dellarco
	o Health Effects Research	Richard Phillips
4:30 p. m.	Discussion	
5:30 p. m.	Concluding Remarks	Erich Bretthauer Terry Yosie Robert Huggett

September 6, 1985

9:00 a. m. - 4:30 p. m. Subcommittee Report Preparation--  
Executive Session