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|---|---|
| **Item ID Number** | 05562 ☐ **Not Scanned** |
| **Author** | |
| **Corporate Author** | Interagency Work Group to Study the Possible Long-Ter |
| **Report/Article Title** | Progress Report |
| **Journal/Book Title** | |
| **Year** | 1980 |
| **Month/Day** | February 15 |
| **Color** | ☐ |
| **Number of Images** | 0 |
| **Descripton Notes** | |

# Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants

## PROGRESS REPORT

February 15, 1980

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INTERAGENCY WORKING GROUP TO STUDY THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDES AND CONTAMINANTS

## SUMMARY OF ACTIVITIES

The Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants met for the first time on February 1, 1980. The Interim Research Agenda attached at Tab B was prepared pursuant to discussions at that meeting.

Discussion at the meeting focussed on the first priority, allegations of health effects resulting from possible exposure to Agent Orange in Vietnam veterans. The Work Group believes that the most pressing need is for the design and conduct of studies that will determine if there is an increase in certain relevant diseases among Vietnam veterans and their offspring. If there is an increased prevalence of these diseases, the group should attempt to identify the possible association between phenoxy herbicides, dioxins or other related contaminants and these diseases. This course is to be taken because the alleged health effects encompass a broad variety of symptoms, many of which can be associated with a variety of agents. Although other agents may be responsible in whole or part for these diseases, this work group will focus only on the chemicals identified above.

It should be noted that conclusive results are not likely, at least in a short period of time. Any attempt to correlate a cause-effect relationship between Agent Orange (which definiti

time and concentration of exposure to U. S. troops is not accurately known) and an alleged pattern of illness that is nonspecific in nature is a tenuous undertaking. Most of the current activities listed separately in this report are directly applicable to the Agent Orange issue. Our plan is to complete the list of activities and commence evaluation to determine their current status and completion schedules and insure that the total effort is comprehensive. Of immediate interest is the proposed Operation Ranch Hand Study currently under review by the National Academy of Sciences, the VA's design of an epidemiology study, the current status of analytical methods for dioxin analyses, toxicology experiments that assess effects of an Agent Orange mixture on male mice and their progeny, and mutation experiments.

The Working Group has also proposed to commit itself to the development of a program that assesses the significance of dioxin contaminants on public health. To properly address this objective, all sources of dioxin exposure must be considered. Dioxins that contaminate phenoxy acid herbicides are a current major concern; other sources of dioxin exposure may be of equal or greater concern. Another family of chemical contaminants, the dibenzofurans, will also be considered since they are often found in products that contain dioxins and, based on toxicologic and medical evidence, the pattern of disease produced by the toxic members of these two chemical classes is similar, if not identical.

INTERAGENCY WORKING GROUP TO STUDY THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDES AND CONTAMINANTS

# INTERIM RESEARCH AGENDA

## I. Sources of Exposure

1. Identify chemicals known to be contaminated with TCDD, TCDF, other dioxins and dibenzofurans.

2. Determine the stages in the production process at which contamination occurs.

3. Quantify the magnitude of contaminant levels.

4. Consider the significance of other means of dioxin or dibenzofuran formation.

## II. Chemical Analyses

1. Determine the quantitative and qualitative reliability of methods, including human tissue analysis.

2. Estimate the quantitative limits of detection required in analyses of selected samples.

3. Determine the analytical standards required and procedures for their procurement.

## III. Human Health

1. Accidental or Occupational Exposures

   A. Evaluate the adequacy of ongoing or completed studies in assessing toxicities associated with exposures.

   B. Attempt to obtain more current information on health status of individuals involved in previous U. S. and foreign exposures.

2. Characterization of the Disease

   A. Determine the symptomology and clinical findings consistently associated with exposure.

B. Identify the toxicity parameters that may be associated with exposures.

C. Adduce the time frame from exposure that toxic symptoms appear and persist.

D. Consider whether dose response parameters can be developed.

3. Vietnam Veterans

A. Collate the alleged disease parameters.

B. Assure that epidemiology study designs will assess possible increases in alleged disease patterns, disease parameters associated with occupational or accidental exposures and selected toxicity parameters identified in laboratory toxicity experiments.

C. Review ongoing or completed activities, i.e., Ranch Hand; selection of appropriate ground troop population; tissue analyses, etc.

D. Determine the most reliable or acceptable means of presuming herbicide exposure.

E. Consider the significance of herbicide and contaminant exposure of military personnel not stationed in Vietnam.

IV. Laboratory Toxicology

1. Collate the comparative toxicity data for the dioxins and dibenzofurans; identify data gaps.

2. Consider comparative studies that correlate dose and duration of exposure with sequential development of toxic symptoms.

3. Reevaluate chemical disposition data as to adequacy.

February, 1980

DEPARTMENT OF AGRICULTURE

Studies on Phenoxy Acids, Dioxans or Related Contaminants

1. Epidemiology Study

The Office of Safety and Health Management (OSHM) is planning a feasibility study on U.S. Forest Service employees that have been exposed to phenoxy herbicides (2,4-D, 2,4,5-T and silvex) in forest management practices. Some of these employees have been exposed to phenoxy herbicides for close to 30 years. The study will begin with a review of job descriptions of various employees to document exposure. Depending on the results of this feasibility study, a larger morbidity and mortality survey may be undertaken.

Contact Person:
Dave Graham
447-8588

Estimated date of completion: June 1, 1980

2. Human Exposure Studies

The Science and Education Administration-Agricultural Research will conduct a human exposure study of pesticide applicators engaged in spraying 2,4-D under actual farm conditions. Participants will be selected from the Fargo, North Dakota and Pullman, Washington area where 2,4-D is used extensively for weed control in wheat. Exposure will be assessed by measuring 2,4-D

residues in dermal, inhalation and urine samples. The urine data will be put into a pharmacokinetic model to calculate the actual dose received during spray operations. Both ground and aerial applicators will be examined.

Contact Person:
Dr. P.C. Kearney
344-3533

Estimated date of completion: Fall-Winter 1980

3. TCDD Residues in Wildlife

An experiment is being conducted on 8 deer placed in an enclosure and treated with 2,4,5-T for conifer release programs. Samples of liver, fat and muscle tissues were taken from the deer at different time intervals after spraying The tissues are now being analyzed for TCDD residues by the University of Nebraska using gas liquid chromatography - mass spectrometry methods.

Contact Person:

Dr. Dave Graham
447-8588

Estimated Date of Completion: Summer 1980

December 8, 1979

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

DEPARTMENT OF DEFENSE (DOD) HERBICIDE ORANGE STUDY UPDATE

This is to follow up our meeting of December 4, 1979, and provide an update on all DoD study efforts to evaluate the long-term human health effects of herbicide orange.

The Air Force Ranch Hand study is our only ongoing human health effect effort. Since your last meeting with the Assistant Secretary of the Air Force (Manpower, Reserve Affairs and Installations), a number of previously discussed activities have now been accomplished:

- The formal protocol review tasking of the National Academy of Sciences (NAS), together with a $10,000 transfer of funds, was made on December 4, 1979;

- A protocol incorporating the comments and recommendations of the three previous peer review groups, the University of Texas at Houston, School of Public Health, the Air Force Scientific Advisory Board, and the Armed Forces Epidemiological Board, has been transmitted to the membership of the Herbicide Orange Sub-Committee of the Committee of Toxicology, Assembly of Life Sciences, NAS, for their review prior to the formal review meeting;

- NAS has established the date of December 18, 1979, for the Air Force formal presentation and the beginning of NAS sub-committee's collective consideration of the protocol;

- The Air Force has written to the NAS expressing its desire to have additional follow-on participation of the Academy in the study, and

- The Air Force has established contact with the Internal Revenue Service in order that former Ranch Hand members who separated from the service may be located. These individuals will probably be contacted and examined after the active duty and retired personnel.

A related activity to the Air Force Ranch Hand study is the DoD participation on the Veterans Administration Advisory Committee on Effects of Herbicides.

We will continue to keep you informed of our activities regarding the long term health effects of herbicide orange and look forward to being a participant on the Interagency work group.

George Marienthal
Deputy Assistant Secretary of Defense
(Energy, Environment & Safety)

February, 1980

ENVIRONMENTAL PROTECTION AGENCY

# Research Activities Related to Phenoxy Herbicides and their Dioxin Contaminants

## I. Chemical Analysis

### A. Methods Development (dioxins)

A multiple-lab participation system of analysis has been developed to obtain validated analyses of environmental samples contaminated with TCDD at very low levels. Current work is directed toward attaining the capability of analyzing samples from a wider range of environmental origins. At the same time efforts are underway to distinguish between the various TCDD isomers and to lower the size of the sample that is required for study.

### B. Studies in progress

1. Special studies (TCDD)

   The system referred to in A is being applied to specific samples derived from water, stream sediments, wildlife, dump sites, etc.

2. Monitoring (phenoxy herbicides)

   a. EPA's National Surface Water and Sediment Residue Network regularly obtains samples from the nation's major drainage areas and monitors them for concentrations of certain phenoxy herbicides

   b. In association with activities of the National Center for Health Statistics, EPA is analyzing urine samples from the general population in the U.S. for the presence and amount of certain herbicides.

## II. Investigation of combustion as a potential source of dioxin contamination

A study has been initiated to investigate the hypothesis that dioxins may be routinely formed during common combustion processes, such as those at power plants and incinerators.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STUDIES ON PHENOXY ACIDS, DIOXINS OR RELATED CONTAMINANTS

I. Epidemiological Studies

1. Establishment of a Dioxin Registry

NIOSH is establishing a registry of U. S. workers who have been exposed to dioxins and certain dioxin contaminated herbicides. The techniques used in establishing the registry will conform to those used by the World Health Organization so that results of the studies can be compared with those from other countries. The registry will allow an evaluation of the morbidity and mortality trends and attempt to identify any excess disease pattern associated with these exposures.

2. Occupational Surveys

a) Health Evaluation of 2,4,5-T workers in Nitro, West Virginia

b) Health Evaluation of 2,4,5-T workers in Jacksonville, Arkansas

c) Health Evaluation of pentachlorophenol workers in Sauget, Illinois.

3. Discussion in progress between NIEHS, NIOSH and International Agency for Research on Cancer, WHO, about update of 1978 report on Long Term Health Effects of Chlorinated Dibenzodioxins and Dibenzofurans.

II. Methods of Chemical Analysis

1. Development and validation of methodologies for tissue analysis of TCDD and related compounds

2. Synthesis of analytical standards for dioxins and dibenzofurans

DHEW Research Grant

| Project No. | Title |
|---|---|
| 5N01CP85945-01 | Polychlorinated Dibenzo-p-Dioxin and Dibenzofuran Synthesis |

III. Animal Toxicology Studies

1. "Agent Orange"

a. Effects of "Agent Orange" components on Male Fertility and Reproduction. A probe study in male mice using large doses of the constituents of Agent Orange to determine effects on fertility and ability to sire normal offspring. -Estimate initial report, July 1980.

b. Reevaluation of the mutagenic potential of components of Agent Orange. Studies of 2,4-D, 2,4,5-T, TCDD in microbial and Drosophila systems are in progress

2. 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD)

Evaluation of the Carcinogenic Effects of TCDD in Rats and Mice. Studies include groups with oral or skin exposure throughout lifespan. Estimate draft report available for peer review March 15, 1980.

DHEW Research Grants

| Project No. | Title |
|---|---|
| 5R01DE04333-03 | PCB and TCDD Orofacial Teratogenesis in M Mulatta |
| 5R01ES01339-03 | Implications of Low Level Exposure to Dioxins (Rats, Monkeys) |
| 5R01ES01552-03 | Mechanism(s) of Toxicity of the Chlorinated p-dioxins (Rats, Mice, Guinea Pigs) |
| 5R01ES01884-03 | Toxicology of Chlorinated Dibenzo-p-dioxins (Mice) |
| 5P01CA22484-02 | Biochemical Studies in Chemical Carcinogenesis |

3. Hexachlorodibenzo-p-dioxins (HCDD)

Evaluation of the Carcinogenic Effect of HCDD in Rats and Mice. Studies include groups with oral or by skin exposure throughout lifespan. Estimate peer review of draft report March 1, 1980.

4. Octachlorodibenzo-p-dioxin (OCDD)

a. Review of previous toxicology studies. Estimate completion March 30, 1980.

b. Studies of chemical disposition and metabolism of OCDD. Estimate completion September, 1980.

5. 2,3,7,8-Tetrachlorodibenzofuran (TCDF)

a. Comparative species evaluation of chemical disposition and metabolism of TCDF in rat, monkey and guinea pig. Estimate completion June 1980.

b. Teratology Evaluation of TCDF in rats or mice. In planning stage; estimated start - third quarter fiscal year 1980.

6. 2,4-Dichlorophenoxyacetic Acid (2,4-D)

Neurotoxicity of 2,4-D in rodents. Study in planning stage.

February, 1980

DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

The Occupational Safety and Health Administration is very concerned about the known and potential adverse health effects of workers exposed to phenoxy herbicides and 2, 3,7,8,-tetrachlorodibenzo-p-dioxin (TCDD) contaminants. The significant animal toxicity of TCDD makes careful exploration of the human toxicity of these materials mandatory.

To date, OSHA has been involved in several inspections where dioxin and TCDD contamination have occurred. Sampling has occurred during each of these inspections and has brought to our attention the analytical difficulties in quantitating dioxin contamination as well as the difficulty in separating TCDD from other tetrachlorodibenzo-dioxins. OSHA along with NIOSH has participated in the development of personal protective clothing and equipment recommendations for workers involved in a dioxin clean-up operation at a corporation in Jacksonville, Arkansas. The Department of Labor has also recently submitted a proposal to HEW to review and assess the problems and potential adverse health effects of dioxins.

OSHA recognizes that more information is needed on the long term health effects of dioxins and TCDD in humans as well as the adverse human health effects of low level exposures before an effective regulatory program can be achieved. OSHA welcomes the opportunity to participate on the Interagency Work Group to study the possible long term health effects of phenoxy herbicides and contaminants and the scientific panel to be headed by Dr. John Moore, to help achieve this goal.

December, 1979

VETERANS ADMINISTRATION

ACTIVITIES WITH REGARD TO HERBICIDES, PARTICULARLY AGENT ORANGE

Under the Administrator's direction, the Veterans Administration performed the following activities with regard to the issue of possible health related effects of exposure to herbicides, particularly Agent Orange, in Vietnam veterans.

1. Information Gathering. In order to assure that the VA has available the highest level of expertise on herbicides, an official Advisory Committee was chartered on April 20, 1979. It consists of representatives from Government and non-Government agencies who are actively involved in scientific activity related to herbicides. Supplementing this, the VA has made contacts with the DOD, EPA and HEW in order to stay knowledgeable on their herbicide related research

2. Dissemination of Information. Formal efforts have been made to inform VA professional staffs about the latest information on herbicides. These efforts have included: (a) An educational "White Paper" discussing herbicides; (b) Conference telephone calls to all VA medical facilities discussing the current medical and administrative aspects relating to the evaluation of Vietnam veterans possibly exposed to herbicides; (c) Written instructions to the VA medical centers (Circular 10-78-219) for the medical evaluations and reporting of veterans possibly exposed to herbicides in Vietnam; and (d) An educational conference in Washington, D. C. on herbicides for physicians representing each VA medical center.

The VA provided testimony in reference to herbicides and the VA medical programs to the Subcommittee on Medical Facilities and Benefits of the Veterans Affairs Committee of the House of Representatives.

An information conference was conducted in VA Central Office for representatives of the Service Organizations.

Individual veteran's correspondence and telephone calls have been replied to in an effort to answer specific questions and educate the veterans on current knowledge in relation to herbicides.

The Veterans Administration has participated in TV programs discussing the topic of herbicide exposure as it relates to the health status of the Vietnam veterans.

3. Performance of Research. The VA has set up a central registry which contains data obtained from performance of comprehensive medical examinations on Vietnam era veterans claiming exposure to herbicides. This registry will be utilized in the performance of a formal epidemiological study on the possible health related effects of herbicides in Vietnam veterans. The VA also is performing a pilot study of the feasibility and diagnostic usefulness of determining dioxin levels in the fat of veterans exposed to herbicides.

In addition to performing its own research, the VA has stimulated appropriate research efforts by other Federal agencies in areas where its expertise was limited. In this regard the VA Administrator has made written requests to DOD and HEW to engage in studies of herbicides outside of the VA's scope of expertise. Both requests have resulted in positive responses.

4. Provision of Health Care Services. Vietnam veterans were provided medical care for any illness, regardless of the etiology, which may have been uncovered during the course of an examination performed in relation to the herbicide program.

5. Processing of Compensation Claims for Herbicide Exposure. The VA processed some 750 claims for compensation arising from possible exposure of veterans to herbicides. Thus far, two claims have been adjudicated as being possibly related to herbicide exposure. These two veterans demonstrated evidence of a skin condition, chloracne.

INTERAGENCY WORKING GROUP TO STUDY THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDES AND CONTAMINANTS

ATTENDEES - February 1, 1980 Meeting*

Department of Health, Education and Welfare

Jodie Bernstein
David Andrews
Leslie Platt
Harold Margulies
Pat Honchar
Peter E. M. Beach
J. A. Moore
David Rall
Anne Cohn
Jacky Simon
Marian Troyer
Doug Hussey

Department of Labor

Stephen Mallinger
Patricia Breslin

Department of Defense

William S. Augerson
Peter Flynn
Jerome G. Bricker

Veterans Administration

Paul Haber
W. J. Jacoby, Jr.
Guy McMichael
Frederic Conway

Department of Agriculture

P. C. Kearney

Environmental Protection Agency

Donald Barnes

Office of Science and Technology Policy

Richard H. Adamson

* Final membership list being developed.