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**Author** Patton, Dorothy E.

**Corporate Author** U. S. Environmental Protection Agency (EPA)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
BEFORE THE ADMINISTRATOR

In re:

The Dow Chemical Company, et al.

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) FIFRA Docket Nos. 415, et al.  
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RESPONDENT'S COMMENTS ON RECENT DOW  
MEMORANDA IN SUPPORT OF COMPULSORY  
DOCUMENT DISCOVERY AGAINST DR. ALLEN

Dorothy E. Patton  
Kevin M. Lee  
Patricia A. Roberts  
Richard P. Bozof  
Timothy D. Backstrom

Counsel for Respondent

U.S. Environmental Protection  
Agency  
401 M Street, N.W.  
Washington, D.C. 20460

January 30, 1980

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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MEMORANDA IN SUPPORT OF COMPULSORY  
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INTRODUCTION

During the last two weeks, The Dow Chemical Company (Dow) has filed five memoranda or pleadings on the question of Dow's Motion for Compulsory Document Discovery Against Dr. James Allen. In the first and second memoranda and in the reply to the Agency's Opposition to Dow's Motion, Dow enlarges upon the bases for the discovery sought through this motion, and contends that documents which Dr. Allen has provided relating to the 500 ppt monkey study are "wholly inadequate."<sup>\*/</sup> (Second Supplemental Memorandum at 1). In the third memorandum and in the addendum to that memorandum, Dow recounts its attempts to obtain certain information relating to Dr. Allen's status at the University of Wisconsin, raises questions regarding the future course of Dr. Allen's work, and states concerns regarding the disposition of his records.<sup>\*\*/</sup>

<sup>\*/</sup> Supplemental Memorandum in Support of Compulsory Document Discovery, January 14, 1980; Second Supplemental Memorandum in Support of Compulsory Document Discovery, January 16, 1980; The Dow Chemical Company's Reply to OGC's January 21 Memorandum in Opposition, January 22, 1980.

<sup>\*\*/</sup> Third Supplemental Memorandum in Support of Compulsory Document Production Against Dr. James Allen, January 28, 1980; Addendum to Third Supplemental Memorandum in Support of Compulsory Document Production Against Dr. James Allen, January 28, 1980.

In this memorandum, Respondent addresses the questions which Dow raises in its most recent pleadings on this matter, and briefly restates the bases for the Agency's continuing opposition to Dow's motion for compulsory document discovery. Finally, the Agency requests that the Administrative Law Judge give special consideration to the impact on FIFRA cancellation proceedings of requiring third-party witnesses to release the preliminary results of ongoing studies.

COMMENT

As requested in Dow's most recent memoranda, Agency counsel have conferred with Dr. Allen and with counsel for the University of Wisconsin regarding the status of Dr. Allen's position and of his research at the University. Dr. Allen informs us that the research will continue under an interim investigator, and counsel for the University has informed us that a co-principal investigator has been appointed to continue Dr. Allen's research.

Counsel for the Agency and for the University agreed that there appeared to be no basis for Dow's concern that Dr. Allen's records might be lost, destroyed or transferred to an unknown third party. However, counsel for the University agreed to transmit Dow's concern to Dr. Allen and to instruct Dr. Allen that his records should not be lost, destroyed, or transferred to an unknown third person. Counsel for the University also indicated that his office will continue to work with and advise Dr. Allen regarding new issues arising out of Dow's motion. Counsel also re-iterated the position

stated in his January 17, 1980 letter (filed January 29, 1980) regarding the University's opposition to compulsory disclosure of work in progress. Respondent believes that this information and these assurances should allay Dow's concerns regarding the future of Dr. Allen's work and records.

The remainder of this comment briefly restates the Agency's position on matters relating to the compulsory production of the documents sought in Dow's motion for compulsory discovery. The recent pleadings indicate that Dow is dissatisfied with the information that Dr. Allen has produced to date, that Dow is curious, perhaps even anxious, about the results of the ongoing studies, and that Dow believes that the results of these studies may assist development of its affirmative case. However, dissatisfaction, curiosity, and anxiety are not bases for compulsory process under Agency regulations. Rather, the Administrative Law Judge may require Dr. Allen to produce the information Dow seeks only if he finds that the discovery sought will not in any way unreasonably delay the hearings, that the information to be obtained is not otherwise obtainable, and that such information has significant probative value. 40 CFR §164.51(a).

The Agency's continuing opposition to Dow's motion is based on factors indicating that the discovery sought does not meet the regulatory requirements<sup>\*/</sup> that information sought

<sup>\*/</sup> Because the starting date for the hearing has recently been changed, it is not clear whether issuance of subpoenas will have any impact on the start of the hearing. However, any prolonged litigation on the subpoena issue may delay the hearing because Agency counsel would be diverted from case preparation. Any such diversion and the related delay would be unreasonable in view of the availability of other means of obtaining the information sought and the uncertain probative value of the information sought.

through compulsory prehearing discovery have significant probative value and that the information is not otherwise obtainable. Two of the studies Dow seeks appear in the published literature. In addition, Dr. Allen has produced all of the data and laboratory records from the 500 ppt monkey reproduction study. Dow thus has the means to examine all data underlying this study, to detect defects in the study, and to explore other aspects of the study for use in preparing its case.

Similarly, the observations and conclusions in EPA's audit of the rat-range finding study are available to Dow and, indeed, Dow and the Agency have applied information in the audit to qualify the data presented in this study. Moreover, because Dow's own scientists, have conclusively established the carcinogenicity of TCDD, the rat-range finding study would appear to add little information of probative value to the existing information. Moreover, Dow could have obtained other information about this study through the interview which Dow refused to accept in November.

Respondent is particularly concerned about the lack of basis for compulsory production of records relating to the 25 and 5 ppt monkey reproduction studies. The probative value of many scientific studies depends in part on the degree of completeness of the study. In the early stages of scientific research, data is continually being generated which may supplement and complement numerical values as well change the

interpretation of data developed in early stages of the research. The biological meaning of pre-existing data is thus subject to change which may attend new data development. Any existing data generated from the 25 and 5 ppt monkey reproduction studies must be classified as early, incomplete scientific data of uncertain probative value.

Dow's request for these studies also fails to meet the criterion relating to the availability of the data by alternative means. In rejecting Dr. Allen's offer of an interview, Dow rejected an alternative method of acquiring the information it seeks. Further, the information Dow seeks can be elicited upon cross-examination. Moreover, if it appears at that time that the data should be disclosed prior to its completion, Dow may request issuance of a subpoena under 40 CFR §164.70.

While the Agency opposes the issuance of a subpoena for any of the studies which Dow seeks, we are particularly concerned that a precedent will be established in these hearings which will have serious, long-term consequences for the planning and conduct of future administrative proceedings under FIFRA. Our concern is based on the special circumstances presented by Dow's request for data from the 25 and 5 ppt studies. These studies differ from the 500 ppt and 50 ppt studies in several significant ways. Neither the 25 ppt or the 5 ppt study has been published in any form, nor has Dr. Allen publicly discussed the results of these studies.



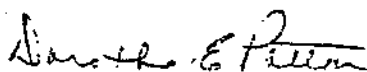
Indeed, his disclosure of the existence of these studies at the meeting of the FIFRA Scientific Advisory Panel was in response to a question from the Panel. Further, the Agency has not utilized any of the data in any aspect of its case preparation, and Dr. Allen will not be testifying on these studies in the course of the hearings. In short, Dow's interest in these studies does not give them a probative value which satisfies the criteria in Agency regulations.

Another Agency concern merits special attention. Issuance of a subpoena in this case would establish a precedent which may seriously hinder the Agency's ability to enlist the aid of third party witnesses in this and future cancellation proceedings. If Agency regulations are interpreted as authorizing the disclosure of data which has not been published in any form, which the Agency has not relied on in any form, and which has uncertain probative value, potential witnesses may understandably be reluctant to agree to participate in FIFRA proceedings. They may fear misuse of the data by the parties, or that their own scientific reputations may suffer from premature release of very incomplete and unvalidated information.

This result should be avoided in any case, but particularly where, as here, the information sought was available through an interview, will be available upon cross-examination, and may be obtained through a subpoena during the course of the hearing, if need be.

Respondent continues to oppose the compulsory discovery Dow seeks. In particular, Respondent is concerned that Dr. Allen not be required to disclose preliminary data from the incomplete 5 and 25 ppt monkey reproduction studies. Accordingly, Respondent respectfully requests that Dow's motion be denied.

Respectfully submitted,



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Dorothy E. Patton  
Kevin M. Lee  
Patricia A. Robert  
Richard P. Bozof  
Timothy D. Backstrom

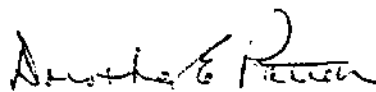
Counsel for Respondent

U.S. Environmental Protection  
Agency  
401 M Street, N.W.  
Washington, D.C. 20460

January 30, 1980

CERTIFICATE OF SERVICE

I hereby certify that copies of "Respondent's Comments on Recent Dow Memoranda in Support of Compulsory Document Discovery against Dr. Allen", were hand-delivered or mailed first class postage prepaid on January 30, 1980 to the persons on the attached list.

  
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Dorothy E. Patton

January 30, 1980

ACTIVE SERVICE LIST

Edward W. Warren  
L. Mark Wine  
Richard L. McConnell, Jr.  
Kirkland & Ellis  
Counsel for Dow Chemical Company  
1776 K Street, N.W.  
Washington, D.C. 20006

William A. Butler, Esq.  
Jacqueline M. Warren, Esq.  
Counsel for Environmental Defense  
Fund, Inc.  
1525 - 18th Street, N.W.  
Washington, D.C. 20036

Margaret M. Breinholt  
Judith A. Wenker  
Terrence G. Jackson  
Room 2036, South Ag. Bldg.  
Office of the General Counsel  
U.S. Department of Agriculture  
Washington, D.C. 20250

Marla Gillham  
Northwest Coalition for  
Alternatives to Pesticides, Inc.  
454 Willamette Street  
Eugene, Oregon 97401

Allen A. Lauterbach  
C. David Mayfield  
John J. Rademacher  
American Farm Bureau Federation  
425 13th Street, N.W.  
Washington, D.C. 20004

Elizabeth M. Whelan, Sc. D., M.P.H.  
Executive Director  
American Counsel on Science & Health  
1995 Broadway  
New York, New York 10023

Robert S. Kirk, Jr., Esq.  
Counsel for Vertac, Inc.  
2414 Clark Tower  
5100 Poplar Avenue  
Memphis, Tennessee 38137

Richard J. Wertheimer, Esq.  
Arnold & Porter  
Counsel for National Forest  
Products Association  
1229 Nineteenth Street, N.W.  
Washington, D.C. 20036

Sonia G. Anderson  
Hearing Clerk (A-110)  
U.S. Environmental Protection  
Agency  
401 M Street, S.W.  
Washington, D.C. 20460

Stephen W. Jacobson  
Joseph E. Stevens, Jr.  
William Ray Price, Jr.  
Lathrop, Koontz, Righter,  
Clagett, Parker & Norquist  
2600 Mutual Benefit Life Building  
Post Office Box 1200  
2345 Grand Avenue  
Kansas City, Missouri 64108