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Corporate Author The Dow Chemical Company

Report/Article Title Environmental Protection Agency (EPA) Before the Administrator, In re: 2,4,5 -Trichlorophenoxyacetic Acid (2,4,5 -T), F.I.F.R.A. Docket Number 295, et al., Dow Prehearing Memorandum (No. 4)

Journal/Book Title

Year 1974

Month/Day March 21

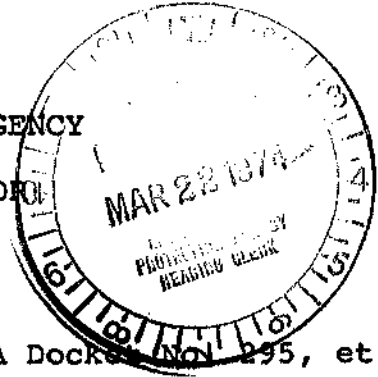
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Descripton Notes

ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR



In re

2,4,5-Trichlorophenoxyacetic
Acid (2,4,5-T)

)
)
) FIFRA Docket No. 295, et al.

DOW PREHEARING MEMORANDUM (NO. 4)

This memorandum is submitted in compliance with the direction of the Chief Administrative Law Judge at the first Prehearing Conference, as modified by the Order dated February 20, 1974. It will be organized as follows:

- A. Witnesses Dow anticipates calling to testify at the Hearing during its affirmative case.
- B. Dow responses to March 11, 1974 submissions of other parties.
- C. Dow Proposed Agenda for March 26, 1974, Prehearing Conference.

A. Dow Witnesses. The following identifies the witnesses whom Dow presently anticipates calling to testify at the Hearing during Dow's affirmative case. It includes a summary of anticipated testimony in the form requested by the Chief Administrative Law Judge.

Most of the listed witnesses are toxicologists, analytical chemists or other scientists in Dow's employment. Ordinarily only one witness has been named in each area, in order to avoid cumulative testimony. However it may be necessary at some later time to request permission to add or substitute one or more other scientists in the same specialty to testify with regard to the same subject matter, for corroboration or because of the unavailability of a witness on account of illness or other special circumstance. The primary difference between the new witness or witnesses and the person listed will be in background and qualifications. Any such request will be made as promptly as possible.

In addition to the specific area of testimony identified in connection with each witness, as supplemented by the bibliography,* each witness will testify with regard to the fundamentals of his own specialty. Thus, for example, witnesses in the teratology area will testify regarding research methodology and witnesses testifying with respect to analytical chemistry will describe the problems incident to distinguishing true findings from background interference or "noise".

* Documents listed in the bibliographies which Dow intends to offer into evidence during its affirmative case will be included in Dow's third Document Repository submission, to be made shortly. However, copies of any bibliography references will be furnished to any party now on request, including those which will probably be used by the witness only for purposes of illustration (such as sample forms).

Dow's identification of anticipated witnesses is based in part upon the January 18 and March 11 submissions of Respondent and EDF. Those submissions set forth positions and identify issues. To the extent that Respondent's and EDF's evidence at the Hearing materially extends beyond these earlier submissions, it may of course be necessary for Dow to request permission to call additional witnesses.

Dow's witness list is also based in part upon the January 18 and March 11 submissions of parties aligned with registrants. Those parties have identified the areas for which they are assuming primary responsibility and in which they expect to adduce evidence. The March 21 submissions of such parties will identify the witnesses they intend to call. To the extent that Dow considers that the lists of witnesses to be called by such parties may not entirely cover the evidentiary areas concerned, it may wish to call additional witnesses. For example, in its January 18 submission AFBF indicated that it intended to assume responsibility for the introduction of evidence bearing on the rice use/benefit area and that it expected to call 3-5 farmer witnesses in this connection. Dow in its January 18 submission stated that it had been preparing this area and expected to call 20 to 30 witnesses, but that it would defer to AFBF. The disparity between the anticipated numbers of Dow and AFBF witnesses may have been because Dow's estimate

included many others besides farmers, such as aerial applicators, distributors and university extension personnel. Dow has not identified any rice use/benefit witnesses below, but may wish to supplement this list after it reviews the AFBF March 21 submissions to the extent such other categories of witnesses are not included. It will do so in its April 5, 1974 submission.

Name: E. L. Bjerke

Address: Senior Research Chemist
Residue Research
Ag-Organics Department
Dow Chemical U.S.A.
P. O. Box 1706
Midland, Michigan 48640

Background: MS - Organic Chemistry

Area of Testimony: Mr. Bjerke will testify regarding 2,4,5-T, TCDD and 2,4,5-Trichlorophenol residues in milk.

Bibliography: DD160, DD164

Name: E. H. Blair

Address: Director, Health and Environmental Research
Dow Chemical U.S.A.
2020 Dow Center
Midland, Michigan 48640

Background: Ph.D. - Organic Chemistry

Area of Testimony: Dr. Blair will testify regarding the history and organization of the Dow 2,4,5-T

effort. He will introduce each of the scientific and other areas involved and identify its relationship to the whole.

Bibliography:

1973. Modern Methods of Research and Analysis (Dow, Rev. Ed. 1973).

Other samples of Dow internal environmental and informational materials, including the weekly "Reports Received Bulletin" and monthly "R&D Document Summaries".

Blair, E. H. 1971. Editor, Chlorodioxins -- Origin and Fate. A Symposium sponsored by Div. of Pesticide Chemistry ACS. Advances in Chemistry Series 120.

1973. American Chemical Society. Chemistry in the Economy -- Pesticides. Social and Economic Impacts. Chapter 11, p. 226-43.

Name: Warren B. Crummett

Address: Research Scientist
Technical Manager Analyses
Laboratory
Dow Chemical U.S.A.
574 Building
Midland, Michigan 48640

Background: Ph.D. - Chemistry

Area of Testimony: Dr. Crummett will testify regarding the interpretation of data suggesting the presence of chemical compounds at extremely low levels (parts per trillion)

and findings with respect to TCDD levels in current manufacture and in residue research.

Bibliography:

DD112 (also EPA1).

Exchange of correspondence between C.W. Collier and others regarding Dec. 13, 1973 EPA conference considering low level (ppt) analyses.

Name:

James L. Emerson

Address:

Pathologist, Dept. of Pathology
and Toxicology
Indianapolis Division Life Science Dept.
Dow Chemical U.S.A.
P. O. Box 68511
Indianapolis, Indiana 46268

Background:

D.V.M., M.S., Ph.D. Pathology

Area of Testimony:

Dr. Emerson will testify regarding 2,4,5-T teratology studies in rats and rabbits.

Bibliography:

DD13 (also EPA1 and USDA1-6),
DD180 (also EPA1 and EDF15).

Name:

Perry J. Gehring

Address:

Director, Toxicology Laboratory
Health and Environmental Research
Dow Chemical, U.S.A.
1803 Building
Midland, Michigan 48640

Background:

D.V.M., Ph.D. Pharmacology

Area of Testimony:

Dr. Gehring will testify regarding the toxicology of 2,4,5-T and TCDD, including specifically accumulation and the differences between the effects

of large and normal doses.

Bibliography:

DD27, DD31, DD34, DD36, DD41,
DD42, DD43, DD44, DD52, DD123
(also EPA1, EDF35, USDA1-27),
DD155, DD156, DD157, DD159,
DD176 (same as DD123), DD178,
DD180 (also EPA1 and EDF15),
DD181.

Albert, A. (1968) Selective Toxicity, Methuen & Co.,
LTD, London, 4th Ed.

Gessner, P.K., Parke P.V. and Williams, R.T. (1961)
Studies in detoxication. 86. The metabolism of
¹⁴C-labeled ethylene glycol. Biochem. J. 79:482-489

Goldenthal, E.I. "Goldenthal Letter" Acting Deputy
Director, Office of New Drugs, Bureau of Medicine,
Food and Drug Administration, Washington, D.C. 26204.
Dated July 15, 1968, sent to every pharmaceutical
and industrial Company in the United States.

Greig, John. Personal communication dated 9th April,
1973.

Kanna, S. and Fang, S.C. Metabolism of ¹⁴C-labeled
2,4-dichlorophenoxyacetic acid in rats. J. Agr.
Food Chem. 14:500-503, 1966.

Matsumura, A. The fate of 2,4,5-trichlorophenoxy-
acetic acid in man. Jap. J. Ind. Hlt. 12:20-25,
1970.

McChesney, E.W., Golberg, L., Parekh, Russell, J.C.
and Min, B.H. Reappraisal of the toxicology of
ethylene glycol. II. Metabolism studies in lab-
oratory animals. Fd. Cosmet. Toxicol. 9:21-28.

Quinn, G.P., Axelrod, J. and Brodie, B.B. (1958)
Species, strain and sex differences in the meta-
bolism of hexobarbitone, amidopyrine, antipyrine
and aniline. Biochemical Pharmacol. 1:152.

Vos, J.G., Moore, J.A., and Zinkl, J.G. Toxicology
of 2,3,7,8-tetrachlorodibenzo-p-dioxin(TCDD) in
C-57Bl/6 mice. Tox. Appl. Pharmacol. (In Press).

Weil, C.S., Carpenter, C.P. and Smyth, H.F. Urinary
bladder calculus and tumor response following either
repeated feeding or diethylene glycol or calcium
oxalate stone implantation. Med. Sur. 36:66-67, 1967.

Name: Milton E. Getzendaner

Address: Research Manager
Residue - Environmental -
Metabolism
Ag-Organics Department
Dow Chemical U.S.A.
P. O. 1706
Midland, Michigan 48640

Background: Ph.D. - Organic Biochemistry

Area of Testimony: Dr. Getzendaner will testify regarding 2,4,5-T and TCDD residue levels in grass and certain other food crops.

Bibliography: DD48, DD49, DD51, DD108, DD120, DD127, DD148-151, DD153, DD157, DD160, DD161, DD164-173 (DD173 also EPA5), DD174, DD175, DD188.

Anonymous, Agr. Res. 21, No. 4, p. 6 (1972).

Getzendaner, M.E., Down To Earth 28, No. 1 pp. 24-29 (1972).

Miller, P.W. Report of The Dow Chemical Company, GH-C 650 (April 26, 1973).

Statistical abstracts of the U.S. 1972, 3rd Annual Edition, U.S. Dept. of Commerce, Bureau of Census (1972). New York 7-9 million, Queens Borough 2.0 million = 9.9 million people.

Name: Harold Gordon

Address: Director, Corporate Medical
Department
Dow Chemical U.S.A.
2030 Dow Center
Midland, Michigan 48640

Background: M.D.

Area of Testimony: Dr. Gordon will testify regard-

ing studies of employees exposed to 2,4,5-T during production operations.

Bibliography: DD50

Name: James Robert Grumbles

Address: Field Specialist - Herbicides
Ag-Organics Department
Dow Chemical U.S.A.
Lubbock, Texas 79408

Background: Ph.D., Range Management

Area of Testimony: Dr. Grumbles will testify regarding the rangeland use of 2,4,5-T.

Name: David J. Jensen

Address: Research Scientist
Residue Research
Ag-Organics Department
Dow Chemical U.S.A.
P. O. Box 1706
Midland, Michigan 48640

Background: Ph.D. - Biochemistry

Area of Testimony: Dr. Jensen will testify regarding residues of 2,4,5-T and TCDD in meat.

Bibliography: DD36, DD48, DD49, DD108, DD121, DD164, DD165, DD167, DD169, DD173 (also EPA5), USDA-2-3.

Bache, C.A., D.J. Lisk, D.G. Wagner, and R.G. Warner. J. Dairy Sci. 47, 93 (1964),

Clark, D.E., J.E. Young, R.L. Younger, L.M. Hunt, and J.K. McLaran. J. Agr. Food Chem. 12, 43 (1964).

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- Khanna, S. and S.C. Fang. J. Agr. Food Chem. 14, 500 (1966).
- Khanna, S., V. Rao, and S.C. Fang. "Metabolism of C¹⁴-Labeled 2,4-D and Plant transformation Products of 2,4-D in Rats." Presented at the 20th Northwest Regional Meeting of the American Chemical Society in Corvallis, Oregon (June, 1965).
- Klingman, D.L., C.H. Gordon, G. Yip, and H.P. Burchfield. Weeds 14, 164-167 (1966).
- Lisk, D.J., W.H. Gutenmann, C.A. Bache, R.G. Warner, and D.G. Wagner. J. Dairy Sci. 46, 1435 (1963).
- Maxie, E.C., M.V. Bradley, and B.J. Robinson. Proc. Amer. Soc. Hort. Sci. 81, 137 (1962).
- Morton, H.L., F.S. Davis, and M.G. Merkle. Weed Science 16, 88 (1968).
- Slife, K.W., J.L. Key, S. Yamaguchi, and A.J. Crafts. Weeds 10, 29 (1962).
- Yip, G. and R. Ney. Weeds 14, 167 (1966).

Name: Julius E. Johnson

Address: Vice-President, The Dow Chemical Company
 Manager, Life Sciences Department
 2030 Dow Center
 Midland, Michigan 48640

Background: Ph.D. - Biochemistry

Area of Testimony: Dr. Johnson will testify regarding the overall Dow effort in the environmental area, including its Ecology Council, its Product Stewardship policy and the need for application of the rule of reason in all aspects of corporate management and operations.

Bibliography: Dow organization chart.
1973 Annual Report.

Name: Eugene E. Kenaga

Address: Associate Scientist
Health and Environmental Health
Research Dept.
Dow Chemical U.S.A.
P. O. Box 1706
Midland, Michigan 48640

Background: M.A. - Entomology

Area of Testimony: Mr. Kenaga will testify regarding evaluation of the impact of 2,4,5-T and TCDD on the environment, particularly fish and wildlife.

Bibliography: DD103, DD105, DD106, DD107, DD109
DD110.

Young, A.L., C.E. Thalken, W. E. Ward and W. J. Cairney. 1974. The Ecological Consequences of Massive Quantities of 2,4-D and 2,4,5-T Herbicides -- Summary of a Five Year Field Study. Presented at Weed Science Society of America, Las Vegas, Nevada, 14 February 1974. Abstract No. 164.

Young, A.L., E.L. Arnold and A.M. Wachinaki. 1974. Field Studies on the Soil Persistence and Movement of 2,4-D, 2,4,5-T and TCDD. Presented at Weed Science Society of America, Las Vegas, Nevada, 13 February 1974. Abstract No. 226.

Name: D. J. Kilian

Address: Director
Industrial Medicine, Toxicology,

and Biomedical Research Laboratory
Dow Chemical U.S.A.
Freeport, Texas 77541

Background: M.D.

Area of Testimony: Dr. Kilian will testify regarding the non-mutagenicity of 2,4,5-T based on karyotyping studies of exposed Dow workers.

Name: Richard J. Kociba

Address: Research Pathologist - Toxicology
Laboratory
Health and Environmental Research
Dow Chemical U.S.A.
1803 Building
Midland, Michigan 48640

Background: D.V.M., Diplomat, American Veterinary Pathologists
Ph.D. - Pathology

Area of Testimony: Dr. Kociba will testify regarding the toxicity of 2,4,5-T and TCDD based on ninety-day studies of repeated oral doses on rats.

Bibliography: DD43, DD44, DD181

Name: Horst G. Langer

Address: Associate Scientist
Dow Chemical U.S.A.
Eastern Research Laboratory
P. O. Box 400
Wayland, Massachusetts 01778

Background: Diploma in Chemistry
D.Sc. - Chemistry
Technical University,
Braunschweig, Germany

Area of Testimony: Dr. Langer will testify regarding the formation of TCDD from thermal stress of 2,4,5-T under ordinary environmental conditions.

Bibliography: DD101 (also EPA1, EDF3), DD154 (also EPA1, EDF4), EDF38 (also EPA1), EPA2 (also EDF5).

Langer, H.G., et al., Chlorodioxins - Origin and Fate, E.H. Blair, ed., Advances in Chemistry Series, pp. 26-32 (1973)

Name: Fumio Matsumura

Address: Professor of Insect Toxicology
Dept. of Entomology
University of Wisconsin
Madison, Wisconsin 53703

Background: Ph.D. - Zoology

Area of Testimony: Dr. Matsumura will testify regarding the bioaccumulation and degradation of TCDD.

Bibliography: DD129 (also EPA1 and EDF36)

Name: Donald D. McCollister

Address: Manager, Product Registration
Section
Health and Environmental Research
Dow Chemical U.S.A.
P. O. Box 1706
Midland, Michigan 48640

Background: B.S. - Industrial Chemistry

Area of Testimony: Mr. McCollister will testify regarding the mammalian toxicology of 2,4,5-T registration and cancellation proceedings; and label and use precautions.

Bibliography: DD30, DD36, DD41, DD42, DD43, DD44, DD45, DD46, DD47, DD108, DD174, DD182-187.

Name: Robert E. Naegele

Address: Manager, Ag-Organics Department
Dow Chemical U.S.A.
P. O. Box 1706
Midland, Michigan 48640

Background: B.S. - Engineering
M.S. - Organic Chemistry

Area of Testimony: Mr. Naegele will testify regarding the marketing of 2,4,5-T.

Name: Jesse M. Norris

Address: Research Specialist in Toxicology
Health and Environmental Research
Dow Chemical U.S.A.
1803 Building
Midland, Michigan 48640

Background: M.S. - Zoology

Area of Testimony: Ms. Norris will testify regarding toxicological studies of TCDD and, to the extent in issue, the relative toxicological properties of the other dioxins which may occur in 2,4,5-T.

Bibliography: DD3, DD24, (also EPA27, EDF7, USDA 1-35), DD28, DD52, DD53, DD180 (also EPA1 and EDF15), USDAL-16, EPA 22, EPA 24.

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Arbeitshygiene 3, 25.

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Tomita, M., Ueda, S. and Narisada, M. (1959). Dibenzop-dioxin derivatives. XXVII. Synthesis of polyhalodibenzo-p-dioxin. Chem. Abst. 53, 13152.

Vos, J.G. and Beems, R.B. (1971). Dermal toxicity studies of technical polychlorinated biphenyls and fractions thereof in rabbits. Toxic. Appl. Pharmac. 19, 617.

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Yartzoff, A., Firestone, D., Banes, D., Horwitz, W., Friedman, L. and Nesheim, S. (1961). Studies of the chick edema factor. II. Isolation of a toxic substance. J. Amer. Oil Chem. Soc. 38, 60.

Name: Virgil B. Robinson

Address: Director, Dept. Pathology and
Toxicology
Indianapolis Division Life
Sciences Dept.
Dow Chemical U.S.A.
P. O. Box 68511

Indianapolis, Indiana 46268

Background: M.S., D.V.M., Ph.D. - Comparative Pathology

Area of Testimony: Dr. Robinson will testify regarding the teratogenicity studies of 2,4,5-T on rats and rabbits.

Bibliography: DD13 (also EPA16 and USDA1-6)

Choudhury, B. and Robinson, V. B. Clinical and Pathologic Effects Produced in Goats by the Ingestion of Toxic Amounts of Chlordan and Toxaphene. Am. J. Vet. Res., 11 (1950):50-57.

Cooperrider, D. E., Robinson, V. B. and Staton L. Dioctophyma Renale in a Dog. J.A.V.M.A., 124 (1954):381-383.

Johnston, R. V., York, C. J., Robinson, V. B. Brueckner, A. H., and Burch, G. R. Immunology of Canine Distemper. Vet. Med. August (1959):405-412.

Johnston, R. V., Robinson, Virgil, and Mayer, Karl. Use and Abuse of Modified Live Virus Vaccines. Allied Veterinarian (May-June) 1958.

Molello, J. A., Gerbig, C. G., and Robinson, V. B. Toxicity of [4,4'-(Isopropylidenedithio)bis(2,6-di-*t*-butylphenol)], Probucol, in Mice, Rats, Dogs and Monkeys: Demonstration of a Species-Specific Phenomenon. Toxicology and Applied Pharmacology, 24, 590-593 (1973).

Newberne, James W., Robinson, Virgil B., and Rising-Moore, Fred. Hemolytic Anemia in Baby Pigs--Report of a Case. J.A.V.M.A. 129: 8 (1956) 361-363.

Newberne, J. W., Johnston, R. V., and Robinson, V. B. Studies on Clinical and Histopathological Aspects of Feline Panleukopenia (Infectious Enteritis). Southwestern Vet., 10 (1957) Winter Issue.

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- Newberne, J. W., Robinson, V. B., and Alter, Mary L. Incidence of Infectious Bovine Rhinotracheitis and Bovine Virus Diarrhea. *Vet. Med.*, 56: 9 (1961) 395.
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- Robinson, Virgil B. and Schell, Fred G. Blastomycosis in a Dog. *N. Am. Vet.*, 32 (1951):555-558.
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York, C. J., Johnston, R. V., and Robinson, V. B. Vaccines in the Control of Leptospirosis in Cattle and Swine. Proc. Am. V. M. A. Meeting (August) 1955.

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Background: M.S. Biochemistry
Sc.D. (honorary)

Area of Testimony: Dr. Rowe will testify regarding the toxicology of 2,4,5-T and TCDD generally, as foundation for the testimony of scientists in specific areas.

Bibliography: DD20 (also USDA1-34), DD24 (also EPA27, EDF7, USDA1-35), DD25, DD41, DD52, DD180 (also EPA1 and EDF15), EDF11.

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Lehman, A.J. 1952. Chemicals in Foods: A Report to the Association of Food and Drug Officials on Current Developments. Part V. Pathology.

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Background: D.V.M., Ph.D. - Pharmacology

Area of Testimony: Dr. Schwetz will testify regarding the effects of 2,4,5-T and, to the extent in issue, the chlorinated dibenzo-p-dioxins, on the developing embryo and fetus.

Bibliography: DD1 (also EDF21), DD3 (also EPA17, EDF22 and USDA1-5), DD4, DD5 (also EPA18), DD6 (also EPA19), DD7, DD13 (also EPA16 and USDA1-6), DD14 (also USDA1), DD15, DD16, DD17 (also USDA1-2), DD18, DD19 (also USDA1-19), DD20 (also USDA1-34), DD21, DD22, DD23, DD24 (also EPA27, EDF7, USDA1-35), DD25, DD27, DD28, DD52, DD163 (also USDA1-29, EDF1) DD180 (also EPA1 and EDF15), DD181.

Stotzer and Niggerschutzer, Private Communications, Dec. 10, 1970 and June 18, 1971.

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Background: M.D., Ph.D. - Pharmacology

Area of Testimony: Dr. Seevers will testify to the

"dose response" and "no effect" level concepts and the extrapolation of observed effects to probable effects at other levels of activity.

Bibliography: "Perspective Versus Caprice In Evaluating Toxicity of Chemicals in Man," 153 Jo. of AMA 1329-33 (Dec. 12, 1953).

Name: Rudolph H. Stehl

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Background: Ph.D. - Analytic Chemistry

Area of Testimony: Dr. Stehl will testify regarding the difficulty of identifying compounds at extremely low levels (e.g., parts per trillion) and the formation of TCDD as the result of the thermal stress of 2,4,5-T.

Bibliography: DD102, DD112 (also EPA1), DD133, DD179, DD188, DD189 (EPA4).

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Background: B.Sc. - Chemical Engineering

Area of Testimony: Mr. Theis will testify regarding the levels of TCDD in Dow's current 2,4,5-T production.

Bibliography: Sample forms of Dow production

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Name: Sylvan H. Wittwer

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Michigan State University
East Lansing, Michigan 40823

Background: Ph.D. - Horticulture

Area of Testimony: Dr. Wittwer will testify regarding
the use of 2,4,5-T for maximum pro-
duction of food crops.

Bibliography: Wittwer, S.H. January 4, 1974. Max-
imum Production Capacity of Food
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B. Dow Responses to March 11, 1974 Submissions.

The January 18, February 22 and March 11 exchanges of memoranda have gone far towards identifying and refining the ultimate issue in this proceeding, which is application of the rule of reason to a number of subsidiary questions. Although it may seem at this point that there will be important questions of fact to be resolved, we do not expect these to persist through the Hearing. They appear to be the result of continuing research and investigation, inadequate earlier disclosure (some of which may be an unfortunate incident of the traditional adversary legal context in which these questions arise) and, perhaps, mistake. If that is so, the parties should be able to resolve them by agreement.

Strong as emotions and feelings may be in this and similar kinds of cases, we believe the instances of deliberate misstatement or misrepresentation will be few and far between.* In final analysis, the issue for determination by the Administrative Law Judge, as with the Alaskan pipeline,

* We regret the tone of some of the exchanges in the memoranda. It may be characteristic of the adversary approach in the ordinary plaintiff vs. defendant litigation, but here it may serve to intimidate scientists (including even those in the employ of a party), who in the past have understandably hesitated to leave their laboratories for fear of just this kind of unpleasantness. We need their unfettered participation in this proceeding, and are hopeful that all parties will refrain from challenging integrity and collateral conduct, except on a reasonably founded basis.

the construction of a nuclear power plant and similar problems in our over crowded, technology-oriented society, will be whether the conceded benefits outweigh the conceded risks from the viewpoint of society as a whole -- not of any single person. Obviously that delicate balancing judgment may properly change as a consequence of an oil embargo or a food shortage.

Unfortunately, our traditional adversary legal process -- the only one we have at this time -- tends to pose issues in simplistic black and white terms: guilty or not guilty, right or wrong, liable or not liable. The memoranda submitted in this case thus far to some extent do the same. Although the "no risk" theory has been dropped, at least in name, the March 11 submissions still appear to take a similar approach by contending, for example, that Dow has not demonstrated a "no effect" level, or that Dow has not shown there to be "no jeopardy" resulting from 2,4,5-T use. We hope this statement will not be quoted out of context, but we submit that such tests cannot be met. There are no absolutes in science; there is no such thing as "no effect" or "no jeopardy" in the lay sense in which Respondent uses these terms. Everything has a cost, including not marketing a product or using precious research resources to negate a possibility where the resources might be better employed to

evaluate (never completely "negate") a more serious possibility.

Nor is this case EDF vs. Dow, except in the procedural mold in which it has been cast by tradition. If the product at issue is cancelled, no one can market it and -- far more important -- no one can buy or use it. Until we develop some better legal method for resolving issues of this kind (which include civil rights, antitrust and other societal issues calling for the balancing of a myriad of intangible interests and values), the Administrative Law Judge must expect that the parties will marshal the evidence for him to judge, will examine and cross-examine the witnesses and perhaps -- although we hope all will try to avoid it -- will occasionally indulge in legal jockeying. But despite this, there is a third party standing in the wings -- the public -- which is the only one which will ultimately win or lose this case.

It may be helpful to consider application of the rule of reason to several of the important questions posed by the memoranda.

1. Legal Burdens: The memoranda discuss at considerable length the traditional concepts of "burden of coming forward" with evidence and ultimate "burden of proof." In the usual litigation, these are concepts to be applied by the

trier of fact in making a decision as to who wins and who loses. If the party with the burden of coming forward (never quantified precisely) doesn't sustain it, he loses; if he does, the party with the burden of proof (50% plus) must then sustain it or lose. But in this case, these burdens translate into the question "Who does what?" Just how much evidence must there be to justify the effort required by long-term carcinogenicity or mutagenicity research, and who should do it? When new analytical methods make it possible to detect residues down to the ppt (parts per trillion) level, who should conduct the research necessary to evaluate the new findings? Should it be Government? Registrants?

Respondent correctly states that the Administrator's Scientific Advisory Committee, in approving continued 2,4,5-T use, recommended certain additional studies. But assuming such studies are appropriate (a determination itself dependent upon a rule of reason evaluation), who should do it? Had the Administrator accepted the Committee's Report contingent upon a further submission by registrants at some later time, Dow would have been faced with a rule of reason de-

cision -- is the research justified in light of all the proper considerations? But the Administrator rejected the Report and continued the cancellation. This posed a different issue to registrants -- is immediate research by them justified in light of all the proper considerations, including the Administrator's adverse determination? Or should they rely on Government to conduct it? Or await the outcome of the litigation?

Dow of course has continued research, and has most recently determined to initiate additional research as the result of the scientific evaluations made at the March 8-9 Scientific Conference in Washington. And Respondent has also recognized a burden in this area. It has already in its January 18 memorandum furnished data not previously disclosed. It is still conducting environmental monitoring projects and other studies which should be helpful in arriving at a balanced risk/benefit judgment in this case. Perhaps the results of these ongoing efforts may indicate that the need for further work is sufficiently great to justify imposing an additional burden on registrants; or that continuing governmental monitoring is called for; or that work can reasonably be stopped -- at

least until some new scientific discovery comes along!*

Nor can these efforts be evaluated simply in terms of their economic costs. For example, Respondent seeks Dow's cooperation in research of TCDD residues in human fat. (See second footnote, EPA March 11 memorandum, page 2.) As earlier described by Respondent, however, this work called for a surgical procedure on a human population. Unless Respondent has new information of which Dow is not yet informed or proposes a non-surgical approach, we question the justification of surgical sampling of humans. But that, again, is a decision for application of the rule of reason by the Administrative Law Judge.

2. No Effect. Respondent emphasizes that Dow has not satisfactorily established a "no effect" level

* We hope there will be no "sandbagging" in this proceeding, with the holding back of test data or results of monitoring studies to spring on some scientist in cross-examination. The result would not only negate the scientific method (for who can deal with new esoteric scientific data off-the-cuff?), but serve to frighten the scientific community away from participating in this and future cases. Data should be disclosed as soon as properly evaluated and ready.

with respect to the use of 2,4,5-T. Although as elsewhere, even scientists in the employ of the same party sometimes use the term with different meanings, the better use of "no effect" is as a technical scientific phrase to characterize the results of certain specific experimental observations. However, Respondent appears to use the term in its lay sense, to mean that the environmental residue levels which may result from use of the product have absolutely "no" adverse toxicological effect.

Again we hope we will not be quoted out of this context, but in true science there simply is no such thing as "no effect" in the above sense. Although Respondent objects to Dow's use of qualifying terms throughout -- and Dow does, and must continue to do so* -- the correct lay phrase should be "no significant effect" or "no

* Indeed, on occasion to avoid redundancy, the January 18 Dow memorandum uses the term "no effect" without a qualifying description. Throughout, however, the term is intended to be used with the qualifications to which Respondent objects.

substantial effect" or "no detectable effect" or "no observed effect" or "no reported effect" or "no discernible effect" or "no untoward effect." Certainty is impossible. When the older participants in this proceeding went to school, they learned the principle of the "conservation of matter." But it wasn't so, and something else won't be so tomorrow. We may now be down at ppt detection levels; but perhaps even before this case is finished, we will be at ppq (parts per quadrillion). What then?

The most science can give us is a confidence level, statistically arrived at, which can be evaluated. For example, a teratology study employing certain protocols and using certain specified dosages of a compound in 100 mice, discloses certain results. Those results can be extrapolated to larger populations of mice, but only within certain confidence levels, not with certainty. Extrapolation can also be made to higher or lower doses, and to different species -- rats, rabbits and humans. But never with certainty -- always with some open area of doubt and risk.

The rule of reason decisions to be made under these circumstances are whether the work done thus far is sufficient to have reduced the level of

doubt and risk below the benefits of use; whether the additional work required to reduce the level of risk even further is worth its associated costs and other detriments; and, if so, whether such risks and doubts are sufficient to require that the added effort be undertaken by registrants (which would otherwise be prohibited from marketing the product) or by Government.

Here again there is not as much difference between the parties as might at first appear. Government has assumed the burden of conducting what is within the scientific community popularly called "mega mouse" research at the National Center for Toxicological Research (NCTR) facility in Pine Bluff, Arkansas. A target goal has been set to achieve a confidence level of 1 in 10,000, requiring something like 800,000 test animals, although at present it appears that a more realistic near-term objective will be 1 in 1,000. Work of this kind seems clearly beyond the realistic present economic capacity of any single registrant -- although the rule of reason cautions that perhaps one day even that may change.

Respondent is correct that terms need definition. As with "no effect", "dose response" is a

phrase used rather widely by toxicologists, but not always with the same meaning; the very different terms "bio-accumulation" and "bio-concentration" are sometimes used interchangeably in memoranda of even the same party (see EDF March 21 memo, pp. 18-19); the same is true of such words as "teratology"* and "accumulation." An effort should certainly be made at the Hearing to see that words are employed uniformly. But an observation is an observation, assuming the validity of the methodology employed and the integrity of the researcher. The question of whether it is a "teratogenic" observation is simply another way of trying to identify and quantify the nature and degree of the risk involved.

It will be of critical importance throughout this proceeding for the parties to try to see that conclusory terms of this kind are properly explained. We can live with different usages if the differences are identified.

* Respondent appears to define teratology to include death, on the ground that it "must be considered the ultimate malformation." (EPA March 11 memo, p.5). This is not one of the usual definitions.

3. Economics: Application of the rule of reason in this litigation cannot be divorced from any legitimate societal value, including economics. Registrants such as Dow are constantly faced with decisions which require the same kinds of balancing of conflicting interests as are involved in the main case itself. Some earlier registrants, including Hercules which was a party here at one time, decided to withdraw completely; even those still involved in the present stage concluded not to oppose suspension of certain uses of the product, such as around the home. When the evidence is all in, it will be obvious that those continuing on here have considered a factor in their rule of reason decision to proceed in addition to the use of 2,4,5-T itself.* That is of course the opportunity which § 6(b)(2) of the new statute affords to develop some better method for resolving these kinds of issues in a rational manner, placing

* We hope the Administrative Law Judge will also conclude at the end of this proceeding, that Dow's research effort has been far above and beyond the call of what should be expected in the routine registration.

the burdens where they should be and eliminating the adversarial "entrapment" kind of approach designed to "win" but not necessarily to achieve the greatest benefit for society. In fashioning such a procedure, we hope the Administrative Law Judge will not consider that the scientific research and even legal effort expended by those aligned with registrants in this case should be replicated in every similar proceeding.

4. Teratology. Although we do not suggest that Respondent has conceded away any issue, a reading of the EPA and EDF briefs suggests that the significant risk areas requiring evaluation in this proceeding all concern teratology -- the possibility of human birth defects resulting from the TCDD contaminant in 2,4,5-T as presently marketed. With respect to all other questions -- carcinogenicity, mutagenicity, other dioxins -- the most that is really contended is that additional study is required. Additional research would be nice, of course, although perhaps an unjustified luxury, but we do not think the evidence as outlined by EPA and EDF is sufficient to call for its conduct by Dow. Whether it is the best use of limited Government resources is a question which

government itself must decide. But the rule of reason approach suggests that at this point a determination can be made on the memoranda themselves that the matter for consideration in this case should be the balancing of the risk/benefit equation in terms of possible human birth defects resulting from exposure to the TCDD contaminant in 2,4,5-T. As the results of additional Government and other research are received, some of which are well under way, we would hope to continue to work with Respondent, where appropriate assuming the responsibility to undertake more effort as indicated. Perhaps one day even less toxic products will be developed, or new scientific method will suggest new approaches. Litigation of issues as tenuous as those other than teratology is not the proper way even under today's inadequate procedures.

* * *

Undoubtedly there will be extremists who testify here, perhaps on both sides, but we hope there will be no serious factual issues. We believe that the task for the Administrative Law Judge will be to evaluate the process by which the scientist comes to the essentially societal

conclusion that "The risk is (or is not) acceptable." We do not let the surgeon do this for us in open heart surgery; we do not let the attorney do this for us in the plea of guilty to crime; we cannot let the scientist do this for us in deciding whether the food, right-of-way and forestry benefits of 2,4,5-T outweigh its risks. But to effectively perform the function requires that the scientist clearly divorce what is scientific observation and accepted scientific opinion from bias and emotion, and that he quantify his conclusions in terms we can understand ("In 4,000 similar open heart surgical procedures, 3% of the patients died and 87% recovered to the same level of activity and health as before the attack"). If this can be accomplished in this proceeding, everyone will win, for justice will have been done.*

* The foregoing discussion is limited to that appropriate to a further pinpointing of the issues, and is not intended to be responsive to all the evidentiary contentions. Thus, for example, Respondent interprets Dow's reference to "environmental use levels" as meaning ".01 ppm [TCDD] in the technical material," (EPA memo, March 11, p. 13), where the relevant figure should be .1 ppm in the product used, or less. All of this is the subject for evidence and summary argument, not prehearing memoranda which are the product of trial counsel's vigorous but not necessarily scientifically qualified efforts. Our silence or failure of response should not be considered admission to any of these evidentiary statements.

C. Dow Proposed Agenda for March 26, 1974,
Prehearing Conference.

The matters which Dow requests be considered at the Second Prehearing Conference are the following:

1. Limitation of Issues (Dow Prehearing Memorandum (No. 3), p. 15.)
2. Privilege (id., p. 20).
3. Consolidation (id., p. 21).
4. Notice (id., p. 25).
5. Further schedule (id., Draft Response attached to Exhibit E, ¶4).
6. Hearing Date (id., p. 22).

We wish to comment further than the above references only with respect to the date for Hearing. We are most hopeful that the Administrative Law Judge will adhere to the present April 23, 1974 date. There are many reasons, which can be argued at the March 26 Prehearing Conference if there is opposition. But the most important and overriding reason, which warrants emphasis now even before any opposition is noted, is the effect of any significant delay on the participation of third party witnesses, most of whom will probably be called to testify by parties other than Dow.

An April Hearing date has been the target beginning ever since last July, when it was fixed by the Assistant Administrator. The interest of many non-party scientists, and of the parties themselves, has been mounting as the time

approaches. This was most recently evidenced by the enthusiasm apparent at the USDA/Dow March 8-9 2,4,5-T scientific conference in Washington, D.C. Experience teaches that one cannot maintain such attention for too long a period; the surfer must capture the crest of the wave before it breaks.

We urge the Administrative Law Judge to adhere to the April 23, 1974 date for commencing the Hearing in this proceeding.

CONCLUSION

From the inception of this proceeding as the result of the Administrator's August 6, 1971, order, an effort has been made informally, by negotiation, and formally, by litigation, to eliminate its adversarial government vs. registrants character. The enactment of § 6(b)(2) of the new statute finally affords an exceptional and perhaps unique opportunity to conduct a true scientific inquiry, not an adversary litigation. If it is successful, it could be the forerunner of similar approaches to many of the important questions of today and tomorrow.

We hope the FIFRA § 6(b)(1) rice use/benefit portion of this proceeding will be recognized as an anachronism, made necessary by the limitations of the old statute. With respect to all other 2,4,5-T uses, the Administrator has made no determination except that this

inquiry is warranted. We hope the Agency, and the parties, will pursue the Administrator's non-adversarial role.

The issues for decision include whether additional research effort is required in a number of areas and, if so, which party has the burden of carrying each project forward. Until final determination, each party has necessarily decided for itself which such work it will undertake. In some instances the results have not yet been published, and some are still being disclosed. Because new data may continue to be presented even during the Hearing (we hope not for the purpose of "surprise"), it is especially important that the parties avoid inflexible or final adversarial positions at this time.

Finally, no party will "win" or "lose" if 2,4,5-T is approved or banned. Even were Dow to bow out (which it has no intention of doing), the public is entitled to a fair and proper conclusion as to whether it may use the product.

It should be the function of the parties to help fashion a proceeding under this new statute, in which science can present its data and conclusions fully and in scientific fashion, without the calumny, invective and charge of improper motivation which have sometimes characterized other proceedings. Dow -- and everyone -- will win if at the end it can be properly concluded that a just and equitable balancing of all the risks and all the

benefits was conducted. The integrity of the process itself is the most important issue of all.

Dated: New York, New York,
March 21, 1974.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the attached Dow Prehearing Memorandum (No. 4), dated March 21, 1974 was served today by postage prepaid mail, upon the persons whose names and addresses are listed below:

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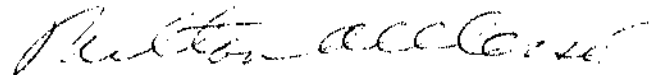
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