| | | |
|---|---|---|
| **Item ID Number** | 05209 | ☐ **Not Scanned** |
| **Author** | Nolting, Alfred R. | |
| **Corporate Author** | United States Dept. of Agriculture (USDA) | |
| **Report/Article Title** | Environmental Protection Agency (EPA) Before the Administrator, In re: 2,4,5 -Trichlorophenoxyacetic Acid, FIFRA Docket No. 295, Response of the Secretary of Agriculture of the United States | |
| **Journal/Book Title** | | |
| **Year** | 1974 | |
| **Month/Day** | March 11 | |
| **Color** | ☐ | |
| **Number of Images** | 10 | |
| **Descripton Notes** | | |

FCR NOV 12, 1973

11 MARCH 74

UNITED STATES OF AMERICA

ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

| | | |
|---|---|---|
| In re: | ) | |
| | ) | |
| 2,4,5-Trichlorophenoxyacetic | ) | FIFRA Docket No. 295 |
| | ) | |
| Acid | ) | |

RESPONSE OF THE SECRETARY

OF AGRICULTURE OF THE UNITED STATES

This response is submitted pursuant to the directive of the Chief Administrative Law Judge at the prehearing conference on November 12, 1973. This response will address:

A. The need for a rule of reason as the basis for the ultimate decision concerning the use of 2,4,5-T.

B. Limiting the issues to be considered at the hearing.

C. The need for field hearings.

D. The necessary distinction that must be made between a § 6(b)(1) and a § 6(b)(2) hearing under FIFRA.

A. The need for a rule of reason as the basis for the ultimate decision concerning the use of 2,4,5-T.

As was stressed both in our Motion to Intervene and in the Statement of Position of the Secretary of Agriculture, we believe it to be of paramount importance that the questions concerning the use of 2,4,5-T, as well as other questions involving the introduction and use of technology, be resolved using a rule of reason. We have emphasized in the Statement of Position (p. 25) that scientific fact must serve as the basis for answering these questions, and that there must be a weighing of both the benefits and risks known to exist. It does appear from EPA's first pretrial brief 1/ that Respondent agrees that a rule of reason must be employed when deciding the 2,4,5-T case, and we hope that all other parties believe that such an approach is necessary.

B. Limiting the issues to be considered at the hearing.

Prior to hearing, it is the desire of USDA to limit the issues to be considered. Respondent has not met its burden of producing evidence to raise a substantial question of safety regarding the use of 2,4,5-T in a number of areas:

1) Mutagenicity. While both the EDF (p. 6) and the Respondent (p. 20) cite studies showing that TCDD is a mutagen, neither Respondent nor EDF cites evidence to show that 2,4,5-T itself as commercially prepared causes mutagenicity. Respondent cited one in vitro study with bacteria which showed no mutagenic effects when exposed to 2,4,5-T (EPA p. 20, fn. 37). EDF cited no studies indicating mutagenicity in higher organisms. In view of the foregoing, USDA respectfully submits that the Administrative Law Judge should find that

---

1/ Respondent would prefer that a decision, herein, rest on thorough scientific information, reasoned inference and reliable prediction, rather than on sheer force of law (p. 52).

there is no evidence to suggest that 2,4,5-T causes mutagenicity; and should hold that there is no valid basis for further consideration of questions regarding that hazard in this proceeding.

2) Carcinogenicity. There is no evidence that 2,4,5-T is a carcinogen. Respondent at p. 21 of its January 18 submission states that TCDD is a potential carcinogen. But again there is "no discernible indication that 2,4,5-T itself is a carcinogen."

EDF omits discussion of carcinogenicity as an issue in its January 18 submission. USDA therefore requests that carcinogenicity be removed from the hearing as a question at this time by the Administrative Law Judge.

3) Teratogenicity. Respondent asserts that tests using 2,4,5-T with a TCDD content of 1 ppm or less indicate that 2,4,5-T is teratogenic (EPA, p. 11). These studies, however, are dependent upon the amount of TCDD present. Where no detectable TCDD is present only a decrease in fetal weight was noted. Adverse effects on the hamster fetus increase as the amount of TCDD increased.

EDF studies offered in support of 2,4,5-T teratogenicity rely on the presence of TCDD in varying amounts for their results (EDF, p. 5).

USDA, as well as other parties, has offered studies that negate the teratogenicity of 2,4,5-T.

Given the controverted evidence over this issue, teratogenicity will remain an issue for determination at the hearing. The USDA and other parties have offered evidence in their pretrial briefs to negate teratogenicity and USDA takes issue with the methods and content of studies offered by EDF and Respondent on this issue.

4) Delayed Lethality and Sub-Lethal Chronic Health Effects. Respondent appears to agree with USDA that because of rapid human excretion of 2,4,5-T, chronic ill health would not be expected from long-term low level exposure to 2,4,5-T (EPA, p. 22). Respondent states that the chronic health effects of TCDD are of major evidentiary concern, yet offers no evidence that TCDD at levels of 1 ppm or less presents any health hazard.

EDF does not treat the issue of delayed lethality and sub-lethal chronic effects in its January 18 memorandum.

It is the position of USDA that delayed lethality and the sub-lethal chronic effects of 2,4,5-T have not been raised as controverted issues in this hearing. Accordingly, USDA respectfully submits that the Administrative Law Judge should now hold that it would be inutile to conduct further inquiry respecting these potential hazards.

5) Effect of 2,4,5-T on Wildlife Habitats. At pp. 25-27 Respondent raises the issue of damage to wildlife habitats from 2,4,5-T use. Up to this point, the issue had not been discussed as a separate question.

USDA submits that this question is one which could be the subject of a lengthy hearing on its own. What evidence is available indicates that the use of 2,4,5-T improves some wildlife habitats while leaving others less palatable to certain species. The pursuit of this issue could broaden the hearing from one in search of scientific resolution of the hazard of 2,4,5-T to human health to one of a speculative discussion of whether certain species find brush or grass a more suitable environment. Therefore, we request the Administrative Law Judge to delimit the metes and bounds of the inquiry regarding wildlife habitats.

Conclusion

USDA respectfully requests that the issues at the hearing be limited to those which the pretrial briefs have shown to be the subject of credible controversy, namely the teratogenicity of 2,4,5-T containing 1 ppm of TCDD or less and the question of balancing the risks, if any, of the use of 2,4,5-T against the benefits.

C. The need for field hearings.

In the Statement of Position of the Secretary of Agriculture, the request was made for field hearings (p. 24). We believe that some field hearings will be necessary to present vital evidence from user witnesses who are unable to make a lengthy trip to Washington to offer testimony. All parties admit to the lack of data on the effects of 2,4,5-T on humans and the difficulty of extrapolating from animal experiments to man. Yet we do have the experience of ranchers, foresters, farmers and applicators exposed to 2,4,5-T for decades to call upon. These user witnesses possess a vast amount of experience regarding the use of 2,4,5-T and can testify both to the benefits derived from the use of 2,4,5-T and the lack of any substantial evidence of risk to man or the environment from the use of 2,4,5-T. Although we agree with Respondent that the issues of this case are scientific and technical, we also believe that the user witnesses will make a significant contribution to a sound, scientific record upon which the ultimate decision regarding 2,4,5-T can be made. Therefore, we disagree with Respondent's position that field hearings are unnecessary.

D. The necessary distinction that must be made between § 6(b)(1) and a § 6(b)(2) hearing under FIFRA.

The United States Department of Agriculture supports the consolidation of the hearings concerning all registered uses of 2,4,5-T, which includes the use of 2,4,5-T on range land, rights-of-way, and forests as well as on rice. However, we do believe it is important to distinguish the § 6(b)(1) hearing, which was instituted for the use of 2,4,5-T on rice, and the § 6(b)(2) hearing which was noticed for the other uses of 2,4,5-T. The § 6(b)(1) hearing is the same that was provided by FIFRA before FIFRA was amended by the Federal Environmental Pesticide Control Act of 1972. The § 6(b)(1) hearing is provided after the Administrator has canceled a registration or changed its classification. It is this hearing that the Administrator of EPA is required to initiate "whenever there is a substantial question about the safety of a registered pesticide." [2] Section 6(b)(2) was added to FIFRA by amendment in 1972 and provides for a hearing to

---

[2] E.D.F. v. Ruckelshaus, 439 F.2d 584, 594 (1971)

determine whether or not a registration should be canceled or its registration changed. Also, issuing a notice of hearing under § 6(b)(2) indicates that the Administrator of EPA has concluded there is not a substantial question about the safety of the pesticide.

The legislative history of Section 6(b) plainly supports our position in this regard:

> Before adopting this compromise proposal, the Committee considered all of the numerous amendments submitted to clarify the procedure for judicial review, third-party participation in the administrative decision-making process, and the grounds which permit the Administrator to cancel a registration before a five-year period. <u>The procedures adopted carry forward the language of present law by which the Administrator cancels where a substantial question exists.</u> * * *
>
> The Committee has determined that the Administrator should be able to call a hearing when he believes it useful rather than issue a notice of intent to cancel. <u>Such a procedure permits the Administrator to initiate formal review without placing a stigma on a product when he is not convinced that the registration should be cancelled</u>. [Emphasis supplied.]
>
> Senate Committee on Agriculture and Forestry Supplemental Report on H.R. 10729, S. Rep. No. 92-838 (Part II), 92 Cong. 2d Sess. (1972).

Therefore, although there is a consolidation of hearings in the present case, we believe it critical to remember that there is only the use of 2,4,5-T on rice that was the subject of a § 6(b)(1) hearing.

Issuing a § 6(b)(2) notice as to the other uses of 2,4,5-T rather than a § 6(b)(1) is tantamount to an administrative conclusion that there is no substantial question of safety as to these cases. This distinction should be paramount if we are to develop a full and complete record.

Respectfully submitted,

Margaret Bresnahan Carlson

Margaret Bresnahan Carlson

Alfred R. Nolting

Alfred R. Nolting

Raymond W. Fullerton

Raymond W. Fullerton

Attorneys for the
Secretary of Agriculture

March 11, 1974

## Certificate of Service

I hereby certify that copies of the foregoing Response of the Secretary of Agriculture of the United States were served this date either by hand or by mailing the same, postage prepaid, to all parties of record as follows:

Mr. R. J. Otten
Manager/Regulatory Affairs
Amchem Products, Inc.
Ambler, Pennsylvania 19002

Harry J. Breithaupt, Jr., Esquire
Phillip F. Welsh, Esquire
Law Department
Association of American Railroads
American Railroads Building
Washington, D.C. 20036

Milton R. Wessel, Esquire
Kaye, Scholer, Fierman, Hays & Handler
Counsel for The Dow Chemical Company
425 Park Avenue
New York, New York 10022

William D. Rogers, Esquire
Richard J. Wertheimer, Esquire
Arnold & Porter
Counsel for National Forest Products
Association
1229 19th Street, N.W.
Washington, D.C. 20036

Mr. J. Robert Hasness
Director of Technical Services
Transvaal, Inc.
P. O. Box 69
Jacksonville, Arkansas 72076

C. E. Lombardi, Jr., Esquire
Blackwell Sanders Matheny
Weary & Lombardi
Counsel for the Thompson-
Hayward Chemical Company
Five Crown Center
2480 Pershing Road
Kansas City, Missouri 64108

J. Thomas Tidd, Esquire
General Counsel
U. S. Department of Transportation
Washington, D.C. 20590

William A. Butler, Esquire
Counsel for Environmental Defense
Fund, Inc., Consumers Union of United
States, Inc., and Harrison Wellford
1525 18th Street, N. W.
Washington, D.C. 20036

C. David Mayfield, Esquire
Office of the Legal Counsel
American Farm Bureau Federation
225 Touhy Avenue
Park Ridge, Illinois 60068

Timothy L. Harker, Esquire
Office of the General Counsel
Environmental Protection Agency
401 M Street, S. W., Room 519-WSMW
Washington, D. C. 20460

Alfred R. Nolting

Alfred R. Nolting
Attorney for the
Secretary of Agriculture

March 11, 1974