



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

OCT 2 1991

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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Transmittal of the Final FIFRA Scientific Advisory
Panel Report on the September 18, 1991, Meeting

FROM: Robert B. Jaeger *RBJ/10/2/91*
Designated Federal Official
FIFRA Scientific Advisory Panel

TO: Douglas D. Campt
Director
Office of Pesticide Programs

The above mentioned meeting of the FIFRA Scientific Advisory Panel (SAP) was an open meeting held in Arlington, Virginia to review the following topics:

1. A set of Scientific Issues Regarding the Agency Peer Review Committee's Classification of Prodiamine as a Group C Carcinogen.
2. A set of Scientific Issues Regarding the Agency Peer Review Committee's Classification of Metolachlor as a Group C Carcinogen.
3. A set of Scientific Issues Regarding the Agency Peer Review Committee's Classification of Triphenyltin Hydroxide (TPTH) as a Group B₂, Probable Human Carcinogen.
4. A set of Scientific Issues Regarding the Agency Peer Review Committee's Review of a Dose-Response Risk Assessment for the Carcinogenic Effects of Ethylene Thiourea (ETU) in Rats and Mice.

Please find attached the Panel's final report on the agenda items discussed at the meeting.

Attachment

| | |
|--------------------|--------------|
| cc: Panel Members | Steve Dapson |
| Linda J. Fisher | John Doherty |
| Victor J. Kimm | Reto Engler |
| Susan Wayland | Don Barnes |
| Penny Fenner-Crisp | Al Heier |
| Mike Ioannou | Mary Beatty |

Freedom of Information (Susan Lawrence)



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FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

SCIENTIFIC ADVISORY PANEL

A Set of Scientific Issues Being Considered by the Agency in
Connection with the Peer Review Classification of
Prodiamine as a Group C Carcinogen

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of a set of scientific issues regarding the Environmental Protection Agency Peer Review Committee's classification of Prodiamine as a Group C Carcinogen. The review was conducted in an open meeting held in Arlington, Virginia, on September 18, 1991. Panel members present for the review were Dr. Edward Bresnick (Chairman), Dr. Mont Juchau, Dr. Peter Magee, Dr. Curtis Travis, and Dr. John Wilson. In addition, Dr. Edmund Crouch of Cambridge Environmental, Inc, Dr. Richard Griesemer and Dr. Christopher Portier of the National Institute of Environmental Health Sciences, served as Agency representatives; and Dr. Dale Hattis of Clark University, and Dr. Ernest McConnell of Raleigh, NC served as Special Government Employees on the Panel.

Public notice of the meeting was published in two Federal Registers on Friday, August 23, and Friday, September 13, 1991.

An oral presentation was made by Dr. Mildred Root of Sandoz Crop Protection Corporation.

Written comments were received from Sandoz Crop Protection Corporation.

In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency, the Panel unanimously submits the following report.

REPORT OF PANEL RECOMMENDATIONS

The Agency requested comments from the Panel relative to the Peer Review Committee's recommendations for the carcinogenicity evaluation of prodiamine.

Specifically:

Does the Panel have any comments with respect to the Agency's weight-of-the-evidence review for prodiamine, particularly the weight given the incidence of thyroid follicular cell tumors in rats?

Panel Response:

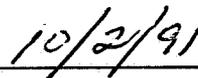
The Panel was in general agreement that the available studies provide minimal evidence for carcinogenicity of prodiamine in experimental animals. A statistically significant increase in the incidence of thyroid follicular tumors was observed at higher doses and a statistically significant positive trend for dose-related effects of the follicular cell tumors in both male and female rats resulted in the final conclusion that a Class C category is appropriate. It was noted that the registrant agreed with the Peer Review Committee that the thyroid follicular cell adenomas were treatment-related. The Panel considered the trend in pancreatic tumor incidence in the rat study to have little significance in the overall weight of evidence. Consideration of a possible "interim" category requested by the registrant was not deemed an appropriate issue for consideration by the Panel. The Panel agreed that the EPA should clearly define the rationale for requests for data from the registrant pertaining to neurotoxicity and thyroid hormone levels. The Panel also agreed that the hormonal studies currently underway are inadequate and not likely to provide useful information, i.e., 2 doses, one of which is very high, and only 1 time point.

FOR THE CHAIRMAN:

Certified as an accurate report of Findings:



Robert B. Jaeger
Designated Federal Official
FIFRA Scientific Advisory Panel



(date)