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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

October 4, 1985

MEMORANDUM

SUBJECT: Scientific Advisory Panel's Review of: 1) a Set of Scientific Issues Being Considered by the Agency in Connection with the Special Review on Daminozide; 2) a Set of Scientific Issues Being Considered in Connection with the Special Review on Captan; and 3) an Addendum to the Pesticide Assessment Guidelines - Data Reporting

FROM: Philip H. Gray, Jr.
Executive Secretary
FIFRA Scientific Advisory Panel

TO: Director
Office of Pesticide Programs

The FIFRA Scientific Advisory Panel (SAP) has completed review of the above mentioned topics in an open meeting held in Arlington, Virginia on September 26-27, 1985.

Attached is the SAP's report on the above three topics.

Attachment

cc: Panel Members
Jim Davis
Susan Sherman
John Melone
Doug Campt
Charles Smith - USDA
Committee Management Officer

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

SCIENTIFIC ADVISORY PANEL

Review of a Set of Scientific Issues being Considered by EPA in Connection with the Special Review on Captan

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The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of a set of scientific issues associated with captan. The review was conducted in an open meeting held in Arlington, Virginia, on September 26, 1985. All Panel members were present. In addition, two new designees to the SAP, Dr. Thomas Clarkson and Dr. James Swenberg, participated in the review.

Public notice of the meeting was published in the Federal Register on Friday, August 30, 1985.

Oral and written statements were received from Stauffer Chemical Company and Chevron Chemical Company.

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

REPORT OF SAP RECOMMENDATIONS

The Scientific Advisory Panel has reviewed the materials prepared to it on captan, and responds as follows to the issues presented to it by the Agency. The four scientific questions posed to the SAP by the Agency, are listed below, together with the Panel's response:

Issue:

1. Several studies have shown that captan is oncogenic in a number of species of test animals: Innes et al., 1969 (mice); National Cancer Institute, 1977 (mice and rats); Chevron, 1981 (mice); Bio/Dynamics, 1983 (mice); Stauffer/Chevron, 1982 (rats). Does the Panel agree with the Agency's qualitative assessment (i.e., weight of the evidence conclusions) of the oncogenic potential of captan?

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Response:

One mouse study demonstrates oncogenic effects in the duodenum of mice exposed to high doses. Two other mouse studies are less convincing, but are supportive because they indicate tumors at the same site. The rat studies are equivocal at best in indicating oncogenicity.

Issue:

2. The Agency calculated the geometric mean of five oncogenicity studies to determine the potency value (Q_1*) for captan. Does the Panel agree with the Agency that this approach is appropriate for estimating dietary and applicator risk?

Response:

Absolutely not. The Panel does not believe this approach is useful because the five studies are not of equal value. Furthermore, the Panel has grave reservations over the procedures and assumptions that go into determination and use of Q Star values. The Panel feels that Agency position documents must stress upper and lower bounds, and provide the best estimate.

Issue:

3. In the absence of acceptable field data on residues of captan in or on food crops, the Agency conducted a "worst-case" calculation of dietary risk. Are the methods used for estimating human dietary exposure to captan appropriate? To what degree should the Agency use FDA's Market Basket Survey data?

Response:

The Panel does not believe the methods used for estimating human dietary exposure to captan are appropriate. First of all, the Panel disagrees with the Agency's practice of estimating human dietary exposures based on tolerances. The Agency should use the best available residue data. In this case, the FDA's Market Basket Survey data should have been used to the maximum extent possible. If EPA does not wish to use Market Basket Survey data, there are alternative methods available for making the estimates more realistic.

Issue:

4. Available data (Robens, 1970) suggested possible teratogenic effects in hamsters. These effects were exencephaly and fused ribs and occurred only at maternally toxic levels. Additional information from a second study (Goldenthal, 1978) on the hamster demonstrated only fetotoxic effects. These effects were reduction in fetal weight at maternally toxic levels. Does the Panel concur with the Agency's judgment that captan is not teratogenic in the hamster? The Panel should note that the Captan PD 2/3 indicates current studies were inadequate and that an additional study on hamsters would be required. However, subsequently the Agency has conducted a reregistration review and determined that an additional hamster study is not needed. That review is enclosed for the Panel's consideration.

Response:

The Panel concurs with the Agency's judgment.

FOR THE CHAIRMAN:

Certified as an accurate report of Findings:

Philip H. Gray, Jr.

Philip H. Gray, Jr.
Executive Secretary
FIFRA Scientific Advisory Panel

Date: Oct. 4, 1985