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

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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: Second Peer Review of Terbutryn - Reevaluation Following the December 15, 1987 Science Advisory Panel Review.

From: Judith W. Hauswirth, Ph.D. Judith W Hauswirth 1/27/88
Section Head, Section VI
Toxicology Branch/HED (TS-769C)

To: Robert Taylor/James Yowell
Product Manager #25
Registration Division (TS-767C)

The Peer Review Committee met on January 13, 1988 to examine the issues raised by the Science Advisory Panel (SAP) with respect to the classification of the carcinogenicity of Terbutryn.

A. Individuals in Attendance:

1. Peer Review Committee: (Signatures indicate concurrence with the peer review unless otherwise stated.)

Theodore M. Farber	Theodore M. Farber
William L. Burnam	
Robert Beliles	
Richard Hill	
Esther Rinde	
John Quest	
Richard Levy	
Marion Copley	
Kerry Dearfield	
Judith W. Hauswirth	Judith W Hauswirth

2. Peer Review Members in Absentia: (Committee members who were unable to attend the discussion; signatures indicate concurrence with the overall conclusions of the Committee.)

Anne Barton

Reto Engler

Diane Beal

B. Material Reviewed:

The SAP response memorandum of December 23, 1987 was reviewed by the Committee.

C. Considerations:

The Panel agreed with Committee's overall assessment of the weight of the evidence on Terbutryn, classifying it as a category C oncogen; however, they felt that the classification should be an interim classification. They stated that they "believe the oncogenicity data on terbutryn is limited to inadequate; tumors were induced at multiple sites only at the highest dose, which exceeded a maximum tolerated dose [MTD, rat study]. Good dose-response data were not available due to the large spread between the doses." They felt that the classification could be reduced to a D if data from another study conducted at more appropriate dose levels were negative for oncogenicity. They also concluded that a quantitative risk assessment should not be performed since tumors were only seen at the MTD.

Issues:

1. Interim C Classification:

The Committee concurred with the SAP decision, but felt that since Terbutryn was classified as an interim C and since the dosage levels for the rat study were poorly choosen, that another rat oncogenicity study should be required with particular attention paid to dose selection. The classification of Terbutryn would be reconsidered upon receipt and review of this study.

2. Quantification of Risk:

The Committee agreed that for now a quantitative risk assessment need not be performed; however, upon receipt of a repeat oncogenicity study in the rat this decision would be reconsidered.