PM SD/IS.
0190-B

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

JUL 15 1985

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Dicofol Oncogenicity - SAP Meeting July 8, 1985

FROM: Susan V. Hummel, Chemist
Special Registration Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Susan V. Hummel

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: RCB Files

Susan Hummel attended the July 8, 1985 SAP meeting regarding the oncogenicity of dicofol. Bruce Kapner presented EPA's position. Statements related to RCB concerns presented were:

As a response to the PD2/3, the registrants proposed to reduce the level of DDTr contaminants to 0.1%. If this level can be achieved, the SAP concluded earlier that it does not appear that there would be a threat to the environment.

As part of the risk assessment of the human oncogenic risk potential of dicofol, the structural similarity of dicofol to other DDT-related compounds, which are oncogens, and the possible metabolism or interconversion of dicofol to DDT metabolites such as DDE were considered. Preliminary results from a poultry metabolism study appear to indicate that dicofol does not metabolize to DDE in poultry. However, the preliminary report had numerous deficiencies.

A Dietary Exposure Assessment was prepared as well. Several approaches were used.

(1) Assume that all racs are contaminated at tolerance level. However, residues on treated crops are not expected to occur at tolerance level.

(2) Using actual field trials, the maximum observed residue and the average observed residue was determined. However, not all acreage for any given rac is treated

and some dilution takes place as treated and untreated racs enter the market.

In general, data on the fraction of residues found in edible and inedible portions of racs and the fate of residues associated with processing, such as cooking, washing, or peeling, are not available.

The quantitative risk assessment (including the dietary exposure and the applicator exposure) was generated at a time when EPA believed the oncogenic potential of dicofol to be greater.

EPA believes that the substantial benefits of dicofol outweigh the environmental risk and the uncertain oncogenic risk, provided that the registrants make certain modifications to the registrations of their products.

EPA proposes to cancel the registrations of any pesticide product containing dicofol unless:

(1) by 30 days after publication of EPA's Final Notice of Intent to Cancel in the FEDERAL REGISTER, the registrant applies to amend the registration of his product to include the following statement: "Skin contact with this pesticide may be hazardous; Wear impervious gloves when mixing, loading, or applying this product;"

(2) by January 1, 1986, the registrant has amended the registration of his product to certify an upper limit on the amount of DDTr (calculated as the total amount of DDT, DDE, DDD, and extra-chlorine DDT) in his product which is equivalent to 2.5 percent of the percentage of technical dicofol in the product; and

(3) by July 1, 1987, the registrant has amended the registration of his product to certify an upper limit on the amount of DDTr (calculated as the total amount of DDT, DDE, DDD, and extra-chlorine DDT) in his product which is equivalent to 0.1 percent of the percentage of technical dicofol in the product.

The SAP had no questions at this point.

Rohm and Haas introduced three pathologists and Dr. Clive Edwards. The pathologists made statements relating to the reading of the slides. One SAP member commented that he had also read the slides.

Dr. Clive Edwards made a presentation at the last SAP meeting on dicofol (S. Hummel, 4/26/85), and prepared a response to the PD2/3 on risk assessment (both dietary exposure and applicator exposure) (S. Hummel 4/24/85). For

the most part, his statement duplicated his response to the PD2/3.

> Dr. Edwards contends that the only valid data which should be used to assess dietary exposure is the FDA Total Diet studies because of the large number of samples, regional samples, and that data are available over the last ten years.
>
> He repeated that all dicofol residues found were in leafy vegetables and fruits, and that no dicofol residues were found in meat, poultry, milk, or eggs. He stated that almost all the residue in citrus is found in the peel which is not used as food. (We disagree with this statement - citrus peel <u>is</u> used as food - both human food and animal feed.)
>
> These statements have been reviewed before (S. Hummel, 4/24/85).
>
> Dr. Edwards commented on the risk assessment tables included in the proposed Federal Register document. He states that the calculations used to arrive at the figures in the tables are not clear and should be more clearly explained. He states the using the mean of positive samples (of FDA monitoring data) gives skewed estimates, and all samples (both positive and negative samples) should be used. He suggests that the quantitative risk assessment be excluded from the final Federal Register document.

Shirley Briggs from the Rachael Carson Trust made a short statement. She emphasized that citrus peel <u>is</u> used as food, and cited a few recipes using citrus peel.

Jim Holder (CAG) explained his assessment of the oncogenic potential of dicofol. This included the structural similarity of dicofol with perthane, chlorbenzilate, DDT, and DDE, which are all oncogens.

The SAP was asked to consider the following questions.

> (1) How strong is the weight of the evidence for the oncogenicity of dicofol?
>
> (2) What weight should be given to the structural linkage and potential metabolism to DDTr in the weight of the evidence?
>
> (3) Should the quantitative risk assessment be included in the final Federal Register document?
>
> (4) Are the methods used to estimate human exposure reasonable?

The SAP determined that the weight of evidence for the oncogenicity of dicofol is weak, and that no weight should be given to the structural linkage and the possible metabolism to DDE, since there are no valid metabolism data. The quantitative risk assessment should not be included in the Federal Register document. The SAP recommended that the TAS (Tolerance Assessment System) be used to estimate dietary exposure. (We note that TAS was part of the agenda for the SAP meeting.) More data are needed to complete the applicator exposure assessment.

cc:R.F., circu, S. Hummel, dicofol special review file, dicofol S.F., B. Kapner (SRB,RD), K. Barbehenn (SIS), R. Hitch (EAB), J. Holder (CAG), PMSD/ISB
RDI:EZ:7/11/85:RDS:7/11/85
TS-769:RCB:SVH:svh:RM:810:CM#2:7/11/85