See attached comment from Joanne Miller PM-23

N Cook 11.15.90

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

November 13, 1990

MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: November 9th, 1990, Dithiopyr Meeting

FROM: Norman Cook, Head Norman Cook
Section # 2
EEB/EFED (H7507C)

TO: James W. Akerman, Chief
EEB/EFED (H7507C)

On November 9th, 1990, I met with Joanne Miller, Stephanie Irene, Gene Wilson, Frank Sanders, and three Monsanto representatives (names unknown) to discuss the possible conditional registration of Dithiopyr on turf and EEB's data requirements. Initially, discussion concerned human safety and Stephanie Irene presented information on HED/Agency activities: HED is reviewing applicator exposure data submitted by Monsanto, dislodgeable residue data will be reviewed once submitted, and a SAR analysis is being done by OTS. In addition, Ms. Irene urged Monsanto to submit a 90-day rat feeding study as soon as possible and said an OPP decision package should be ready for presentation to Doug Campt by January, 1991.

Monsanto pursued discussion of HED and human safety concerns and indicated that what Ms. Irene had presented was significantly different from information obtained in discussions with Anne Lindsay. They presented background information on how Dithiopyr was developed and stated that the data requirements HED is imposing now are significantly different from those HED previously gave to them. Further discussion followed and topics covered included: Agency time-frames for review of data, meetings and discussions with Anne Lindsay, the Agency's increased concern with lawn-care chemicals, the dislodgeable residues data, Monsanto's belief that they are getting the "run-around" from the Agency, and proposed resolutions (e. g., submission of the 90-day rat feeding study with Agency commitment to a quick review) concerning human safety data requirements.

We discussed the avian reproduction study next with Monsanto saying that based on their changed use pattern (one application ??) and draft guidelines, avian reproduction studies are not required. (Apparently, the draft guidelines they referred to were draft FIFRA 88/reregistration guidance which indicated avian reproduction studies are required if: (1) a pesticide is applied more than three times during the use season; (2) the pesticide has a half-life greater than one month; or (3) the pesticide is applied

at >= 10 lbs. per acre.)[1] I indicated that EEB considered Dithiopyr a persistent pesticide and, therefore, required an avian reproduction study. At some point during the meeting I presented all of EEB's data requirements, but acknowledged that the avian reproduction study was the major concern as outlined previously by Mr. Akerman. I then presented EEB's determination of why the Branch considered Dithiopyr persistent:

> -- EFGWB's "Executive Summary" (from their May 24, 1990, review) indicates Dithiopyr is resistant to hydrolysis and photodegradation with half-lives of 523 to 639 days in soil.
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> -- EFGWB's May 24, 1990, review under "Terrestrial field dissipation", indicates half-lives of .6 to 68 days for the EC formulation, 14 to 58 days for a micro-encapsulated formulation, and 3 to 96 days for the granular formulation.
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> -- The Dithiopyr label contains directions/statements that indicate persistence: e. g., reseeding or sprigging within 3 to 6 months after application may inhibit the growth of grasses, grass clippings from treated areas are not to be used for mulching around vegetables or fruit trees, the early postemergent use of Dithiopyr may result in the delay of establishment of turf grasses planted in the fall. (These label statements imply that Dithiopyr will persist throughout the turf's growing season or from spring to fall.)

Discussion on the above continued with Anne Lindsay joining the meeting at this point. Monsanto asked if they submitted the chronic mammalian data (which they apparently developed to support a rice registration in Japan), would that help to alleviate EEB's avian reproduction concerns. I indicated that submission of such data would help, but stated that:

> -- Only one of the four criteria which trigger the avian reproduction study requirement have to be met.[2] Therefore, even if the chronic mammalian studies showed adverse effects only at high treatment levels, technically Dithiopyr has triggered this requirement

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[1] These criteria were reviewed during their development by EEB and found unacceptable. It is my understanding that the criteria presented in Part 158 and Subdivision E were retained as reregistration guidance to registrants.

[2] I've attached the four criteria from Subdivision E, marking those which Dithiopyr has triggered, based on the presently available data -- i. e., criteria (i) and (ii).

and it would be up to the EEB Branch Chief to determine if EEB would still require the avian reproduction study or if EEB could go along with a conditional registration, but one that included an avian reproduction study requirement.

-- Even though EEB is willing to examine the chronic mammalian data, normal procedure dictates that HED must validate such data first before we utilize said data. Since these data are very complex, HED requires a significant amount of time to review them; consequently, EEB most likely would not utilize such data for months.

At this point some discussion on the avian reproduction study, the chronic mammalian data, and what Monsanto could do continued -- the major issue for Monsanto being the need for an Agency decision by the end of 1990 so that their management could make decisions concerning registration of Dithiopyr. Then Anne Lindsay summarized the issues putting into perspective what each party needed to do and indicating that RD would contact HED and EEB early next week (Tuesday, November 13th) to discuss the above issues. The meeting then adjourned.

Attachment

cc: C. Moulton, EEB
J. Miller, RD

(1) Large and relatively scarce mammals.

Agr. Res. Service, U.S.D.A. Animal Disease and Parasite Research Division. 1969. The toxicity of some organic herbicides to cattle, sheep, and chickens. A.R.S. Production Research Report No. 106. U.S. Dept. Agriculture, Wash., D.C.

(2) Small mammals LC50. The following reference contains an acceptable protocol for determining the dietary toxicity in small animals.

McCann, J.A., Teeters, W., Urban, D.J., and Cook, N. 1981. "A Short Term Dietary Toxicity Test on Small Mammals," Avian and Mammalian Wildlife Toxicology: Second Conference, ASTM STP 757, D.W. Lamb and E.E. Kenaga, Eds., American Society for Testing and Materials, Pp. 132-142.

§ 71-4 Avian reproduction test.

(a) When required. (1) Data on avian reproductive effects are required by 40 CFR § 158.145 to support the registration of an end-use product which meets one or more of the following criteria:

* (i) Its labeling contains directions for using the product under conditions where birds may be subject to repeated or continuous exposure to the pesticide or any of its major metabolites or degradation products, especially preceding or during the breeding season.

* (ii) The pesticide or any of its major metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in avian feed.

(iii) The pesticide or any of its major metabolites or degradation products is stored or accumulated in plant or animal tissues, as indicated by the partition coefficient of lipophilic pesticides (§§ 165-3, -4, and -5 of Subdivision N) metabolic release and retention studies (§ 85-1 of Subdivision F), or as indicated by structural similarity to known bioaccumulative chemicals.

(iv) Any other information, such as that derived from mammalian reproduction studies (§ 83-4 of Subdivision F), that indicates the reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the pesticide product.

(2) Applicants for registration of avicides should consult with the Agency prior to conducting this test.