122804

NOTE TO FILE 9-12-89

FROM: Dan Rieder

SUBJECT: Meeting with Merck and PM on field testing requirements for Abamectin

On 9-12-89, James Akerman, Dan Rieder and Adam Heyward of EPA met with representatives of Merck Company. Merck requested the meeting to further discuss the need for field testing requirements.

In previous reviews, EEB requested that Merck perform field testing for both aquatic organisms and mammals to measure effects from the use of Abamectin on citrus and cotton. In several responses, Merck challenged the need for these tests based on how I used certain data. The data pertained to both the aquatic and mammals hazard assessment.

The majority of the issues had been presented earlier, and I had already responded. These old issues included:

1. Halflife used in the model;

2. Kd value used in model;

3. Use of maternotoxicity test NOEL for acute concern; and

4. Use of "weanling" LD50 - they said the study was conducted with infant rats only 1-2 days old.

There were new issues presented:

1. The registrant proposed a 100 yard buffer zone to protect aquatic habitat. They believed that the proposed 100 yd. buffer would adequately protect against exposure due to drift;

2. They also proposed that the label (for cotton) be modified to allow use only West of the Mississippi, as that is where most of the mite problem exists, and they felt exposure from runoff would be thus reduced; and

3. They proposed to limit the number of applications for citrus and cotton to no more than 3, with 21 day intervals, to avoid a continuous chronic exposure.

They did suggest that we had already [redacted] with regards to exposure via runoff and they felt cotton was the only use with such a problem.

On the mammal issue, they continued to question the use of the NOEL from the maternotoxicity study (0.05 mg/kg/day) rather than some sort of an LD50. I agreed that the data for abamectin was unusual, and it required many decisions on exactly how to use it. They specifically wanted me to reconsider an LD50 for pregnant

females, since it shows that the LD50 is about 7 mg/kg; much greater than the NOEL for the maternotoxicity test. I indicated I would reconsider[1].

They suggested that crop areas such as cotton, citrus and celery are not prime mammal habitat and that even trying to control rodents in some areas was a problem considered how prolific they are. Thus hinting that we should have minimal concerns for mammals.

Jim indicated that he wanted to separate the citrus/cotton uses which had already been issued from the other uses which were still being proposed [redacted]

Some questions that arose from the meeting:

1. Will we accept their risk reduction measures such as 100 yard buffers, limiting the use of abamectin (on cotton) to west of the Mississippi River, and reducing the number of applications per season and specifying a minimum between harvest interval as a means of reducing risk and to avoid performing field studies?

2. Was the use of the NOEL from the maternotoxicity study too conservative? Should I stick to the more traditional LD50 values to assess potential acute exposure?

3. Should the soil halflife be used in the SWRRB model where it asks for soil degradation? They wanted to use the photolytic halflife.

4. At what point (between harvest interval) do repeat applications shift from a set of separate unrelated acute exposures to a series of treatments resulting in chronic exposures?

5. How are we going to use the sediment toxicity test using daphnia exposed to contaminated suspended particles?

6. Is it true that EEB is not concerned with runoff from [redacted] growing areas?

7. Is cotton the only use proposed for abamectin with a runoff problem?

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[1] I had used the maternotoxicity NOEL for my level of concern for acute hazard, since one of 20 females died at 0.075 mg/kg/day. It seems that value is significant, and that it could just be my wording that allows their argument to sound convincing that the LD50 should be used. I suggested to Jim that possibly a peer review may be appropriate, since the abamectin data set is somewhat different than the standard data set.

They are going to submit their proposals on label changes and reiterate their interpretation of the mammal data. The EEB will consider the label restrictions and the reinterpretation of the mammal data. The fate values used will be reconsidered in conjunction with EFGWB.