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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Certified Mail

Melvin K. Tolliver
Bayer Corporation
Agriculture Division
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013

JUL 6 1998

Subject: Fenamiphos Reregistration
Your May 7, 1998 Request to Terminate Fenamiphos Groundwater Study

Dear Mr. Tolliver:

The Agency has reconsidered your request to terminate the ongoing fenamiphos prospective groundwater monitoring study in Georgia and has concluded that you have not provided a sufficient basis to terminate this important study. As indicated in the enclosed review from the Environmental Fate and Effects Division, the Agency does not believe that the environmental fate of fenamiphos is adequately understood to abandon the study at this time. Given that other field studies have demonstrated that fenamiphos is capable of leaching into groundwater, your reasons for terminating the Georgia study are inconclusive and premature. The Agency is still concerned about the potential of fenamiphos to contaminate groundwater.

In future progress reports, please include the analytical results from soil core sampling, as well as results from soil pore water and ground water samples. Such data could have some bearing on any future consideration to terminate some part or all of the study.

If you have any questions, please contact Michael McDavit at (703) 308-0325.

Sincerely,

Jack E. Housenger, Associate Director
Special Review and
Reregistration Division

Enclosure

1

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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

May 27, 1998

MEMORANDUM

SUBJECT: Fenamiphos prospective ground water study termination request, revisited

FROM: Jim Carleton, Chemist
Fate and Monitoring Branch
Environmental Fate and Effects Division

TO: Judy Loranger
Special Review and Reregistration Division (7508W)

DP Barcode: D246088

Bayer has submitted a request for reconsideration of the Fate and Monitoring Branch's (FMB) decision (E. Behl, 2/23/98) not to allow Bayer to terminate the Georgia prospective ground water monitoring study on fenamiphos. The previous request was accompanied by the 4th quarterly progress report from the study (DP242559). FMB denied the previous request based on several data and reporting deficiencies identified in that report. Deficiencies included the absence of any tabulated information on fenamiphos or fenamiphos sulfone residues in collected samples, reporting ambiguities for apparent nondetects, and the fact that the bromide tracer front had not yet moved through the ground water.

In their reconsideration request, Bayer has clarified some of these issues, explaining that fenamiphos and fenamiphos sulfone results were not reported because no detections for them occurred, in soil pore water or ground water samples. Bayer agrees with EPA that the bromide front did not move through the ground water, but argues that continued sampling is not needed because the absence of residues in samples collected thus far demonstrates "no indication of leaching" for fenamiphos. However, fenamiphos and its degradates have been demonstrated to leach to ground water in other field studies. It is not clear that leaching will not eventually occur at the Georgia site as well. The fate of fenamiphos at this site is not yet fully understood. For

instance, while Bayer reported collecting soil core samples (0 to 12 inch depth) at this site, they have not yet reported any analytical results for these samples. This information may be crucial to understanding why no leaching of the chemical has apparently yet occurred. It is thus the position of FMB that termination of the study would be premature at this time. Future progress reports should include results from soil core sampling as well as soil pore water and ground water.

(3)

DP BARCODE: D246088 REREG CASE # 0333

CASE: 819346 DATA PACKAGE RECORD DATE: 05/15/98
SUBMISSION: S542501 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 623 INITIATE RED CHAPTER
CHEMICALS: 100601 Fenamiphos %

ID#: 100601
COMPANY:
PRODUCT MANAGER: 53 WALTER WALDROP 703-308-8062 ROOM: CS1 2C3
PM TEAM REVIEWER: JUDITH LORANGER 703-308-8056 ROOM: CS1 3G5
RECEIVED DATE: 05/15/98 DUE OUT DATE: 08/13/98

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 246088 EXPEDITE: Y DATE SENT: 05/15/98 DATE RET.: / /
CHEMICAL: 100601 Fenamiphos
DP TYPE: 102 Phase V Review
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	/ /	/ /
BRAN: FMB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 06/14/98
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Attn: EFED Betsy Behl
In their 5/7/98 letter attached, Bayer is requesting that we reconsider our decision and allow them to terminate the Georgia GW study in addition to other proposals listed in the letter. Please comment. They would like a decision as soon as possible. Thanks Judy Loranger

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

(9)

Bayer

Agriculture Division

Bayer Corporation
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013
Phone: 816 242-2000

May 7, 1998

Judy Loranger
Chemical Review Manager
Special Review and Reregistration Division, H7508W
Office of Pesticide Programs
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Subject: NEMACUR (Fenamiphos)
EPA Chemical No. 100601
4th Progress Report for Georgia Prospective Groundwater Monitoring Study
Termination Request

Dear Ms. Loranger:

In the Agency's April 20, 1998 letter, we received a February 23, 1998 memorandum from the Environmental Fate and Effects Division (EFED) regarding our request to terminate the subject study. In the Agency's letter we were requested to respond within 30 days with a discussion of our plans for the Georgia Prospective Groundwater study.

Bayer's Future Plans:

1. Bayer requests that EFED reconsider termination of the study, based on Bayer's responses to EFED's review of the termination request (see below). **Bayer requests a response as soon as possible.**

2. Bayer will re-initiate analysis of bromide and fenamiphos residues in samples collected between October 1997 and May 1998 (month 23). Analysis is expected to be completed by mid-June.

3. If EFED does not approve termination, based on Bayer's responses given below, the new analyses will be provided in Progress Report # 5, at which time, Bayer will again request termination of the study.

4. Pending termination of the study, water sampling will occur in June (2 year interval), August, October, and December 1998, and then quarterly in 1999 (Mar, Jun, Sep, Dec). Soil sampling will be terminated after the June 1998 sampling event.

(5)

In the February 23, 1998 EFED memorandum, there were a number of comments which we are responding to. We have numbered these comments for clarity.

EFED Comment 1: The report submitted by Bayer includes almost no data for fenamiphos residues.

Bayer Response: All fenamiphos residue detections, at concentrations greater than 0.05 µg/L, were given in Tables 6-7 and Figure 5.

EFED Comment 2: Tables 6 and 7 show fenamiphos sulfoxide in soil pore water (averaged and individual sample concentrations). There are no companion tables for fenamiphos parent or fenamiphos sulfone.

Bayer Response: Soil pore water samples did not contain fenamiphos or fenamiphos sulfone, therefore the tables were not presented (see Progress Report page 3, section 5.2, second paragraph).

EFED Comment 3: In Table 7, concentrations of fenamiphos sulfoxide in soil pore water are listed as 0.0 µg/L. Is this accurate? What is the LOQ?

Bayer Response: "-" indicates that each analyte was less than 0.05 µg/L. For calculation of average residues in this table, any value less than 0.05 µg/L was considered 0.00 µg/L. The LOQ is 0.1 µg/L with a reporting limit of 0.05 µg/L (see progress report page 2, section 5.0).

EFED Comment 4: Figure 5 is a graph of total residues (fenamiphos plus two degradates) in soil pore water. Individual samples are not presented, only depth averaged and maximum values. There are no graphs separately presenting the distribution of these three compounds.

Bayer Response: As presented in Tables 6-7, the only residues were fenamiphos sulfoxide (no fenamiphos or fenamiphos sulfone; see Progress Report page 3, section 5.2, second paragraph). It is not clear what additional graphs EFED is requesting: "total residues" in the individual lysimeters, or depth averaged and maximum residues of the individual analytes. Bayer requests clarification.

EFED Comment 5: There are NO DATA on the fenamiphos, fenamiphos sulfoxide, or fenamiphos sulfone residues in any ground water monitoring wells. Without these basic data we cannot consider the request for termination of the data.

Bayer Response: Fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone were not detected at concentrations above 0.05 µg/L in ground water (see Progress Report page 3, section 5.3). Tables and graphs were not prepared since there was no data to present.

EFED Comment 6: A cursory look at the bromide data submitted indicates the front has not moved through either the soil water (table 4) or ground water (table 8). Thus it is not clear upon what basis Bayer can conclude that "..the patterns of transport for bromide and fenamiphos residues have been determined and the goals of the study have been met".

Bayer Response: The bromide front moved through the soil water to a minimum depth of 15 feet, as evidenced by the decreasing concentration in each of the 15-foot lysimeters (Bayer is defining the "front" as the peak concentration). Bayer agrees that the bromide front did not move into the ground water (bromide was detected in four of eight well clusters). However, fenamiphos residues (fenamiphos sulfoxide) was only detected in 5 lysimeter samples, each at less than 0.2 µg/L, and these detections did not indicate any pattern of leaching. Therefore water (bromide) moved rapidly through the soil profile to a depth greater than 15 feet below ground surface, but pesticide residues show no indication of leaching, and the few detections in soil pore water were at very low concentrations (<0.2 µg/L).

EFED Comment 7: Request information/clarification: (a) date of sampling, (b) LOQ, (c) LOD, (d) no sample, (e) data presented in tabular and graphical form, (f) chronology of events.

Bayer Response: (a) Date of Sampling - given in Tables 4, 6 and 8

(b) LOQ - The LOQ is 0.1 µg/L. The method was shown to be linear to 0.05 µg/L, which was chosen as the "Reporting Limit" for the study.

(c) LOD - The limit of detection was not determined. It is estimated to be 0.02 - 0.03 µg/L for each analyte. A reporting limit of 0.05 µg/L (2.5% of the Health Advisory Level), is sufficient to detect any concentrations which may be of concern to human health. If EFED is requesting that Bayer review the entire study data, to distinguish detects from non-detects, Bayer requests that EFED provide a rationale or purpose for this data (new findings would provide only detections at less than 0.05 µg/L).

(d) No sample - A blank indicates a sample was not collected (Table 6 footnote).

(e) Data presented as tabular and graphical - Tables and graphs were presented for data with detections greater than 0.05 µg/L. In the final report, tables for each analyte and sample will be presented. Additional graphs will also be prepared.

(f) Chronology of events - The chronology of events is given in each progress report, for the period covered by the report (total of four progress reports). Characterization, instrumentation, planting, application, and sampling and irrigation events are presented in the attached field report for each progress report.

If you have any questions concerning this submission, please contact Mr. Melvin Tolliver of my staff at (816) 242-2150.

Sincerely,

BAYER CORPORATION
AGRICULTURE DIVISION

John S. Thornton
Director, Product Registrations
and Regulatory Affairs

MKT:ec