25/6/1#34134B

(21PP)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 5, 1999

MEMORANDUM

SUBJECT: Phase 5 -- Meeting with Bayer Corporation

From: Todd Peterson, Ph.D.
Chemical Review Manager
Reregistration Branch 3
Special Review and Reregistration Division

To: OPP Docket Room

Please enter the enclosed meeting minutes (1 page) and paper copy of the registrant's handout (19 pages) into the fenamiphos OP docket (**OPP-34134B**)

If you have questions concerning this material, I can be reached at 308-7224.

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**Fenamiphos Meeting Minutes**

**November 2, 1999**

The OP/Pilot process is separated into six phases. During the current phase for fenamiphos, Phase 5 (September 2 to November 14), the Agency is available to meet with any stakeholder who wishes to present information concerning risk management. Bayer Corporation requested this meeting to discuss risk management issues in relation to the Agency's surface-, ground-, and drinking water assessments.

The two hour meeting was held November 2, from 10 AM to Noon, in Arlington, Virginia. The Agency was represented by B. Behl (EFED), S. Knizner (HED), Michael McDavit (SRRD), and T. Peterson (SRRD). The registrant was represented by M. Tolliver, V. Clay, P. Coody, and D. Dyer.

Bayer presented information in a format that is illustrated by a set of overheads (see handout with slides printed two to a page). The registrant initially presented information on surface water followed by a summary of issues related to ground water. The Agency acknowledged receiving Bayer's recent submission of: 1) the final report of the Georgia prospective ground water study, and 2) the quarterly report of the ongoing California prospective ground water study. The meeting concluded with a brief discussion of additional information the registrant can supply to the Agency and on how a more comprehensive interim report may be compiled to describe the California study.

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## Fenamiphos Exposure via Drinking Water:

Clarifying the Issues...
Working for Solutions...



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## Status of the FQPA Assessment for Fenamiphos

- Dietary Risk is Low at 99.9$^{th}$ Percentile Exposure
  - US population: 28% aPAD 4% cPAD
  - Nursing Infants: 68% aPAD 14% cPAD
- Drinking Water Risk is High based on Tier I/II surface water modeling and limited ground water monitoring in vulnerable areas.
- Drinking water exposure exceeds the aPAD
- Aggregate (FQPA) risk is High due to drinking water





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# Evaluation of Product Usage

- Product usage is a primary driver of exposure.
- Analysis of the 1998 product usage suggests the potential for exposure is geographically limited.
  - Nematode pressure is highest in warm, light-textured soils
  - Pest control costs typically limit usage to high-margin crops:
    - Tobacco
    - Cotton
    - Grapes
    - Citrus



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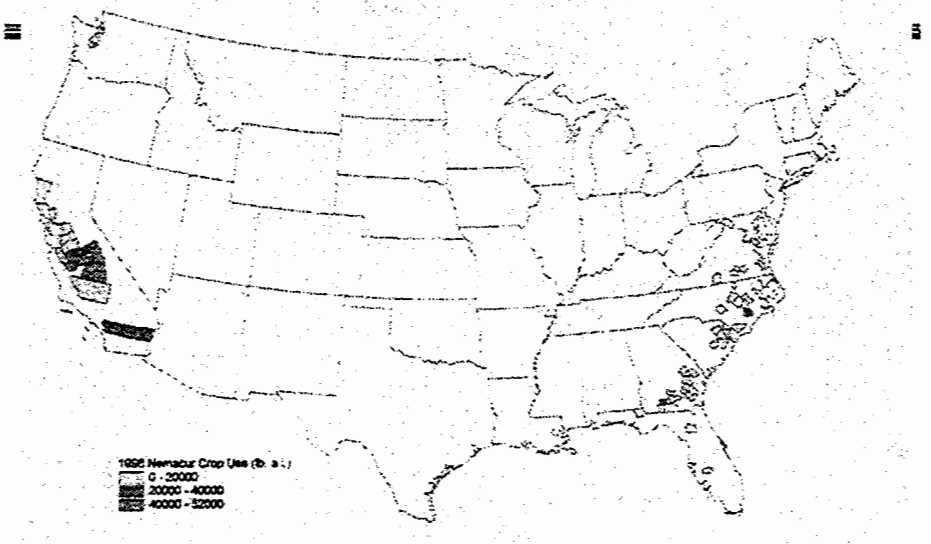
## 1998 Nemacur Use (lb. a.i.) on Crops





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# Focusing on Surface Water

- Current risk analysis is based on Tier I (turf) and Tier II (other crops) predictions.
- All agree that monitoring data are limited, and generally do not include important degradates.
- Current EPA policy suggests that predictive models will not be used in final tolerance assessment decisions:
  - Stephen Johnson Memo of November 17, 1997 to OPP Directors
  - EPA Science Policy 5



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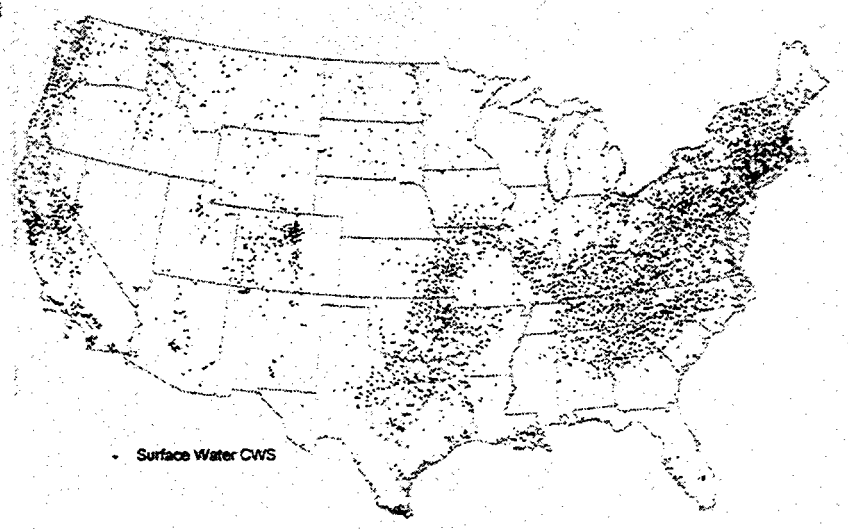
## Surface Water CWS in the United States





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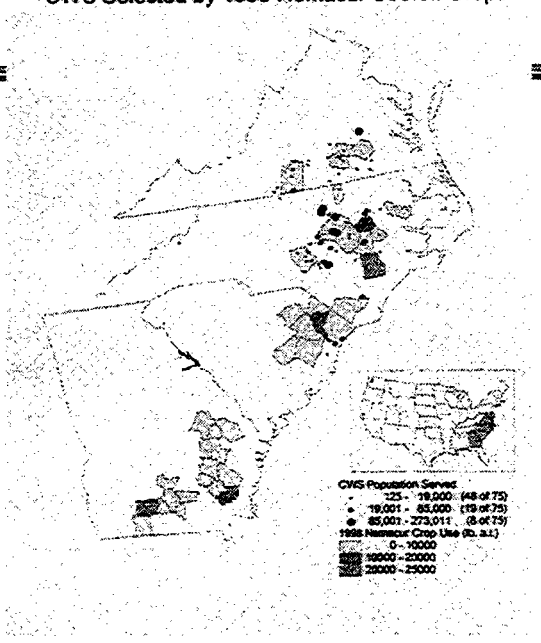
## CWS Selected by 1998 Nemacur Use on Crops



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## Clarification of the SW Issue

**"Reliable Exposure Data" are clearly needed to refine the SW exposure assessment**

- Product Use is a driver of exposure. Where are the "hot spots" of concern
- Runoff data can be used to refine the assessment and provide "a reality check"
- Where do we go from here as the product is in Phase 5 of the regulatory process with insufficient exposure analyses for surface water?
  - What can Bayer and EPA do to help resolve this shortcoming at this time?



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## Using Field-Measured Runoff Results in a Refined (Tier 2.5?) Drinking Water Assessment

- Runoff studies were performed by Bayer (1990) and Wauchope (in 1992-3, unpublished)
  - Bayer: Tobacco and Cotton seedbeds in Meigs, GA
  - Wauchope: Corn seedbed in Tifton, GA
- Typical "meso-plot" methods were used in both studies, making them very similar in design - the results can be directly compared.
- This drinking water assessment summarizes the runoff results and uses the EPA Farm Pond as the basic exposure scenario
- This is consistent with EPA Tier I/II modeling.



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## Overview

- Briefly describe meso-plot runoff study concepts
- Show results for two similar field studies
- Detail how results are used in an exposure assessment to provide a more reliable "worst case exposure"
- Present results and describe limitations
- Compare to existing exposure results
- Seek the Agency's input on this concept as means of moving toward "reliable information" for a fenamiphos exposure assessment



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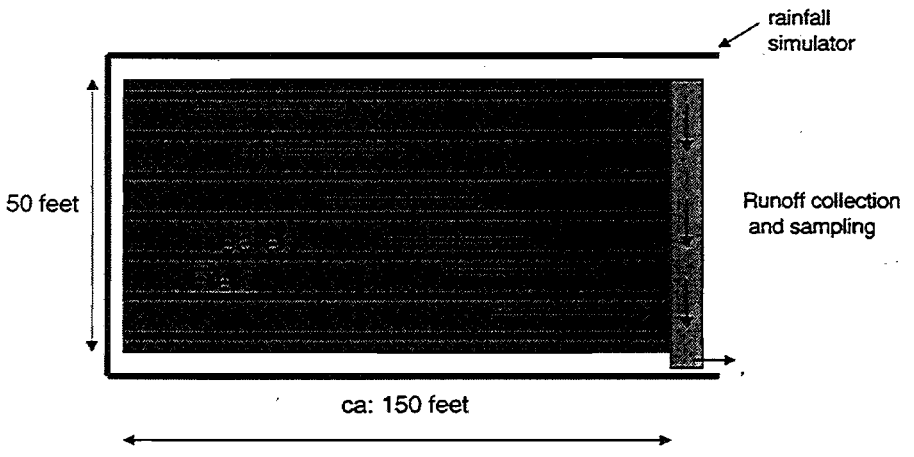
# Meso-Plot Runoff Concepts



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# Meso-Plot Runoff Testing

- Farming practices are performed with commercial equipment - typical farm practices
- Test compound is applied following normal practices
- Heavy rainfall can be imposed any time after treatment as needed for exposure assessment
- Field staff is present for critical runoff sampling and test plot maintenance
- A *relatively* controlled test system at the field scale



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# Summary of Bayer Runoff Study in GA

| | Test Plot | | | | |
|---|---|---|---|---|---|
| | EP1 | EP2 | EP3 | GP1 | GP2 |
| Crop | Tobacco | Tobacco | Tobacco | Cotton/Peanuts | Cotton/Peanuts |
| Formulation | 3 EC | 3 EC | 3 EC | 15G | 15G |
| Treatment (lb ai/acre) | 6 | 6 | 6 | 2.55/banded | 2.55/banded |
| Incorporation | Disked/bedded | Disked/bedded | Disked/bedded | Scratch Incorp. | Scratch Incorp. |
| Days from Applic. To Runoff | 1 | 2 | 3 | 1 | 2 |
| Rainfall (cm) | 9.22 | 5.18 | 9.60 | 4.78 | 9.40 |
| Rainfall (L) | 64,242 | 36,103 | 66,896 | 33,271 | 65,481 |
| Runoff (Ft3) | 624 | 181 | 677 | 31 | 504 |
| Runoff (L) | 17,670 | 5,125 | 19,171 | 878 | 14,272 |
| Runoff (%) | 28 | 14 | 29 | 3 | 22 |
| Fenamphos Residues (mg) | 982 | 651 | 1,867 | 334 | 405 |
| Sulfoxide Residues (mg) | 728 | 319 | 1,219 | 71 | 2,703 |
| Sulfone Residues (mg) | Not Detected | Not Detected | Minor Detection | Not Detected | Not Detected |
| Total Residues (mg) | 1,711 | 987 | 3,086 | 405 | 2,703 |



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# Wauchope Runoff Study in GA

| | 1992 | | 1993 | |
|---|---|---|---|---|
| Test Plot ID | A | B | A | B |
| Crop | Corn | Corn | Corn | Corn |
| Formulation | 3 EC | 3 EC | 3 EC | 3 EC |
| Treatment (lb ai/acre) | 5.98 | 5.98 | 5.98 | 5.98 |
| Incorporation (REQUIRED) | Rototilled | Rototilled | Rototilled | Rototilled |
| Days from Applic. To Runoff | 1 | 1 | 1 | 1 |
| Rainfall (cm) | 5 | 5 | 5 | 5 |
| Rainfall (L) | 30,958 | 30,958 | 30,958 | 30,958 |
| Runoff (L) | 4,372 | 5,624 | 9,360 | 8,301 |
| Runoff (%) | 14 | 18 | 30 | 27 |
| Fenamphos Residues (ug/L) | 293 | 394 | 94 | 93 |
| Sulfoxide Residues (ug/L) | 322 | 322 | 427 | 269 |
| Sulfone Residues (ug/L) | 2 | 0 | 4 | 4 |
| Total Residues (mg) | 2,699 | 4,027 | 4,915 | 3,034 |



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# A Simple Exposure Assessment

## Measured runoff data is used with the EPA's Farm Pond

***Note: linear spatial scaling leads to overestimating runoff losses at the field scale***

Runoff is from extreme storm events in the field studies

Runoff results are projected to the larger field area.

Water concentrations are based on fixed pond volume.

Aquatic degradation is not represented



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# Exposure Summary

| | Mobay Corporation Study Number 102638 | | | | | Wauchope, 1999 (personal communication) | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Location: Meigs, GA Soil: Tifton Loamy Sand | | | | | Location: Tifton, GA Soil: Tifton Loamy Sand | | | |
| Growing Season | 1990 | 1990 | 1990 | 1990 | 1990 | 1992 | 1992 | 1993 | 1993 |
| Crop Seeded | Tobacco | Tobacco | Tobacco | Cotton/Peanuts | Cotton/Peanuts | Corn | Corn | Corn | Corn |
| Formulation | 3 EC | 3 EC | 3 EC | 15G | 15G | 3 EC | 3 EC | 3 EC | 3 EC |
| Treatment (lb ai/acre) | 6.0 | 6.0 | 6.0 | 2.55/banded | 2.55/banded | 6.0 | 6.0 | 6.0 | 6.0 |
| Application Placement | Broadcast | Broadcast | Broadcast | Banded | Banded | Broadcast | Broadcast | Broadcast | Broadcast |
| Incorporation | Disked/bedded | Disked/bedded | Disked/bedded | Scratch | Scratch | Rotofilled | Rotofilled | Rotofilled | Rotofilled |
| Days from Applic. To Runoff | 1 | 2 | 3 | 1 | 2 | 1 | 1 | 1 | 1 |
| Plot Size (ha) | 0.070 | 0.070 | 0.070 | 0.070 | 0.070 | 0.062 | 0.062 | 0.062 | 0.062 |
| Rainfall (cm) | 9.2 | 5.2 | 9.6 | 4.8 | 9.4 | 5.0 | 5.0 | 5.0 | 5.0 |
| Runoff (%) | 27.5 | 14.2 | 28.2 | 2.6 | 21.8 | 14.1 | 18.2 | 30.2 | 26.8 |
| Fenamiphos Residues (mg) | 981.9 | 651.5 | 1,267.2 | 334.2 | 405.5 | 293.0 | 394.0 | 94.0 | 93.0 |
| Sulfoxide Residues (mg) | 728.0 | 319.3 | 1,219.2 | 71.3 | 2,703.3 | 322.0 | 322.0 | 427.0 | 269.0 |
| Sulfone Residues (mg) | Not Detected | Not Detected | Minor Detection | Not Detected | Not Detected | 2.3 | 0.0 | 4.3 | 3.5 |
| Total Residues (mg) | 1,711 | 967 | 3,066 | 405 | 2,703 | 2,699 | 4,027 | 4,915 | 5,084 |
| EPA's Worst Case Drinking Water Exposure Result (ppb) | 12.3 | 7.1 | 22.1 | 2.9 | 19.4 | 21.8 | 32.5 | 39.7 | 24.5 |





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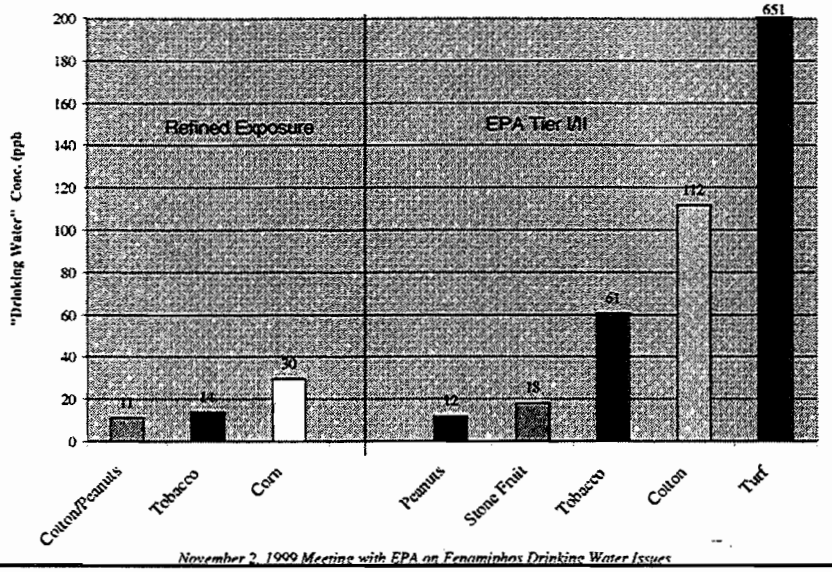
# Comparison of Results

***(conservative farm pond concentrations)***






# Refined Exposure Summary

- The refined (Tier 2.5) exposure assessment provides values on the range of 0.1(cotton) to 1 (peanuts) times EPA Tier II values.
- The refined results are still *very conservative* based on the following assumptions
  - Drinking water comes from farm ponds with 100% application in watershed
  - Runoff results can be scaled linearly from meso-plot to field (this conservative method violates MUSLE)
- The worst case numbers are slightly above the DWLOC, but considering the conservative nature suggest the real world exposure should be within the "Risk Cup".
- This case study is not fully developed, but may provide a reality check for the current regulatory values.



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## Clarification of the GW Issue

- Current exposure assessment is based on Florida PGW monitoring results: The history and results of that study in a regulatory setting.
- Details of two new studies not considered in the current exposure assessment.
- Where do we go from here?



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## Florida Retrospective Study -- 1989

- **Location**: Lake Placid, Highlands County, Florida
- **Crop**: Citrus
- **Soils**: Sand (to water table)
- **Application:**
  - NEMACUR 3EC; 10 lb a.i./acre
  - 50% Band (20 lb a.i./acre in treated zone); Incorporated via irrigation
- **Results:** Maximum Concentration -- fenamiphos + sulfoxide + sulfone = 253 µg/L
- **Actions:**
  - **Label Rate for Citrus reduced to 5 lb/acre.**
  - **FL PGW Study required to study mitigation measures**





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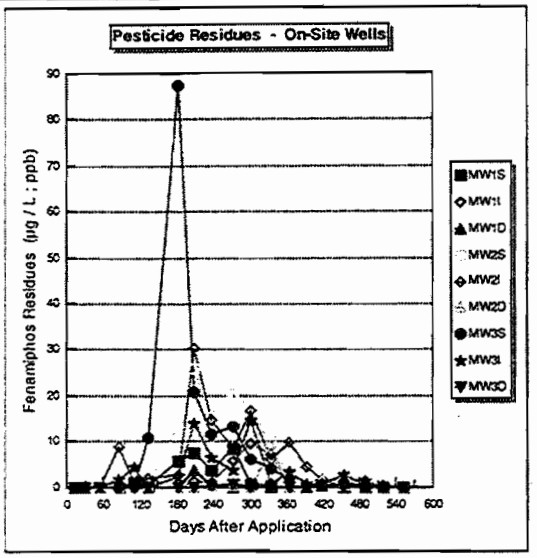
# Florida PGW 1995 -- Ground Water



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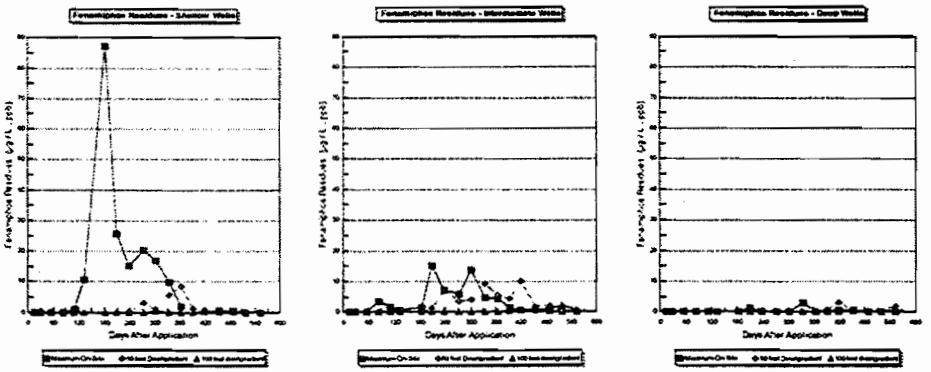
# Florida PGW 1995 -- Ground Water



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## Georgia PGW 1996 -- Study Overview

- **Location**: Byromville, Dooly County, Georgia
- **Crop**: Tobacco
- **Soils**: 0-6" **loamy sand**; 87% sand, 8% clay; 1.4% OM; pH 5.6
  0.5-12ft **loamy sand**; 88-82% sand, 6-14% clay, <2.2% OM
  >12 ft **sand** (predominantly)
- **Depth to Water: ~27 feet**
- **Application: June 5, 1996**
  - NEMACUR 3EC; 6.6 lb a.i./acre (110% of maximum label)
  - Broadcast Spray; Mechanical Incorporation to ~4 inches
  - KBr -- Applied at 50 lb/acre as a broadcast spray
- **Water: 200 inches (147% of 30-year average)**
- **Status: Final Report Submitted October 1999**



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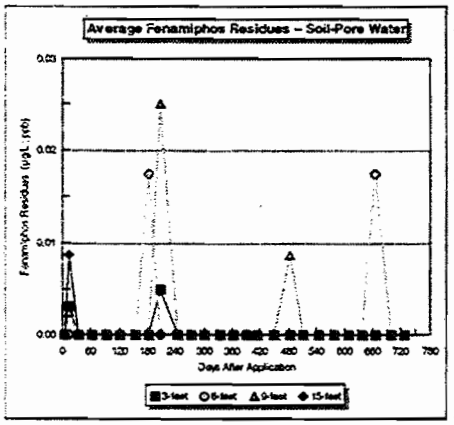
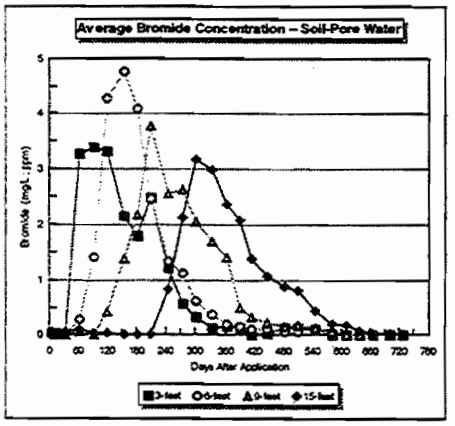
## Georgia PGW 1996 -- Soil-Pore Water

Fenamiphos detected in 3 samples, fenamiphos sulfoxide detected in 5 samples.








15 of 21

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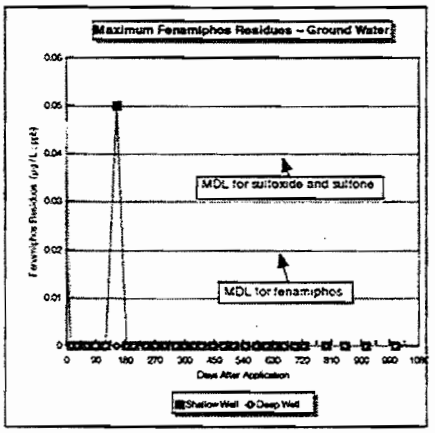
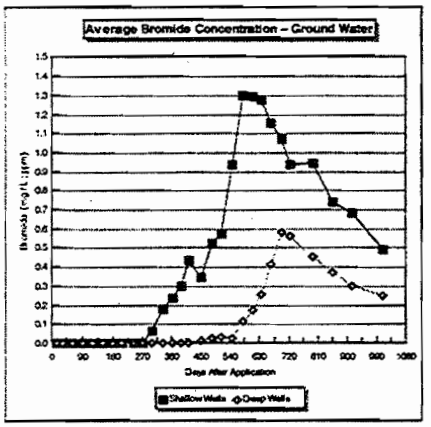
## Georgia PGW 1996 -- Ground Water

Fenamiphos sulfoxide detected in 2 samples (0.05 and 0.04 µg/L, 153 DAT).



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## California PGW 1997 -- Study Overview

- **Location**: Sanger, Fresno County, California
- **Crop**: Grapes
- **Soils**:
  - 0-6" **loamy sand**; 86% sand, 6% clay; 0.8% OM; pH 6.8
  - 0.5-8ft **loamy sand**; 90-79% sand, 3-13% clay, <0.2% OM
  - >8 ft **sand** (predominantly)
- **Depth to Water: ~20 feet**
- **Application: October 15, 1997**
  - NEMACUR 3EC; 6.6 lb a.i./acre (110% of maximum label)
  - 50% Band (13 lb a.i./acre in treated zone); Incorporated via irrigation
  - KBr -- Applied at 55 lb/acre as 50% band
- **Water: 60 inches (through April 1999)**
- **Status: Progress Report Submitted October 1999 (610 DAT)**



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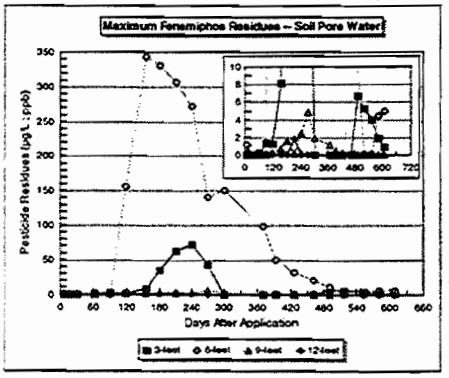
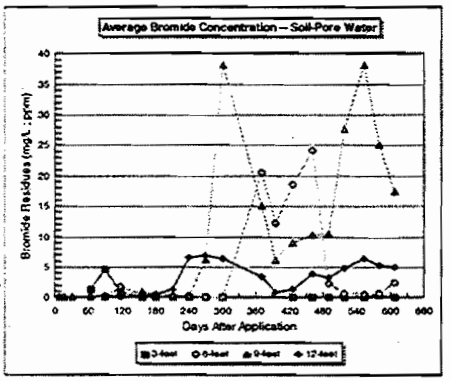
# California PGW 1997 -- Soil-Pore Water



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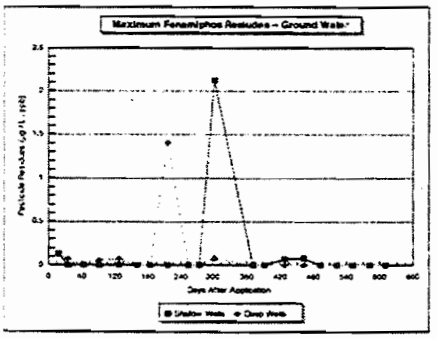
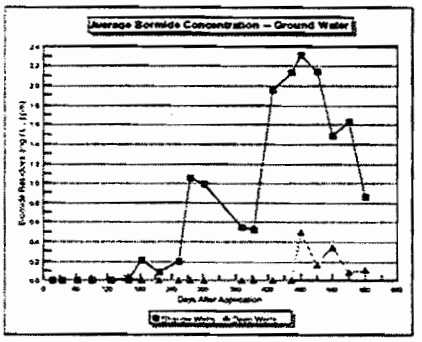
# California PGW 1997 -- Ground Water

Fenamiphos detected in 1 sample, sulfoxide in 13 samples, sulfone in 1 sample.
**Maximum Total Fenamiphos Residue = 2.1 µg/L**



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## Vulnerability Assessment -- Tobacco

- Soils suitable for tobacco production selected from NRCS's NRI database.
- Limited to states with significant NEMACUR use and tobacco production:
  - NC, GA, SC, VA, MD, FL
- PRZM3 used to model soil/weather combinations.
- Weather Data -- Artificial year of rainfall at 120% of the 30-year average was constructed from 30-year history for each of the regional stations.
  - Irrigation is not typical for tobacco except during drought.
- 340 modelling runs



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## Vulnerability Assessment -- Tobacco

- Scenarios run for 5 consecutive years.
- Concentration of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone, measured at 6 feet below ground surface.
- Concentrations summed (fenamiphos + sulfoxide + sulfone), and ranked by concentration.
- Acres associated with the individual soils/runs was then summed from low to high concentration.
- Total acreage percentiles determined for the GA ground water soil (Lucy loamy sand).

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## Adsorption to PGW Soils

- To determine a possible unique binding in the soil from the Georgia PGW, single point adsorption coefficients were determined.
- 0 to 6-inch and 18 to 24-inch soils from the GA and CA PGW sites were studied.
- The GA 18-24 inch soils were slightly heavier and had a strong red color, both factors that suggested this layer could have higher binding capacities.
- **Results: No extreme differences in binding of fenamiphos, sulfoxide or sulfone in the GA or CA soil (fenamiphos Kd in GA 18 to 24-inch soil ~75% greater than 0 to 6-inch); Kd for fenamiphos (171 to 345 L/kg) was similar to Kf values.**



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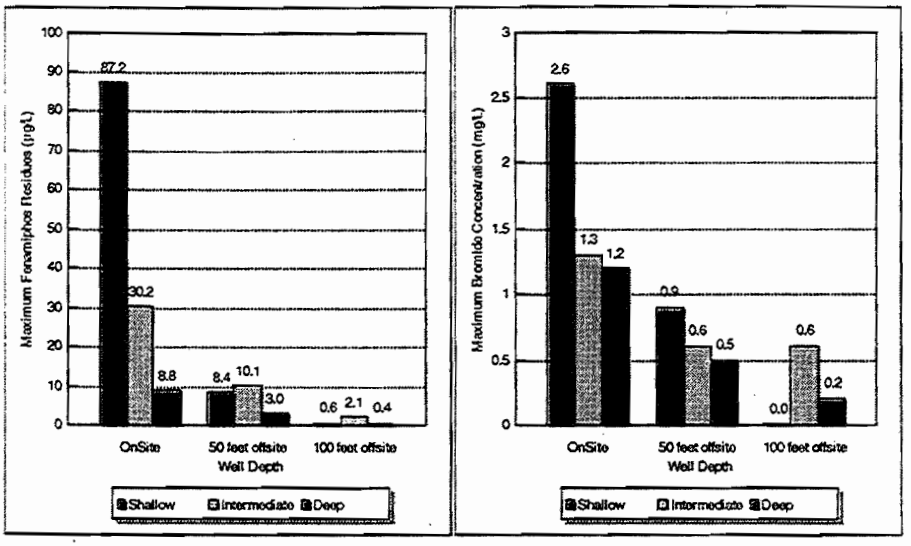
## Are Fenamiphos Residues Persistent in Ground Water?

- Page 27 of EFED's Environmental Risk Assessment: "...but persistent contaminants (such as the fenamiphos degradates) could eventually find their way into drinking water supplies."
- Although laboratory data suggest that fenamiphos residues are stable to hydrolysis, field data suggests that fenamiphos residues dissipate in ground water.
- Compared fenamiphos residue dissipation (degradation+dilution) to bromide dissipation (dilution only), with depth and distance from Test Plot (FL PGW 1995).

## Are Fenamiphos Residues Persistent in Ground Water?

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## Are Fenamiphos Residues Persistent in Ground Water?

- Decrease of fenamiphos residues with well depth and distance from Test Plot is significantly greater than bromide decreases.
- Assuming bromide decreases are sue to lateral and vertical movement (dilution) in the ground water, **the greater decrease in fenamiphos residues must be due to degradation or other factors.**
- Impact to drinking water may not be significant, unless wells are located very near a treated field.

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