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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

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SUBJECT: Review of Final Study Reports on Tile Drain Studies for Isoxaflutole in Bagley and Dawson, Iowa and Galatea and New Hampshire, Ohio.

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This memorandum presents our review of the final study reports for four of five tile drain monitoring studies conducted with isoxaflutole, the active ingredient of BALANCE® WDG herbicide. The September, 1998 conditional registration (EPA Reg. No. 264-567) for this chemical required five tile drain studies in midwestern corn fields to assess the potential for isoxaflutole or its metabolites to contaminate water resources (the fifth study was started in May, 2000). The concern was that water drained from such fields might flow to a stream large enough to be used for irrigation, and then be used on other sensitive crops, thereby causing damage to those crops. There was also a concern for endangered plant species. A level of concern (an EC25 or effective concentration for 25% of tested crops) was set at 22 parts-per-trillion from a vegetative vigor study on turnips.

<u>Conclusions</u>

The four tile drain studies reviewed in this report indicate the following:

1. Water resources were contaminated with the first metabolite of isoxaflutole (RPA202248 or DKN) at concentrations *well above* the 22 ppt EC25 for vegetative vigor for 1 to 2 months immediately following application of 2.25 oz ai/acre, at all four sites.

2. Consistent with its environmental fate properties, large spikes in DKN concentration

are well-correlated with rainfall events, indicating that this transformation product is very mobile, and tends to run-off to surface water, where *it can contaminate potential irrigation water*. This was true even when the "stream" in question was five miles downstream from the study site.

3. Detections of DKN above the 22 ppt EC25 for vegetative vigor occurred as long as seven months after a single application, indicating *a potential for carry-over* of isoxaflutole from one growing season to another. This pattern has also been observed for ten drinking water reservoirs in Missouri (Eckel to Kenny memo on DP barcode 273607, 3/23/01).

4. There was evidence of contamination in an Ohio river (Rocky Ford River) coming from upstream of the study area at Galatea. If monitoring data from this river reflect the state's water resources, this *may indicate widespread contamination of Ohio water resources*, as was observed in Iowa in 1999 and 2000 (Mary Skopec, Iowa Geological Survey Bureau, 2/25/01 personal communication).

5. The registrant's conclusion that no phytotoxic symptoms were observed at any study site *was not supported by any data* at all in the final reports. This conclusion is rejected until properly supported.

6. The registrant's presentation of the concentration data (Figure 1 in each report) may be *misleading*. It should have been on a scale of log(parts per trillion), so that the numerous detections of DKN above the 22-ppt level of concern could be observed. Had the data been plotted on a log scale, DKN detections near the 22 ppt EC25 for vegetative vigor would have been more pronounced.

<u>Description of the Studies</u>

The four fields studies were located near Bagley, Iowa; Dawson, Iowa; Galatea, Ohio; and New Hampshire, Ohio. BALANCE® WDG herbicide was applied at the maximum labeled use rate for the location, soil type and application technique at each site. A tracer substance (potassium bromide salt) was also applied at 100 lb/acre. Field corn was then planted, and the concentrations of isoxaflutole and its two metabolites (RPA202248 or DKN for diketonitrile; and RPA203328) were monitored in tile drain water, ditch water, and stream/river water daily for 100 days, then every 10-14 days for 10 events. Data on rainfall, and tile drain flow rate were also collected. The study protocol also called for observations of phytotoxic symptoms (bleaching of chlorophyll) to be made along the ditches.

<u>Bagley, Iowa (MRID 453287-02)</u>

This site was an approximately 3 acre southeast corner section of a 160-acre field at the corner of M Avenue and 340th Street, Greenbrier Township, Greene County, Iowa, near the town of Bagley. The field is tiled with an outlet that empties into a ditch that flows south to

Mosquito Creek. The soil consisted predominantly of Webster silty clay loam. The distance from the field to the Mosquito Creek sampling site is approximately 6000 feet, or more than one mile (fig. 1, p. 96). BALANCE® WDG herbicide was applied on May 11 at the rate of 2.25 oz ai/acre. The corn was planted May 25, 1999. Water sampling began on May 11, 1999 and continued daily to August 19, 1999, and then about every two weeks until December 2, 1999. Rainfall during the study was 4.23 inches in May (11-31); 6.73 in. in June; 4.02 in. in July; and 5.28 in. in August (1-19).

Dawson, Iowa (MRID 453287-01)

This site was an approximately 3 acre isolated field in Dallas County, Iowa, near the town of Dawson. The field is tiled with an outlet to Bucks Branch, which flows east to the North Raccoon River. The soil consisted of Nicollet loam and Canisteo silty clay loam. The distance from the field to the North Raccoon River sampling site is approximately 5 miles (study protocol, p. 7 of 21). BALANCE® WDG herbicide was applied on May 13 at the rate of 2.25 oz ai/acre. The corn was planted May 27, 1999. Water sampling began on May 13, 1999 and continued daily to August 21, 1999, and then about every two weeks until December 2, 1999. Rainfall during the study was 2.98 inches in May (13-31); 9.25 in. in June; 3.40 in. in July; and 5.70 in. in August (1-21).

Galatea, Ohio (MRID 453287-04)

This site was an approximately 10 acre isolated field in Wood County, Ohio, near the town of Galatea. The field is tiled with an outlet to a ditch that flows north to the Rocky Ford River. The soil consisted of Hoytville clay. The distance from the field to the Rocky Ford River sampling site is approximately 4 miles (fig. 1, p. 94). BALANCE® WDG herbicide was applied on May 5 at the rate of 2.25 oz ai/acre. The corn was planted May 15, 1999. Water sampling began on May 5, 1999 and continued daily to August 23, 1999, and then about every two weeks until November 21, 1999. Rainfall during the study was 1.50 inches in May (5-31); 0.80 in. in June; 2.70 in. in July; and 0.60 in. in August (1-12). This was about 7.5 inches below the 1930-1959 average rainfall.

New Hampshire, Ohio (MRID 453287-03)

This site was an approximately 20-acre SE corner section of a 285-acre field in Auglaize County, Ohio, near the town of New Hampshire. The field is tiled with an outlet to a ditch that flows into the Scioto River. The soil consisted of Milford silty clay. The distance from the field to the Scioto River sampling site is approximately 2 miles (fig. 1, p. 101). BALANCE® WDG herbicide was applied on May 5 at the rate of 2.25 oz ai/acre. The corn was planted May 12, 1999. Water sampling began on May 5, 1999 and continued daily to August 24, 1999, and then about every two weeks until January 12, 2000. Rainfall during the study was 1.92 inches in May (6-31);1.30 in. in June; 4.10in. in July; and 0.10 in. in August (1-12). This was about 5 inches below the 1957-1975 average rainfall.

Results

Isoxaflutole Concentrations in Water. The data for the first metabolite of isoxaflutole (RPA202248 or DKN), which is known to be herbicidally active and is more mobile than the parent chemical, is graphed for each site in Figures 1-4. The concentration scale in Figs. 1-4 is logarithmic in parts-per-trillion, since the peak concentrations measured (approx. 5 ppb) are 1000 times the EC25 for vegetative vigor (22 parts-per-trillion). If these data are graphed on a linear concentration scale in ppb, as the registrant has done in each final study report, it is not possible to see the EC25, nor is it possible to see for what period of time the EC25 is exceeded. The registrant's graphical presentation of the results (Figure 1 in each final report) is therefore quite misleading.

Bagley, Iowa. Figure 1 shows the concentrations of DKN in the tile drain, ditch, and Mosquito Creek from May 12 through November. Peak DKN levels in the tile drain water were nearly 3200 ppt in late May and had declined only to 100 ppt by early July. Two spikes in DKN levels above the EC25 occurred in mid-August after storms of 3.5 and 1.0 inches. There was a spike in the DKN concentration every time it rained (and there was flow from the drain).

DKN concentrations in the ditch peaked at about 320 ppt in late May, and then were below the 22 ppt EC25 except for two spikes in late June and early July.

Mosquito Creek DKN levels peaked at over 100 ppt in late May, and then were below the 22 ppt EC25 for June, July and August.

Overall, DKN concentrations in the tile drain water were above the EC25 from late May to early July, and again in Late August. DKN concentrations in the ditch were above the EC25 on 9 occasions from late May to late June, and in Mosquito Creek, the EC25 was exceeded four times in late May.

Dawson, Iowa. Figure 2 shows inches of rainfall, and RPA202248 (DKN) concentrations in the tile drain, Bucks Branch, and North Raccoon River from May 13 to August 21, 1999. DKN concentrations in the tile drain water exceeded 1000 ppt on 34 days from mid-May to mid-July, a period of eight weeks. These concentrations are at least 50 times greater than the 22 ppt EC25 for vegetative vigor and peak at over 200 times that level. DKN was last detected in tile drain water on the last day of flow (Aug 25) at 135 ppt. DKN levels rose sharply each time it rained.

DKN concentrations in Bucks Branch peaked at over 200 times the EC25 (in mid-May) and were continuously above that level mid-May to mid-July, again a period of eight weeks. DKN levels rose sharply each time it rained. DKN levels in Bucks Branch remained at about the 10 ppt level through the end of the 100-day period (August 21) and was still detected on the last sampling date (December 2) at 3 ppt.

DKN concentrations in the North Raccoon River, a distance of about 5 miles from the study site, peaked at over 100 ppt in mid-May and spiked upward with each rainfall. The 22-ppt EC25 was exceeded 7 times through early June. DKN levels were generally below 22 ppt, and were still detectable as late as August 21 (2 ppt).

Overall, DKN concentrations in the tile drain water were above the EC25 from late May to late July, and again in late August. DKN levels in Bucks Branch were continuously above the EC25 from mid-May to mid-July, and were still detectable in late November. DKN concentrations in the North Raccoon River (5 miles away) were above the EC25 seven times from mid-May to early June, and were still detectable in late August.

Galatea, Ohio. Figure 3 shows the results for Galatea, including the tile drain, ditch, and Rocky Ford River. Peak concentrations in the tile drain water were over 1,000 ppt in mid-June and dropped to about 32 ppt (log = 1.5) in early July. At that point, drought conditions caused the tile drain and ditch to go dry. The tile drain resumed flow in November, at which point the DKN concentration jumped to over 100 ppt (four times the EC25).

The most interesting feature of Figure 3 is the data for the Rocky Ford River. DKN concentrations in the river were higher than in the ditch through June and July, and persisted through August even though the tile drains and ditch were dry. This means that DKN (RPA202248) was entering the river from some up-stream site, indicating that contamination of this river with DKN may have been widespread.

Overall, DKN levels in the tile drain water were above the EC25 from late May through late June. DKN concentrations in the ditch exceeded the EC25 twice, in early June and early July. DKN in the Rocky Ford River were above the EC25 for about 2 weeks in late June.

New Hampshire, Ohio. Figure 4 shows DKN concentrations in the tile drain, ditch and Scioto River (about 2 miles from the field) from May 5 to November 20, 1999. Concentrations in all three waters peaked at or above 1000 ppt in late May.

DKN concentrations in the tile drain water were continuously above 100 ppt from late May through early July, and thereafter was not measured because the drain was not flowing. On January 12, 2000, seven months after the single application, DKN was detected in tile drain water at 51 ppt, over 2 times the EC25. This indicates the persistence of isoxaflutole, and its ability to contaminate water resources over long periods of time.

In the ditch, DKN concentrations peaked twice above 1000 ppt, were above 10 ppt through late July, and were as high as 93 ppt as late as September 3 (the last sample taken).

DKN concentrations in the Scioto River, 2 miles from the study site, peaked at nearly 1000 ppt in late May. Levels remained above 10 ppt through late June, and were 5 ppt to over 30 ppt through early August. DKN was detected at 3 ppt as late as December 9, 1999, the last sample taken.

Overall, DKN in the tile drain water was above the EC25 continuously from late May to mid-July. The same was true for the ditch, except that in late June and early July it fell below the EC25 for 3-4 days at a time. DKN concentrations in the Scioto River were above the EC25 on 17 days from late May to early July.

Phytotoxicity. In each study report, the registrant claims to have made "visual observations" for phytotoxicity in native plants along the drainage ditch. These observations were to have been recorded in field notebooks.

No protocol for the observation of phytotoxicity was submitted. No data from the observations were included in the final study reports, and no photographs were submitted. The registrant did not indicate what kind of native plants were observed, nor whether it was known if they were sensitive to isoxaflutole. The registrant did not submit data on the presence or absence of native plants known to be sensitive to isoxaflutole. Finally, there was no data submitted on possible crop damage to the corn.

For these reasons, EFED must reject the registrant's claim that the water drained from the four test sites caused no damage to native plants.

Figure 1: Bagley, Iowa

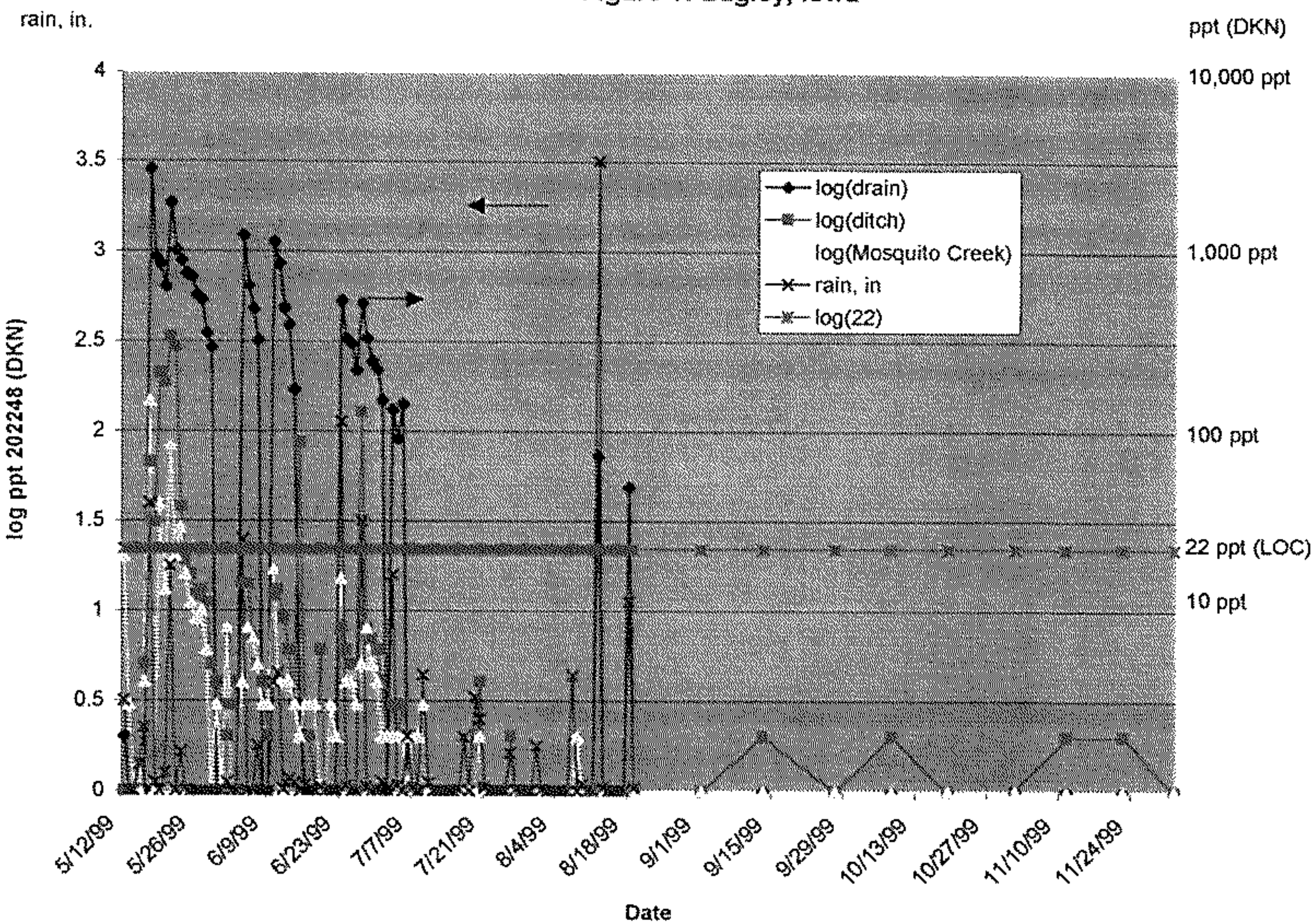

Figure 2: Dawson, Iowa

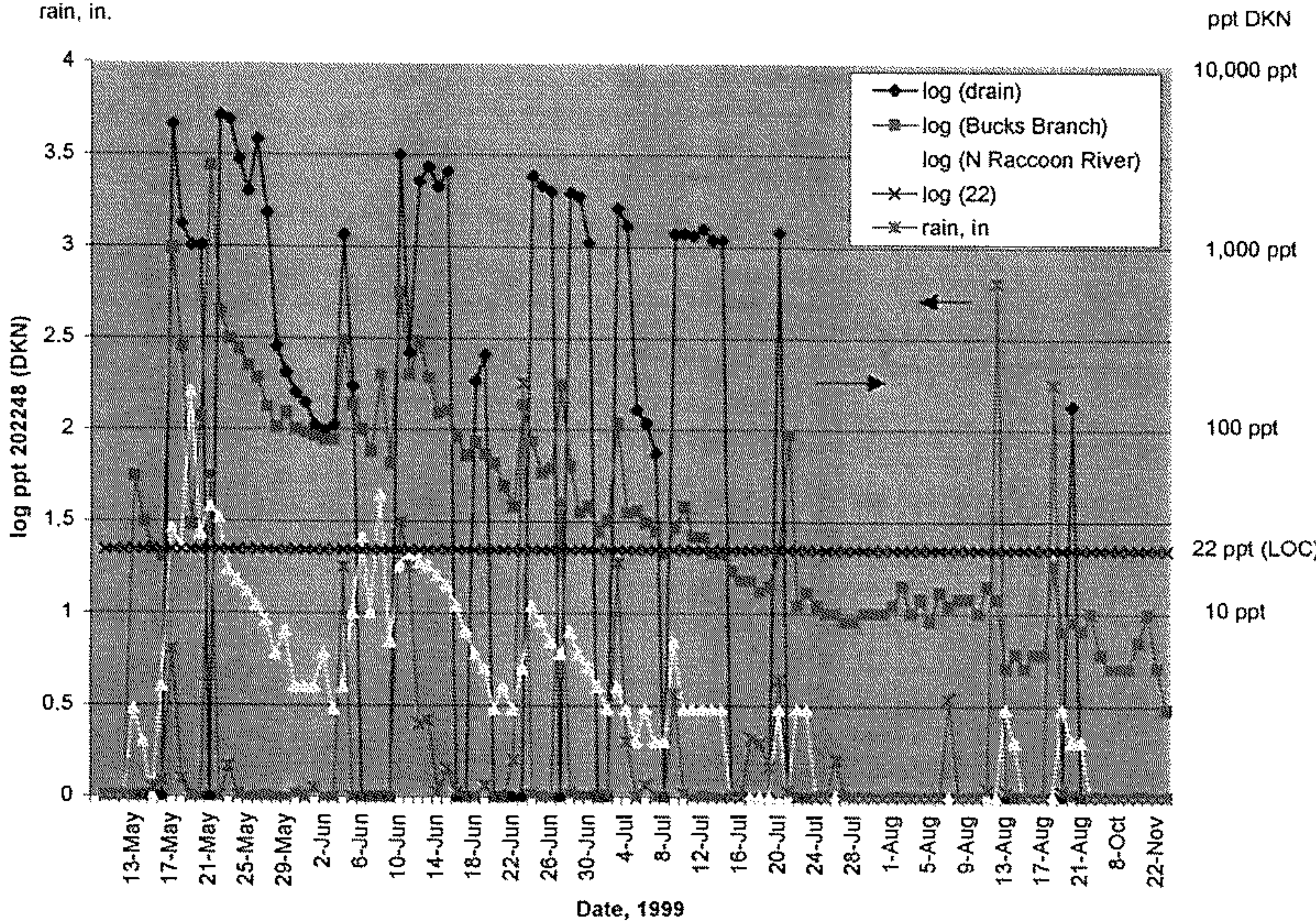

Figure 3: Galatea, Ohio

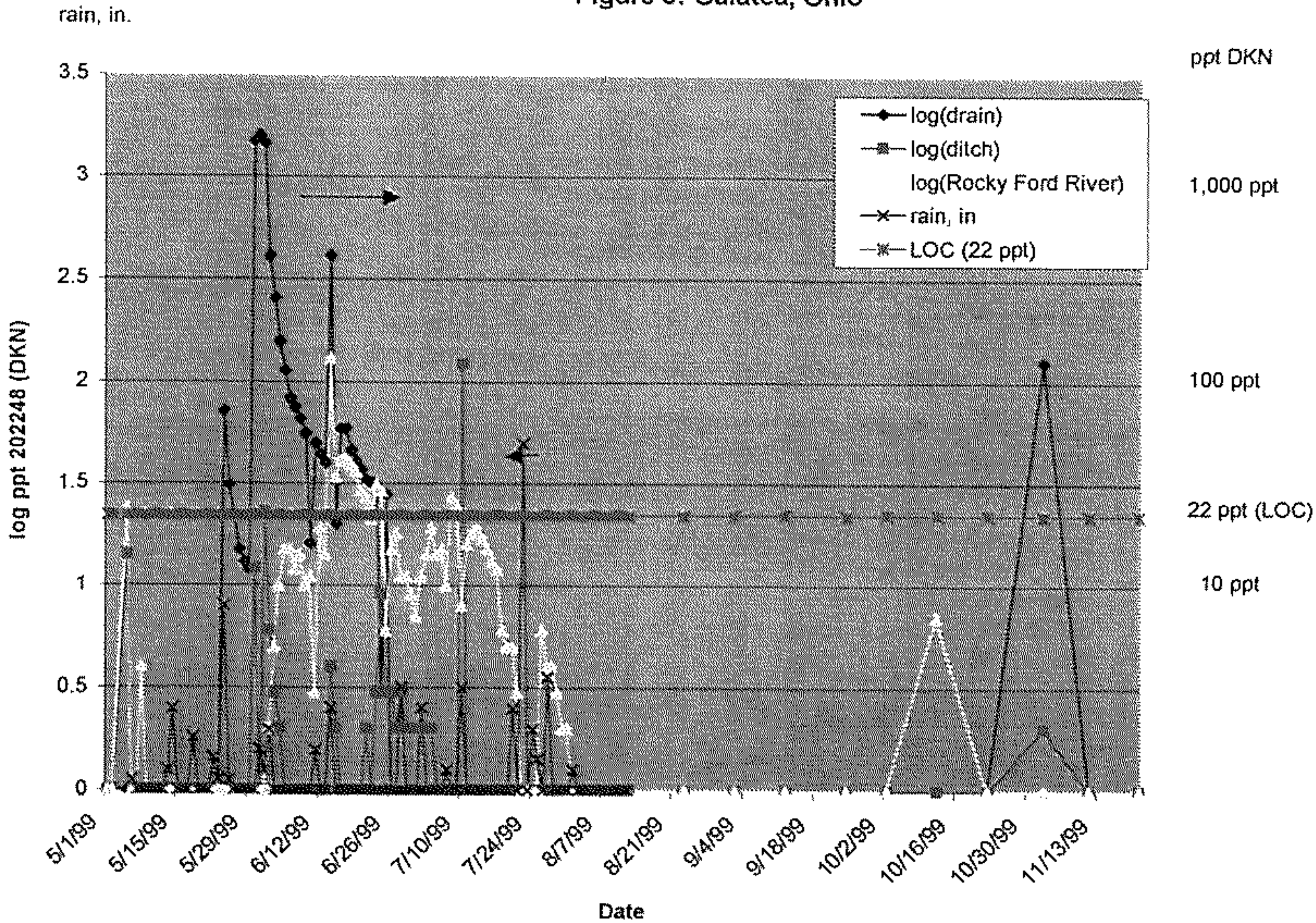

Figure 4: New Hampshire, Ohio