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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: Response to Bayer CropScience's "White Paper: Flubendiamide Benefits, Aquatic Risk Assessment Summary and Proposed Path Forward" (no MRID number) submitted through email dated June 30th, 2015

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Introduction

Bayer CropScience (BCS) submitted comments in a document entitled "White Paper: Flubendiamide Benefits, Aquatic Risk Assessment Summary and Proposed Path Forward". This submission follows a series of back-and-forth comments and responses following the Flubendiamide farm pond monitoring study reports submitted by BCS (MRIDs 49415301 to 49415303) and addresses four topics: 1) agronomic benefits; 2) aquatic risk assessment; 3) risk assessment uncertainties; and 4) proposed path forward. EFED will defer to the Biological and economic Division (BEAD) on comments concerning agronomic benefits, but will provide responses to topics 2 through 4. **After consideration of this information, EFED concludes that the information contained in this submission would <u>not</u> change the conclusions of**

previous EFED responses subsequent to the pond studies or previous EFED risk assessments.

Aquatic Risk Assessment

Pond Monitoring

BCS's comments on the pond monitoring study (MRID 49415303) compare the maximum monitored pond and stream/river data from the pond monitoring study as well as BCS-adjusted pond monitoring concentrations to the No Observed Effect Concentrations (NOECs) for flubendiamide and its degradate, des-iodo. Additionally, a graph of the temporal trend in BCS-adjusted pond concentrations is presented for the North Carolina pond. BCS concludes that there is a "lack of imminent concern for aquatic environments" and attributes any appearance of long-term accumulation pattern to fluctuations of application timings and rates.

The problem with comparing the unadjusted monitoring data to NOECs is that only a fraction of the maximum seasonal application rates were applied to the pond watersheds. Therefore the pond data and stream data immediately downstream of the ponds is biased low relative to the expected concentrations from the maximum seasonal application rates. To purportedly address this issue, BCS devised a method to adjust the observed concentrations from each year by the difference between the actual rate applied and the maximum seasonal application rates. This BCS-adjustment method is scientifically invalid because it does not allow the additional adjusted pesticide applications to wash-off in subsequent years as would be expected from actual applications of a persistent pesticide.

Regarding trends in pond monitoring data, BCS states:

> *The highest concentrations observed at these sites have tended to occur during the most recent growing season, which is being interpreted by EFED as a long-term accumulation pattern. However, these results can also be explained as annual fluctuations due to application timings and rates (specifically higher rates in NC).*

EFED has updated the trend analysis of the three years of pond and stream/river data from MRID 49415303 with the additional 6 months of data provided in **Appendix A**. In the ponds, flubendiamide and des-iodo accumulate in very consistent and statistically significant trends across all media (water column, sediment, and pore water) for all three ponds. Fluctuations in application timings and rates only occurred at one pond (North Carolina). With high certainty, it can be concluded that flubendiamide and des-iodo concentrations are following "a long-term accumulation pattern" which *cannot* "be explained as annual fluctuations due to application timings and rates" since such fluctuations only occurred in the North Carolina pond's watershed. The registrant's characterization of these trends is simply wrong.

USGS Stream Monitoring

BCS summarized the results of the BCS stream/river monitoring, USGS stream/river monitoring, and BCS pond monitoring in a tabular format showing maximum observed concentrations. In parentheses next to the maximum pond monitoring values, BCS again presents the adjusted maximum pond concentrations based on the scientifically invalid method described in the last section. EFED only disagrees with these adjusted concentrations.

Low Extent of Des-iodo Formation

BCS argues that the lack of a degradation pathway for des-iodo should be less of a concern since little des-iodo is formed in aerobic and semi-aerobic environments. The Agency has chronic risk concerns for both flubendiamide and des-iodo. Any less des-iodo formation simply means that more flubendiamide remains. Additionally, the nine des-iodo pond trends depicted in **Appendix A** show that des-iodo is accumulating in all three of the ponds monitored in water column, sediment, and pore water. In the North Carolina pond (which was the only pond without grassed waterways in the watershed), the concentrations of des-iodo (and flubendiamide) observed closely approximates the concentrations expected from exposure modeling.

Limited Numbers of Ponds Adjacent to High Use Areas

BCS argues that relatively few farm ponds are in arid flubendiamide use areas and farm ponds are more common in wetter climates where ponds would be expected to overflow. This line of discussion seems to be predicated on the idea that the Agency is only concerned about farm ponds; therefore, any flubendiamide- and/or des-iodo-laden runoff not captured by a farm pond is of no concern to EPA. As previously discussed relative to farm pond overflow, any flubendiamide and des-iodo in runoff *not* accumulated in a farm pond will simply accumulate in the depositional zone of some other higher-value aquatic environment (reservoirs, lakes, or estuaries) causing more problems. EFED models farm ponds because they are relatively easy to model and serve as surrogates for other aquatic environments, not because farm ponds are the only aquatic resource of concern.

Lower Toxicity Compared to Main Competitor Products

BCS summarized toxicity data for flubendiamide, des-iodo, and several pyrethroids (bifenthrin, gamma cyhalothrin, lambda cyhalothrin, permethrin, cypermethrin, deltamethrin, cyfluthrin, fenpropathrin, and esfenvalerate). EFED appreciates the data summary, but would point out that there are non-pyrethroid competitor products. EFED will reserve comment until a more thorough comparison is completed.

Risk Assessment Uncertainties

Fate of Flubendiamide and Des-iodo in Streams under Real World Conditions

BCS proposed aquatic photolysis as an explanation for the 66-day mesocosm half-life. In the flubendiamide aerobic and anaerobic aquatic metabolism studies (MRIDS 46816913 and 46816914) as well as the mesocosm study (MRID 46817002), flubendiamide is introduced similarly into the water layer and then partitions into the sediment. In the aerobic and anaerobic aquatic metabolism study, the flubendiamide concentration in sediment exceeds the concentration in water within 4 days (*i.e.*, the majority of flubendiamide has partitioned or moved from water into sediment within 4 days). However in the mesocosm study the concentration in sediment never even approaches the concentration in water within the 112 day duration of the mesocosm study.

The amount of material measured in the mesocosm study water samples appears to be relatively similar to the aerobic and anaerobic aquatic metabolism studies (*i.e.*, appears to be slowly partitioning to sediment in a dynamic equilibrium at similar rates across all three studies). It is the mesocosm sediment data that does not make sense when compared to the aerobic and anaerobic aquatic metabolism studies' sediment data. There simply does not appear to be enough

material in the mesocosm sediment to maintain the dynamic equilibrium between the sediment and water concentrations in the mesocosm study.

Aquatic photolysis which occurs in the upper layers of water would not explain the lack of flubendiamide in the sediment. As stated previously, it is far more likely that the mesocosm half-life is problematic rather than the aerobic and anaerobic aquatic metabolism studies since the mesocosm study is not designed to measure half-lives whereas the aerobic and anaerobic aquatic metabolism studies are designed to measure half-lives.

Additionally, the aquatic photolysis study produced two additional identified degradates (and other unidentified degradates) that would probably be of concern to the Agency because the identified degradates are structurally very similar to flubendiamide and des-iodo. Therefore even if aquatic photolysis were a suitable explanation for the mesocosm half-life (which it is not), EFED still would not use the mesocosm half-life because the additional degradates of concern in the aquatic photolysis study were not measured in the mesocosm study (*i.e.*, we would need the data for the additional photolysis identified and unidentified degradates to calculate the total half-life for all of the degradates of concern).

Interpretation of 3.5-Year Monitoring Data – Farm Pond Accumulation

BCS seems to be offering to continue monitoring at the sites sampled in the pond monitoring study (MRID 49415301) for an additional "two to three more years". EFED has described the problems with this study in detail in this study's data evaluation record (DP412791+) and, in light of these problems, does not feel that continued monitoring at these sites is particularly useful. The key findings from the pond monitoring study are that: 1) flubendiamide and des-iodo accumulate in farm ponds similar to the accumulation predicted by EFED's exposure modeling; and 2) Vegetative Filter Strips (VFSs) are ineffective in preventing this accumulation in downstream waterbodies. Continued monitoring at these sites are unlikely to change this understanding.

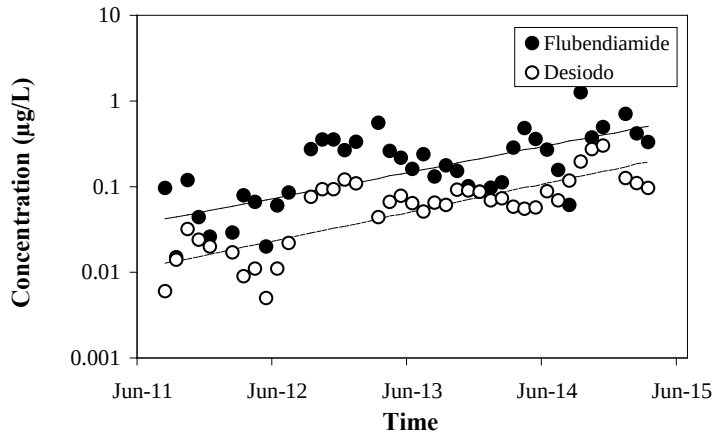
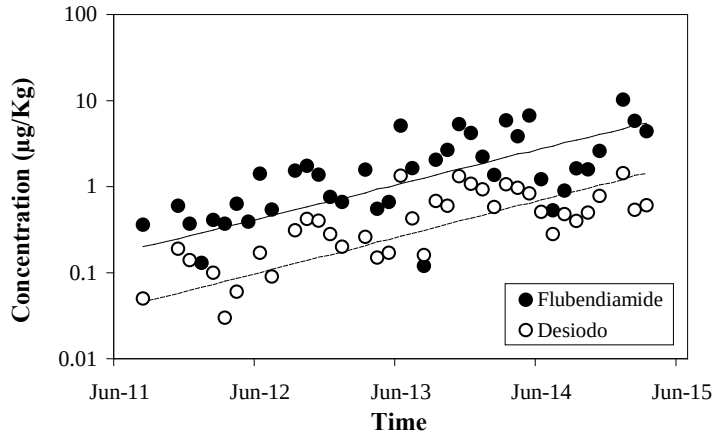
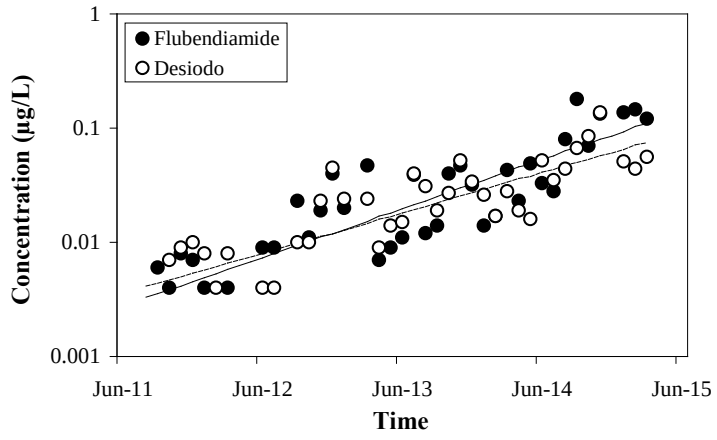
BCS hopes to show that EFED's exposure modeling is "too conservative" through an extended pond monitoring data set. However, two of the three pond monitoring sites have grassed waterways in their watersheds, which render their data unusable for comparing observed and predicted long-term accumulation trends. The third pond does not have issues with grassed waterways, but does have issues with low and variable application rates (variable in terms of annual application rate and application date). Even if the maximum application rates could be consistently applied for all future years of sampling for this third pond, there would be only a single temporal trend to consider at the end of the study. Little could be concluded with certainty from such an unreplicated study.

Proposed Path Forward

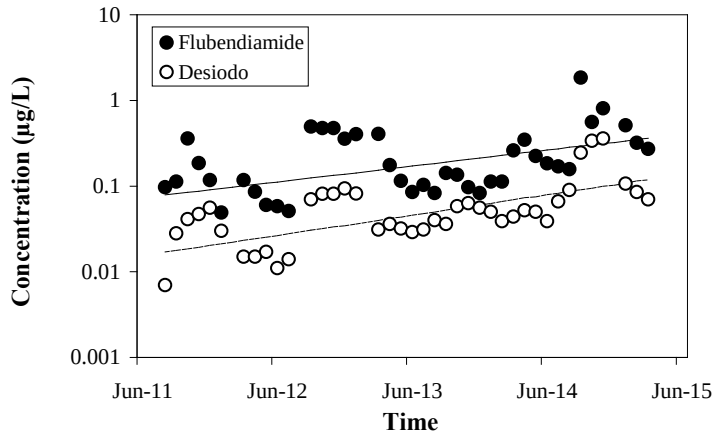
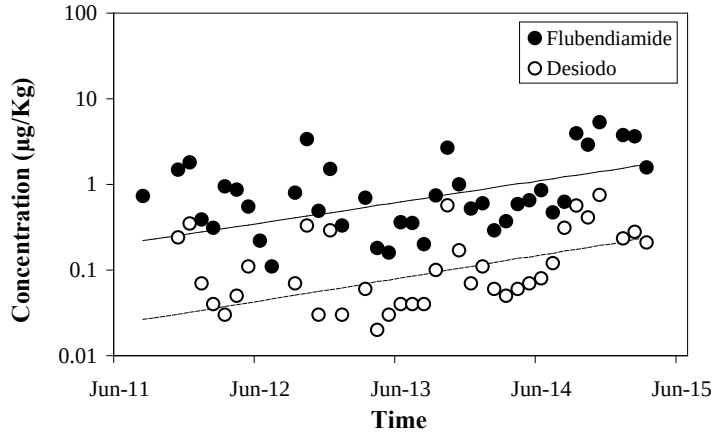
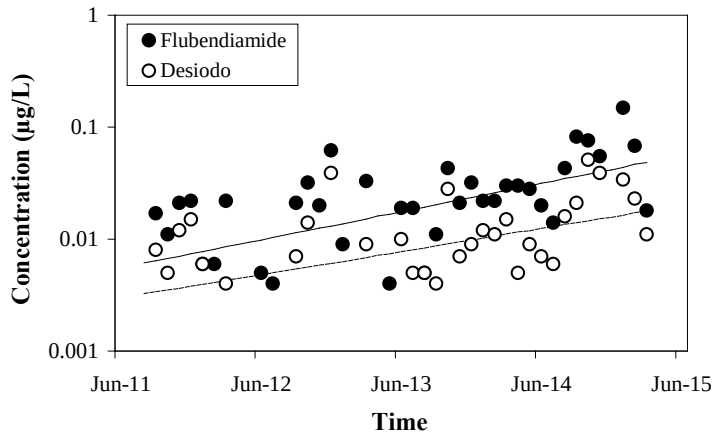
BCS proposed path forward is to continue monitoring (BCS and USGS) for "several more years" and potentially generate additional information on the degradation of flubendiamide and des-iodo. BCS's proposals are not described in detail. While additional data could always be generated, EFED believes that the existing data set provides a rather comprehensive understanding of the risks posed by environmental applications of flubendiamide.

Appendix A. Temporal Trends in Bayer CropScience Pond and Stream/River Monitoring

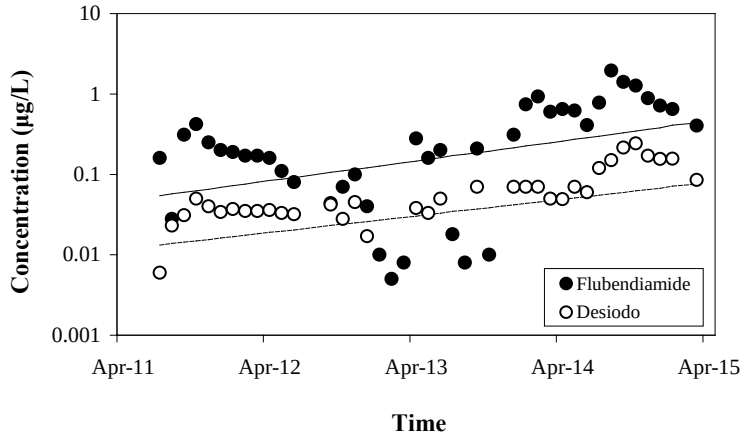
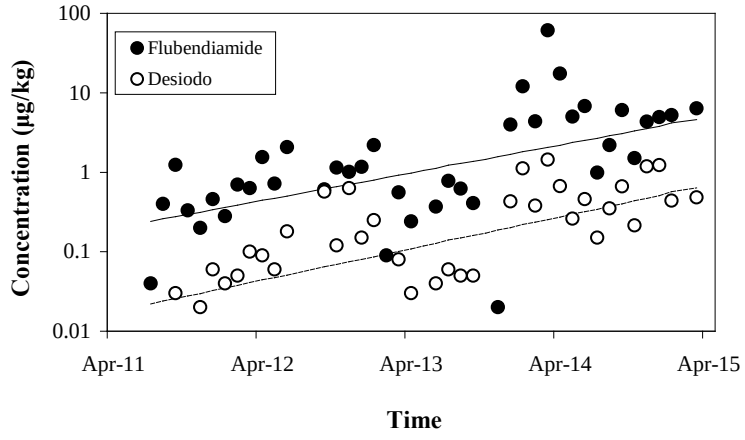
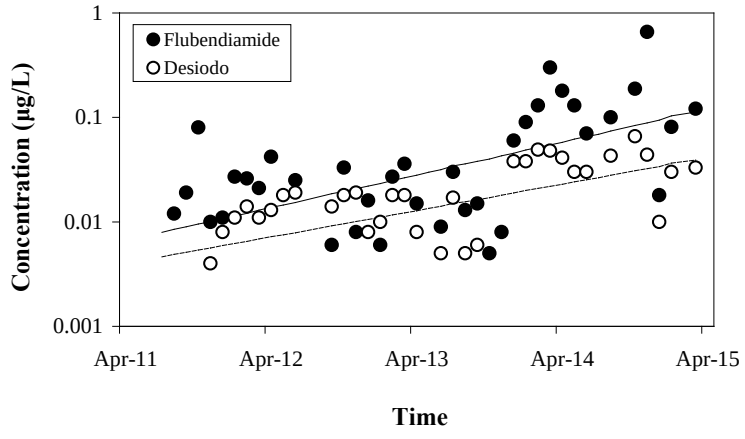
Site: Georgia Pond #1

Concentration Data Over Time	Accumulation (change from beginning to end of trend line)
Water Column 	Flubendiamide: Increased 12× (0.042 to 0.50 µg/L) Upward exponential trend is statistically significant (P < 0.0001) Des-iodo: Increased 15× (0.013 to 0.19 µg/L) Upward exponential trend is statistically significant (P < 0.0001)
Sediment 	Flubendiamide: Increased 27× (0.20 to 5.5 µg/kg) Upward exponential trend is statistically significant (P < 0.0001) Des-iodo: Increased 31× (0.046 to 1.4 µg/kg) Upward exponential trend is statistically significant (P < 0.0001)
Pore Water 	Flubendiamide: Increased 33× (0.0033 to 0.11 µg/L) Upward exponential trend is statistically significant (P < 0.0001) Des-iodo: Increased 18× (0.0041 to 0.075 µg/L) Upward exponential trend is statistically significant (P < 0.0001)

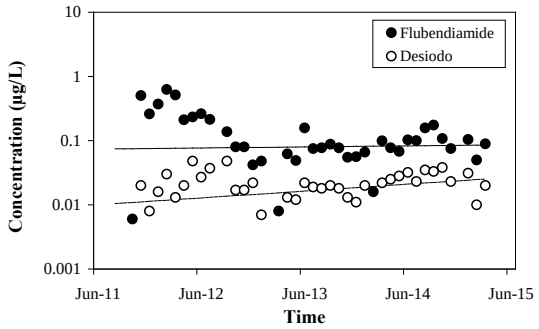
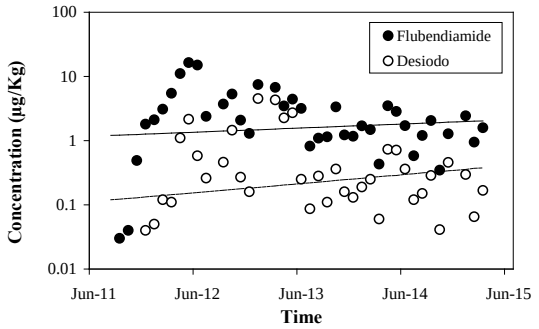
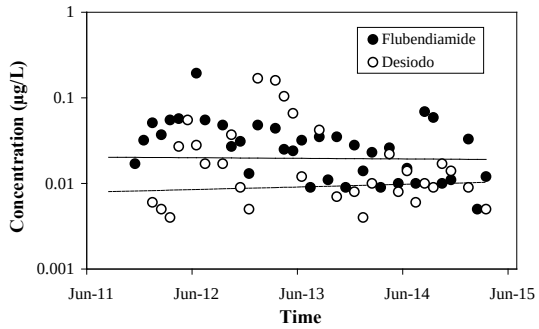
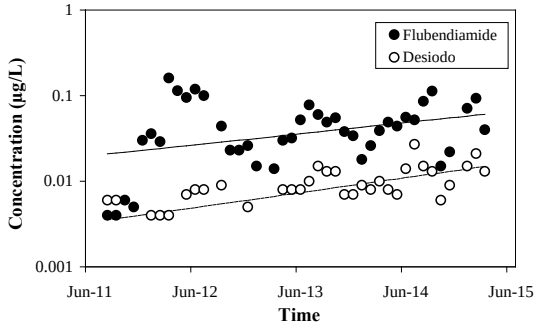
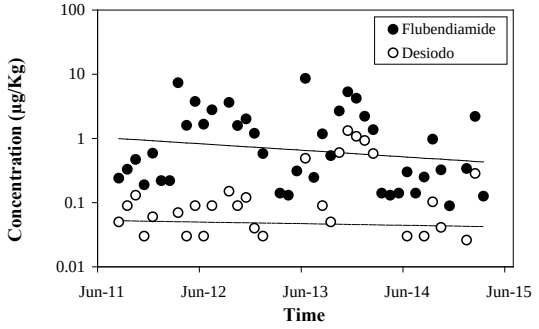
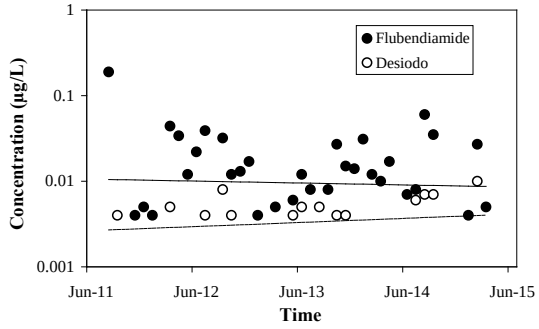
Site: Georgia Pond #2

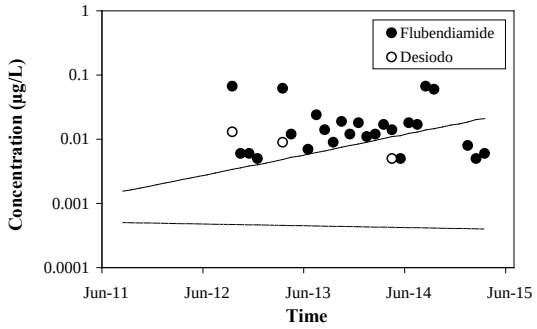
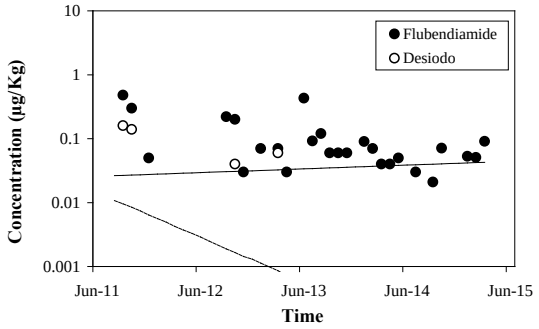
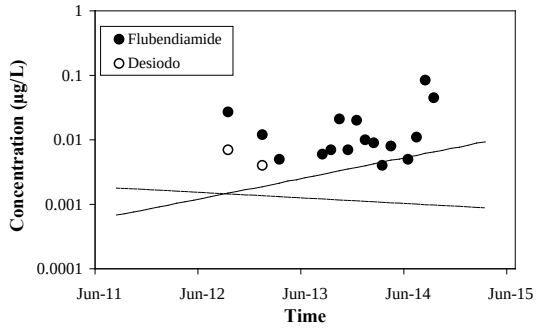
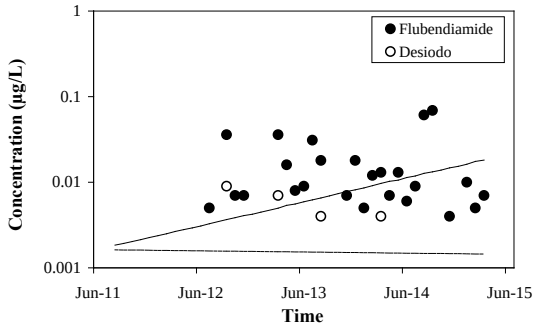
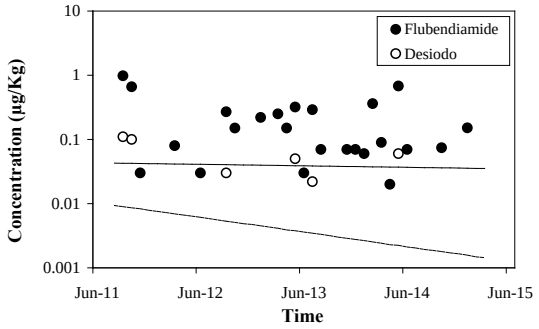
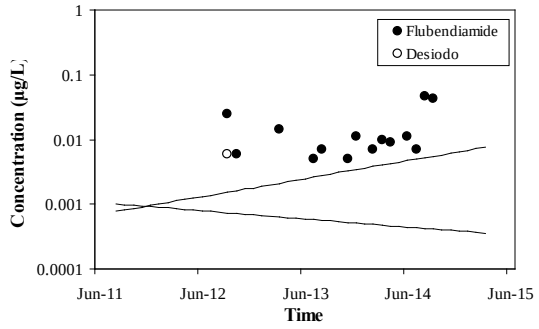
Concentration Data Over Time	Accumulation (change from beginning to end of trend line)
Water Column 	Flubendiamide: Increased 4.5× (0.079 to 0.36 µg/L) Upward exponential trend is statistically significant (P = 0.0016) Des-iodo: Increased 6.9× (0.017 to 0.11 µg/L) Upward exponential trend is statistically significant (P < 0.0001)
Sediment 	Flubendiamide: Increased 7.7× (0.22 to 1.7 µg/kg) Upward exponential trend is statistically significant (P = 0.0006) Des-iodo: Increased 8.9× (0.027 to 0.24 µg/kg) Upward exponential trend is statistically significant (P < 0.0001)
Pore Water 	Flubendiamide: Increased 7.8× (0.0062 to 0.048 µg/L) Upward exponential trend is statistically significant (P < 0.0001) Des-iodo: Increased 5.4× (0.0033 to 0.018 µg/L) Upward exponential trend is statistically significant (P < 0.0001)

Site: North Carolina Pond

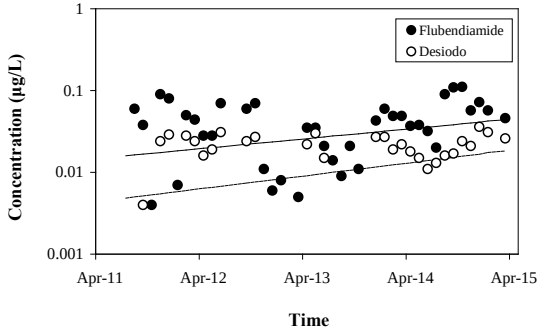
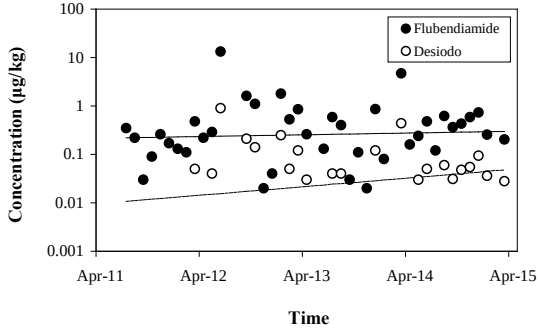
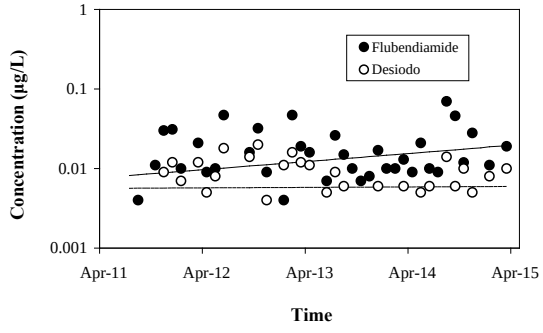
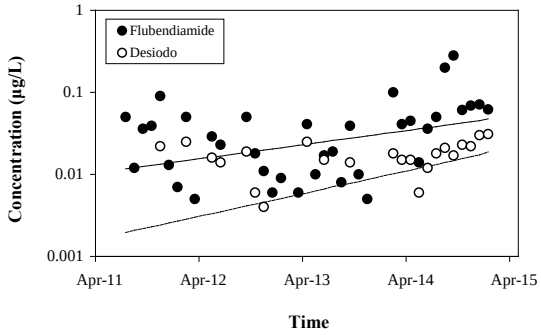
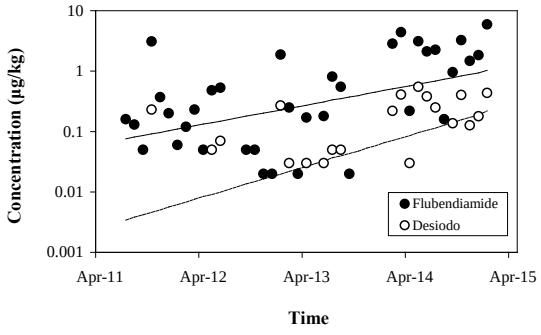
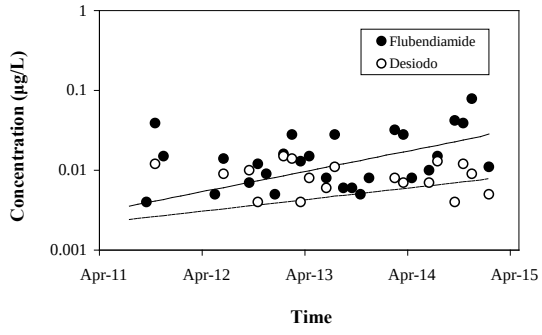
Concentration Data Over Time	Accumulation (change from beginning to end of trend line)
Water Column  	Flubendiamide: Increased 8.1× (0.054 to 0.44 µg/L) Upward exponential trend is statistically significant (P = 0.0104) Des-iodo: Increased 5.7× (0.013 to 0.076 µg/L) Upward exponential trend is statistically significant (P = 0.0086)
Sediment  	Flubendiamide: Increased 19× (0.24 to 4.6 µg/kg) Upward exponential trend is statistically significant (P = 0.0001) Des-iodo: Increased 29× (0.022 to 0.64 µg/kg) Upward exponential trend is statistically significant (P < 0.0001)
Pore Water  	Flubendiamide: Increased 14× (0.0079 to 0.11 µg/L) Upward exponential trend is statistically significant (P < 0.0001) Des-iodo: Increased 8.5× (0.0046 to 0.039 µg/L) Upward exponential trend is statistically significant (P < 0.0001)

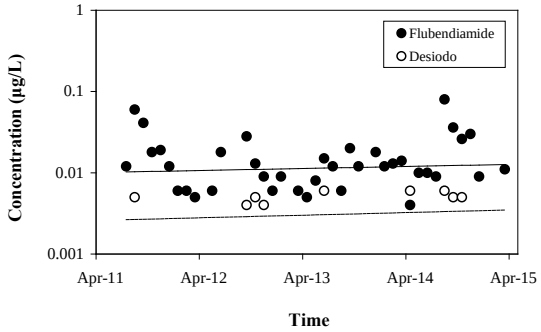
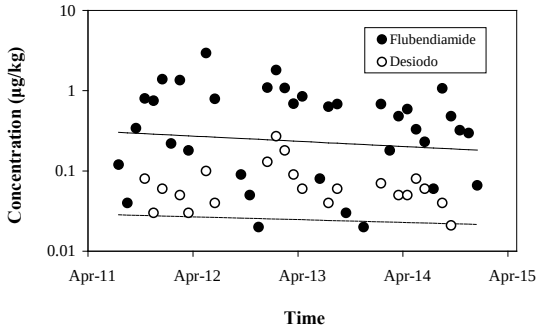
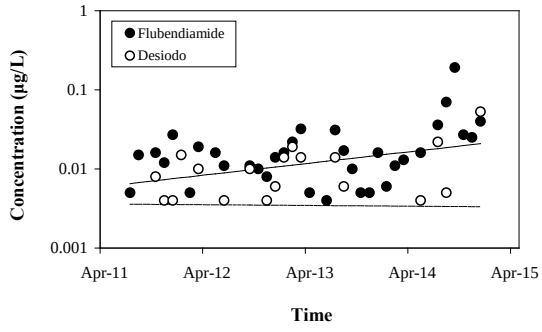
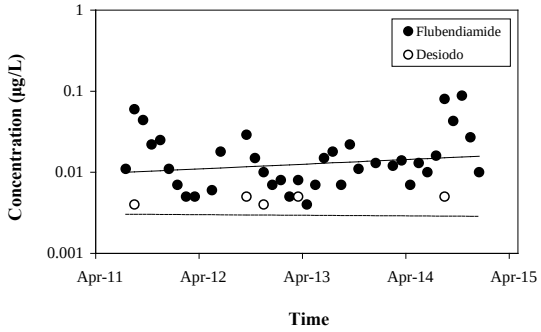
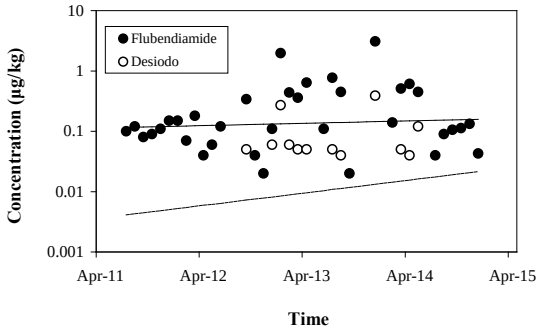
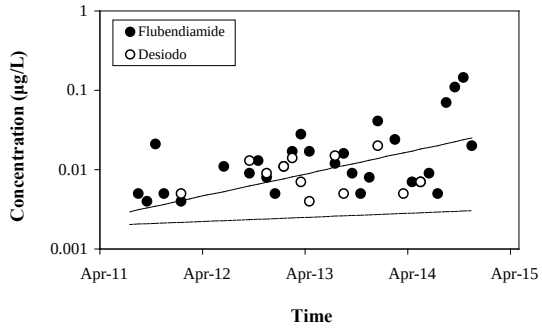
Georgia Flowing-water Sites (located at different points in a larger watershed that contains the Georgia Ponds) – EFED does not anticipate continuous accumulation at these flowing-water sites because any accumulation is continuously (water) or periodically (sediment) flushed downstream.

Water Column	Sediment	Pore Water
Upstream Intermittent Stream Site 		
Flubendiamide P = 0.8337; Des-iodo P = **0.0236**	Flubendiamide P = 0.4928; Des-iodo P = 0.1674	Flubendiamide P = 0.9109; Des-iodo P = 0.7362
Downstream Intermittent Stream Site 		
Flubendiamide P = **0.0151**; Des-iodo P **< 0.0001**	Flubendiamide P = 0.2134; Des-iodo P = 0.8191	Flubendiamide P = 0.7603; Des-iodo P = 0.1666

Water Column	Sediment	Pore Water
Upstream Perennial Stream Site 		
Flubendiamide P = **0.0006**; Des-iodo P = 0.8836	Flubendiamide P = 0.5211; Des-iodo P = 0.0972	Flubendiamide P = **0.0123**; Des-iodo P = 0.4647
Downstream Perennial Stream Site 		
Flubendiamide P = **0.0006**; Des-iodo P = 0.8748	Flubendiamide P = 0.8542; Des-iodo P = 0.1838	Flubendiamide P = **0.0207**; Des-iodo P = 0.5788

North Carolina Flowing-water Sites (located at different points in a larger watershed that contains the North Carolina Pond)

Water Column	Sediment	Pore Water
Upstream Intermittent Stream Site  Flubendiamide P = 0.0641; Des-iodo P = **0.0355**	 Flubendiamide P = 0.6842; Des-iodo P = 0.1145	 Flubendiamide P = **0.0474**; Des-iodo P = 0.8994
Downstream Intermittent Stream Site  Flubendiamide P = **0.0113**; Des-iodo P = **0.0006**	 Flubendiamide P = **0.0034**; Des-iodo P **< 0.0001**	 Flubendiamide P **< 0.0001**; Des-iodo P = **0.0222**

Water Column	Sediment	Pore Water
Upstream Perennial Stream Site 		
Flubendiamide P = 0.6180; Des-iodo P = 0.3158	Flubendiamide P = 0.5353; Des-iodo P = 0.6892	Flubendiamide P = **0.0182**; Des-iodo P = 0.9149
Downstream Perennial Stream Site 		
Flubendiamide P = 0.2992; Des-iodo P = 0.7932	Flubendiamide P = 0.6560; Des-iodo P = 0.2024	Flubendiamide P < **0.0001**; Des-iodo P = 0.6013