UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Bayer CropScience LP and Nichino America, Inc.,	)	FIFRA-HQ-2016-0001
	)	
	)	
Petitioners.	)	

VERIFIED WRITTEN STATEMENT OF BERNARD ENGEL, PH.D. ON BEHALF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

TABLE OF CONTENTS

Page

I. BACKGROUND AND EXPERIENCE

Q: Please state your name, and where you are employed.

A: My name is Dr. Bernard Engel, and I am employed in the Department of Agricultural & Biological Engineering at Purdue University.

Q: Please describe your education background and professional training.

A: I am educated and trained as an agricultural engineer with a focus on agricultural hydrology, water quality, and soil and water conservation. I hold Bachelor's of Science and Master's of Science degrees in Agricultural Engineering from the University of Illinois at Urbana-Champaign and a Doctor of Philosophy degree in Agricultural Engineering from Purdue University. I hold a Professional Engineering (PE) license in Indiana.

Q: Please summarize your occupational history.

A: For the past 31 years, I have taught undergraduate and graduate level courses and conducted research in hydrology, water quality, hydrologic/water quality modeling, environmental decision support systems, and soil and water conservation at Purdue University. During this time, I have held titles of Assistant Professor and Associate Professor, and currently I am Professor and Head of the Department of Agricultural and Biological Engineering. I have served as mentor and primary research advisor for 45 graduate students completing Master's of Science and Doctor of Philosophy degrees and on the research advisory committees for an additional 115 graduate students in the fields noted above.

PBNX 50 is a copy of my curriculum vitae further describing my qualifications, experience, and publications.

Q: Please describe your research and professional accomplishments.

A: My research accomplishments in hydrology, water quality, hydrologic/water quality modeling, environmental decision support systems, and soil and water conservation are widely recognized for their quality and impact. I was named the outstanding young researcher in my professional society (American Society of Agricultural Engineers – now called American Society of Agricultural and Biological Engineers) in 1999. I received the outstanding research award from the Purdue University College of Agriculture in 1998 for my research. I was recognized as the outstanding graduate educator by the Purdue University College of Agriculture in 2006 based on research conducted by graduate students I mentor. I was recognized as a Fellow of my professional society (American Society of Agricultural and Biological Engineers) based on career contributions in research, teaching, and leadership.

Q: How has your research affected the development of hydrologic and water quality models?

A: I am globally recognized as a leading researcher in nonpoint source pollution modeling based on the impact of my research in peer reviewed journal papers published in this area over the past 20 years. I have developed and improved multiple hydrologic/water quality models, including the Soil and Water Assessment Tool (SWAT), Groundwater Loading Effects of Agricultural Management Systems (GLEAMS), and Agricultural Non-Point Sources (AGNPS) model. These efforts are documented in peer reviewed journal papers.

Q: Please describe your professional publications.

A: I have authored more than 165 peer reviewed journal papers, 8 book chapters, and more than 250 papers published in conference proceedings and papers distributed at national and international meetings focused on hydrology, water quality monitoring and modeling, environmental decision support systems, and soil and water conservation.

Q: Have you ever served on a FIFRA Scientific Advisory Panel ("SAP")?

A: Yes, I have served on numerous Scientific Advisory Panels and Boards for the U.S. government as an expert in the areas identified above, including FIFRA SAPs on Development of a Spatial Aquatic Model (SAM) for Pesticide Risk Assessment in 2015, Problem Formulation for the Reassessment of Ecological Risks from the Use of Atrazine in 2012, and Two-dimensional Exposure Rainfall-Runoff Assessment (TERRA) Watershed Model and its Use in the FIFRA Ecological Risk Assessment for Antimicrobial Uses of Copper in 2011, among others.

Q: Please describe your areas of expertise.

A: I am an expert in, among other things, hydrology, water quality, hydrologic/water quality modeling, water quality monitoring, soil and water conservation, and environmental decision support systems. My research, teaching, and consulting activities in these areas include pesticides, nutrients, and soil erosion/sediment.

II. SCOPE OF TESTIMONY

Q: Please describe the scope of testimony that you have been asked to provide.

A: I was engaged by Bayer CropScience LP (Bayer) to review and evaluate the United States Environmental Protection Agency's (EPA's) assessment of current and predicted future concentrations of flubendiamide and its primary environmental degradate, des-iodo flubendiamide (hereafter referred to as des-iodo), that will occur in water bodies from the use of flubendiamide products in agriculture. More specifically, I was asked to (a) review the available monitoring and sampling data, related reports and studies, modeling, and risk assessments related to current and potential future environmental exposure to flubendiamide and des-iodo in water bodies, (b) determine whether EPA had properly evaluated the available data, (c) evaluate EPA's use of modeling to predict current and potential future flubendiamide and des-iodo concentrations, and (d) determine whether EPA's proposed cancellation of flubendiamide products based on a conclusion that concentrations have exceeded or will exceed Agency-identified levels of concern is based on sound science.

In my analysis, I considered EPA documents regarding flubendiamide available on EPA's flubendiamide cancellation website, additional EPA documents and Bayer documents and data provided by Bayer, including the data and results from the Bayer monitoring studies as of March 17, 2015 that were provided to EPA, more recent information and results from the ongoing monitoring studies provided by Bayer, flubendiamide and des-iodo flubendiamide data from the USGS website, and journal articles and other materials cited in this Written Statement.

Q: Bayer and Nichino offer Dr. Engel as an expert in the areas of hydrology; water quality; hydrologic/water quality modeling; water quality monitoring; and soil and water conservation.

III. SUMMARY OF CONCLUSIONS

Q: Please provide a summary of the conclusions you reached in your analysis.

A: Based on my review and analysis of materials and data provided and other materials described in this Written Statement, it is my opinion that EPA's assessment of current and future environmental exposure to flubendiamide and des-iodo from the use of flubendiamide products is flawed and incorrect, and that the data and information on environmental exposures and concentrations do not support EPA's proposed cancellation decision.

More specifically, based on my review and analysis I conclude that:

- Basic hydrologic principles suggest flubendiamide and des-iodo will not accumulate in the environment to concentrations of regulatory concern.
- The registrants' monitoring data offer useful insight into the seasonal and annual trends of residue concentrations, showing clear signs of chemical inputs and subsequent declines that are either missed or ignored by EPA's Environmental Fate and Effects Division (EFED).

- EFED does not interpret the effects of buffers and grassed waterways in a consistent manner in their analyses, stating at times they do not impact chemical transport and at other times minimizing the regulatory value of the Georgia test site due to the presence of a grassed waterway.

- EFED modeling that EPA uses to predict current and future residue concentrations in farm ponds is wrong and erroneously over predicts environmental concentrations. Predictions of future concentrations under the modeling become irrational.

- EFED modeling neither fits the existing field data nor is there a statistical basis to suggest it has power to predict future trends.

- Statistical analysis of the EFED modeling indicates that the model has unacceptable predictive value. The mean of the observed monitoring data provides a better estimate of environmental concentrations than does the model.

- In light of the quantitative analysis confirming the unacceptable performance of the EFED modeling approach, regulatory decisions should be made based on monitoring results, not EFED's modeling.

- After almost five years of monitoring, the registrants' monitoring data show no exceedances of the toxicological endpoints identified by EPA, and no evidence that concentrations are accumulating or will accumulate to levels of concern.

- The USGS data do not show "widespread" detection or accumulation of flubendiamide and des-iodo.

- Continued monitoring is justified in this case.

IV. OPINIONS AND ANALYSIS

A. <u>Basic Hydrologic Principles and Movement of Compounds</u>

Q: Please provide an overview of the hydrologic cycle and the movement of compounds through watersheds.

A: In evaluating EPA's conclusions with respect to environmental exposures to flubendiamide and des-iodo, it is important to understand how materials that are slow to degrade (such as flubendiamide and des-iodo) or that do not degrade (such as heavy metals or phosphorus) move through the environment. Examining the hydrologic cycle provides a basis for much of the movement of constituents that move primarily with water flow as does flubendiamide. Materials move through watersheds at varying rates depending on factors including precipitation, constituent properties, and characteristics of the watershed such as soils, slopes, and land uses. These materials would typically be moved through primary pathways of runoff and associated with soil particles that are eroded and moved by the runoff. Flubendiamide and des-iodo would move primarily in surface runoff and associated eroded soil particles or sediment carried in the runoff.

As materials are transported through a watershed, they may be temporarily delayed. Soil initially eroded from the watershed landscape may be deposited in small channels, streams, or rivers before later being scoured and moved further through the stream and river network. Ponds and small lakes may also be sources of delays.

Ultimately, materials that move through the watershed will reach large water bodies (large lakes and oceans) where accumulation at very low levels may occur. Given the large volumes of water and masses of sediments in these systems and the comparatively small masses of the materials, observed concentrations will typically be very low, even if some accumulation occurs. Factors such as degradation and burying of sediment will also limit accumulation in large water bodies.

Q: How do the processes you just described relate to metals and nutrients?

A: The above processes would be similar for metals and even for a nutrient such as phosphorus, for which there is a significant body of scientific literature. Phosphorus transport is particularly relevant to this case because, like flubendiamide and des-iodo, its equilibrium state favors relatively insoluble mineral forms that favor binding to sediment or precipitation out of the water column. Yet, phosphorus concentrations do not accumulate to infinitely large values in small water bodies and lakes, but rather phosphorus concentrations reach some plateau and fluctuate around that level depending on continued loading to the water body. *Masses* may continue to increase in the water body, including its sediment, as the materials are covered by new incoming sediment, but *concentrations* would not continue to increase unbounded.

Q: Would you expect flubendiamide and des-iodo concentrations in water bodies to behave in a similar fashion?

A: The expectations for flubendiamide and des-iodo would be similar because the small masses that reach ponds or small lakes would be buried in the sediment or otherwise flow with the water exiting the pond and watershed. Contrary to this, the EFED projections and interpretation of flubendiamide and des-iodo data and model results for small ponds suggest continued increases in flubendiamide and des-iodo concentrations without bounds, which is unreasonable and seemingly impossible.

B. The Bayer Monitoring Studies Do Not Show Long-Term Accumulation of Flubendiamide or Des-Iodo.

1. Study Design and Conduct

Q: What is your understanding of the monitoring studies that Bayer has conducted?

A: Bayer has conducted almost five years of monitoring for flubendiamide and des-iodo at two sites in North Carolina and Georgia. These studies were conducted as required by EPA. EFED reviewed and approved the monitoring sites, study design, and supporting protocols prior to initiation of the monitoring studies.

Q: Please describe how these studies are conducted.

A: Each site includes intermittent and perennial streams and a farm pond that receives drainage from an adjacent treated field. The field sites have the approximate properties of EFED's "farm pond scenario," where a small pond receives its entire runoff loading from an adjacent, treated field approximately 10 times larger than the pond. EFED defines this 10:1

drainage-to-pond ratio as the reasonable worst case for exposure assessment, and results derived from these studies are intended to be protective of the greater agricultural environment.

Flubendiamide and des-iodo concentrations in all sampling locations at these sites have been determined approximately once per month for these constituents in the sediment, water column, and sediment pore water. Bayer has conducted monitoring at these sites for almost five years. The monitoring is ongoing.

Q: What monitoring data were provided to you for your analysis?

A: For this analysis I was provided and reviewed monitoring data available through March 17, 2015, which I understand were finalized and submitted to EPA. In addition, at my request Bayer provided information and results from the ongoing monitoring studies through October 2015, that are reflected in the Figures and discussions below.

2. The Monitoring Data Confirm Movement of Flubendiamide and Des Iodo Through the Watershed.

Q: What do the monitoring data show, if anything, with respect to the movement of flubendiamide and des-iodo through the watershed?

A: The observed data from both of these sites show trends that are consistent with delayed movement through an agricultural watershed as described above. Monitoring data at the North Carolina and Georgia pond sites show declines in flubendiamide and des-iodo each year as these constituents move out of the ponds via water flowing through the ponds. This was confirmed at both study sites by photographs showing water flowing into an overflow pipe or over the spillway of the pond during the study period.

Q: Did the monitoring data indicate accumulation of flubendiamide or des-iodo in up- and downstream sampling locations?

A: No. Data collected by Bayer at the Georgia and North Carolina study sites indicate flubendiamide and des-iodo do not accumulate in the up- and downstream sampling locations. In discussing the Georgia flowing water sites, EFED agrees that flubendiamide and des-iodo will not accumulate to a substantial degree, stating that "EFED does not anticipate continuous accumulation at these flowing-water sites because any accumulation is continuously (water) or periodically (sediment) flushed downstream."[1]

Q: What is your opinion on the potential long-term accumulation of flubendiamide and des-iodo in the environment?

A: Under the hydrologic principles described above, flubendiamide and des-iodo will move through the watershed and ultimately reach large water bodies (large lakes and oceans). Given the small masses of flubendiamide applied in the landscape, and its degradation processes, accumulation of flubendiamide and des-iodo to levels of concern will not occur in these water bodies. A degradation pathway via photolysis for des-iodo has been identified by Bayer which provides sufficient reactivity to ensure long-term accumulation in the environment should not take place.[2]

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[1] PBNX 25 at 8 (EFED Response to Bayer CropScience LP White Paper (July 15, 2015)).

[2] L.L. McConnell, Bayer CropScience, [Phthalic acid ring-UL-14C]Flubendiamide-desiodo Phototransformation in Aqueous pH 7 Buffer, Final Report, Report No. MEAMN004 (2016).

3. **The Pond Monitoring Data Do Not Show That Long-Term Accumulation Is Occurring or Will Occur.**

Q: Do any of the observed concentrations of flubendiamide or des-iodo from the North Carolina and Georgia ponds exceed levels of concern identified by EPA?

A: The observed flubendiamide and des-iodo concentrations in the North Carolina and Georgia sites show no accumulations above levels of concern nor do they suggest that accumulations will occur reaching levels of concern, since the study has now extended to the point where the concentration plateaus for both locations are being reached or will be in the near future.

Q: What is your understanding of EPA's position on the flubendiamide and des-iodo monitoring data and what they show with respect to accumulation?

A: EPA contends that the monitoring data show that flubendiamide and des-iodo are accumulating and will continue to accumulate.

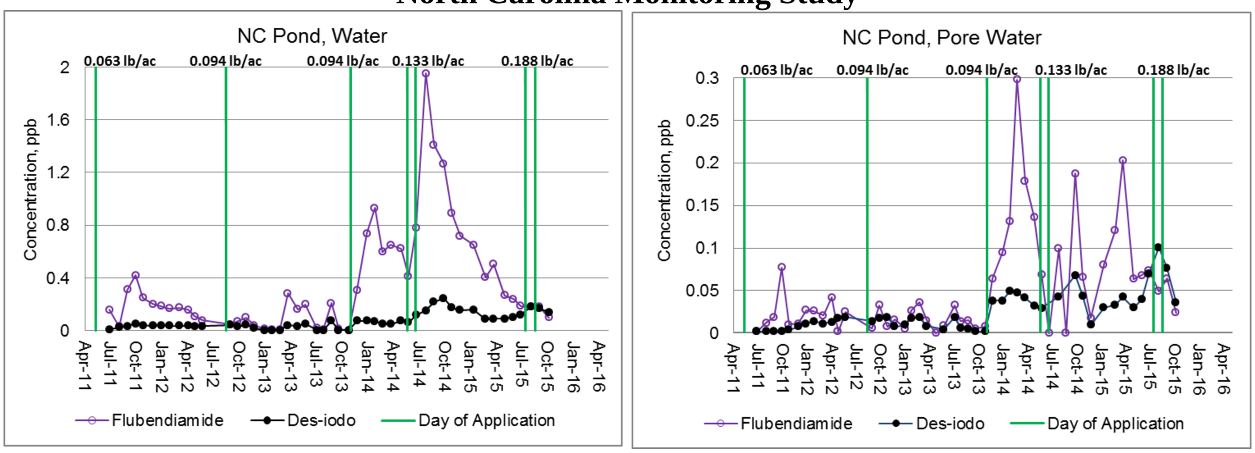
Q: What is your opinion on this position?

A: EPA's assumption that flubendiamide and des-iodo are accumulating based on the observed data in the North Carolina and Georgia monitoring sites is unfounded. As described below, variability in observations in North Carolina is explained by variability in flubendiamide application rates, conditions, and timing. EPA wrongly discounts the Georgia data because of the presence of grassed waterways at that site. Further, based on the sediment sampling approach to obtain pore water concentrations, until flubendiamide is present in the top 5 cm of pond sediment, the concentrations of constituents may increase, but then would be expected to plateau. The EFED modeling does not account for any of these conditions. Likewise, EFED's use of and interpretation of trend lines fit to the observed data are incorrect for failing to account for any of these factors.

Q: Have you reviewed any recently updated data regarding the concentrations of flubendiamide and des-iodo in the ponds at the two monitoring sites?

A: Yes. At my direction, Bayer updated previously produced figures showing the behavior of flubendiamide and des-iodo over time in the water column and pore water for the North Carolina and Georgia monitoring sites to include additional data through October 2015. These updated figures are provided below as Figure 1. A copy of Figure 1 is included at PBNX 80.

North Carolina Monitoring Study



Georgia Monitoring Study

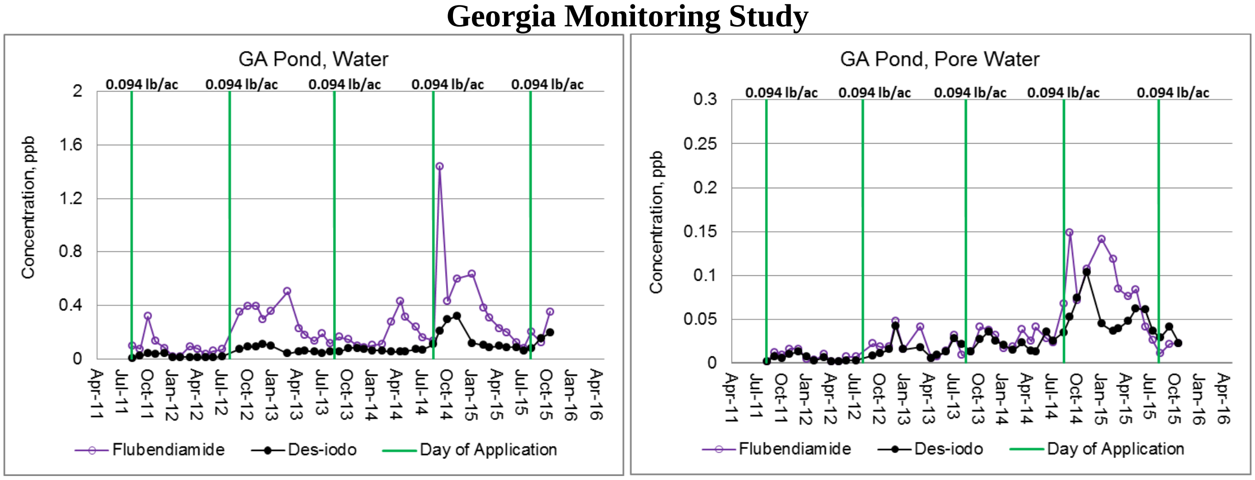


Figure 1. Monitoring results of flubendiamide and des-iodo in water column (left side) and pore water (right side) from North Carolina (top) and Georgia (bottom) ponds.

The charts in Figure 1 show measured concentrations of flubendiamide (in purple) and des-iodo (in black). The timing of Belt® (flubendiamide) applications to the pond watershed is shown by vertical lines, with the amount applied shown at the top of the chart.

Q: Based on your examination of the updated pond monitoring data, what conclusions have you drawn about flubendiamide's and des-iodo's attributes?

A: Examination of the observed data shows several important attributes of flubendiamide and des-iodo behavior. Examining the water column and pore water data for both flubendiamide and des-iodo shows observed concentrations increasing following flubendiamide application in the watershed (as would be expected), reaching a peak, and then declining prior to the next year's application. These observed declines at both the North Carolina and Georgia monitoring sites are largely counter to the EFED model that at best predicts only trivial declines due to pond outflow.

Q: Are the observed concentrations at the North Carolina site indicative of long-term accumulation?

A: No, the observed concentrations at the North Carolina site are not evidence of a trend toward long-term accumulation as EPA suggests. Instead, the change in application rates and timing, rainfall timing and magnitude, and conditions for flubendiamide application at the North Carolina site explain much of the trend in the observed data at this site.

Q: Please elaborate on the effect of application rates on the North Carolina observed data.

A: For compounds such as flubendiamide, movement of the material in runoff and with sediment is proportional to application rate, meaning that doubling of the application rate will result in doubling of its movement in runoff and sediment (assuming similar rainfall patterns).

At the North Carolina site, the 2012 flubendiamide application rate was 1.5 times the rate for 2011. The application rate for 2014 was more than double that of 2011. The application in 2013 occurred under unusual circumstances that are not typical (applied in November to the ground without an actively growing crop) and represent conditions of high potential for movement of the material with runoff and sediment. Timing and magnitude of rainfall following field application of flubendiamide further explain magnitudes of movement with runoff and sediment to the pond as well as declines in concentrations in the water column as water flows through the pond. The parameterization of the EFED model in the manner in which it was applied at the North Carolina site does not appropriately account for these factors.

Q: In your opinion, are the observed concentrations of flubendiamide and des-iodo at the North Carolina site evidence of long-term accumulation?

A: No. The concentrations of flubendiamide and des-iodo would be expected to increase at the North Carolina monitoring site based on the factors discussed above, rather than their chemical properties. Thus, EFED's conclusion that the data show long-term accumulation as predicted by EPA's model has no basis; the increased concentrations observed are explained by increased application rates, field conditions at the time of the 2013 application, and rainfall magnitude and timing. Further, as described below in the section on statistical analysis of the model, the suggestion that the EFED model matches observed data at the North Carolina site is incorrect.

Q: How do the Georgia pond monitoring data compare to the North Carolina pond data?

A: The Georgia monitoring data also show increases in flubendiamide and des-iodo concentrations in the water column and in sediment pore water following field application. The concentrations reach a peak and then decline until an application in the following year. The variability from year to year is much less at the Georgia site than at the North Carolina site. The flubendiamide application rate and timing each year are consistent for the Georgia site, while these were not consistent for the North Carolina site as discussed above.

Q: How does EPA assess the Georgia monitoring data?

A: EFED discounts use of the Georgia data throughout their analysis as the magnitude of these data remain more uniform over time and significantly below the EFED model predictions. EFED attempts to attribute this to the presence of grassed waterways, suggesting the grassed waterways are preventing flubendiamide and des-iodo from reaching the pond, even though EFED elsewhere states that grassed buffers are not effective mitigation measures for flubendiamide and des-iodo (see discussion of EPA's inconsistent position on buffers below). Grassed waterways and buffers cannot capture all runoff constituents for conditions such as those in Georgia. The magnitude of flubendiamide reaching the Georgia pond would be reduced by the grassed waterway, but the presence of grassed waterways would not prevent observation of a trend should one exist. In summary, the Georgia pond experiment informs the exposure assessment by again confirming the constituents decline seasonally with trends that cannot be captured by the EFED model.

Q: Are there any other factors that could affect the concentrations of flubendiamide and des-iodo in the ponds at the two monitoring sites?

A: Yes. Any observed increases in pore water flubendiamide and des-iodo concentrations in the monitored data at the Bayer monitoring sites to date can also be explained by the sediment pore water sampling methodology. Pore water is sampled from the top 5 cm of sediment. A 5 cm depth of sediment in these ponds would represent sediment reaching the pond over some period of time, likely several years or more. Thus, as new sediment containing flubendiamide and des-iodo is deposited in a pond, the pore water concentration of these constituents would be expected to increase until 5 cm of sediment was deposited that contained these constituents. Beyond this period, pore water concentrations would plateau and fluctuate around the plateau value based on amounts of constituents represented in the most recent 5 cm of sediment (recall the phosphorus trends discussed above).

Q: What effect would the sediment layering process have on sediment pore water concentrations?

A: This layering of constituents in the sediment will preclude the continued growth in constituent concentrations in sediment pore water predicted by EFED's model. Constituents in sediment below the top 5 cm of sediment will be buried and unavailable to contribute to concentrations in the top 5 cm of sediment pore water. Ultimately, however, the pond sediment and any materials in the pond sediment would be scoured and continue downstream, moving through the watershed as described above.

4. <u>The Stream Monitoring Data Confirm Movement Through the Watershed and Do Not Show Accumulation.</u>

Q: Please describe the samples from other water bodies analyzed in Bayer's monitoring studies.

A: The Bayer monitoring studies also include samples from intermittent and perennial streams, and provide samples of upstream water (control samples) prior to being influenced by the test site and downstream water that is influenced by the test site to define exposures beyond the farm pond. Figure 2 provides concentrations of des-iodo, which is the residue of greater EFED concern, in the flowing water bodies in the monitoring study. A copy of Figure 2 is included at PBNX 81.

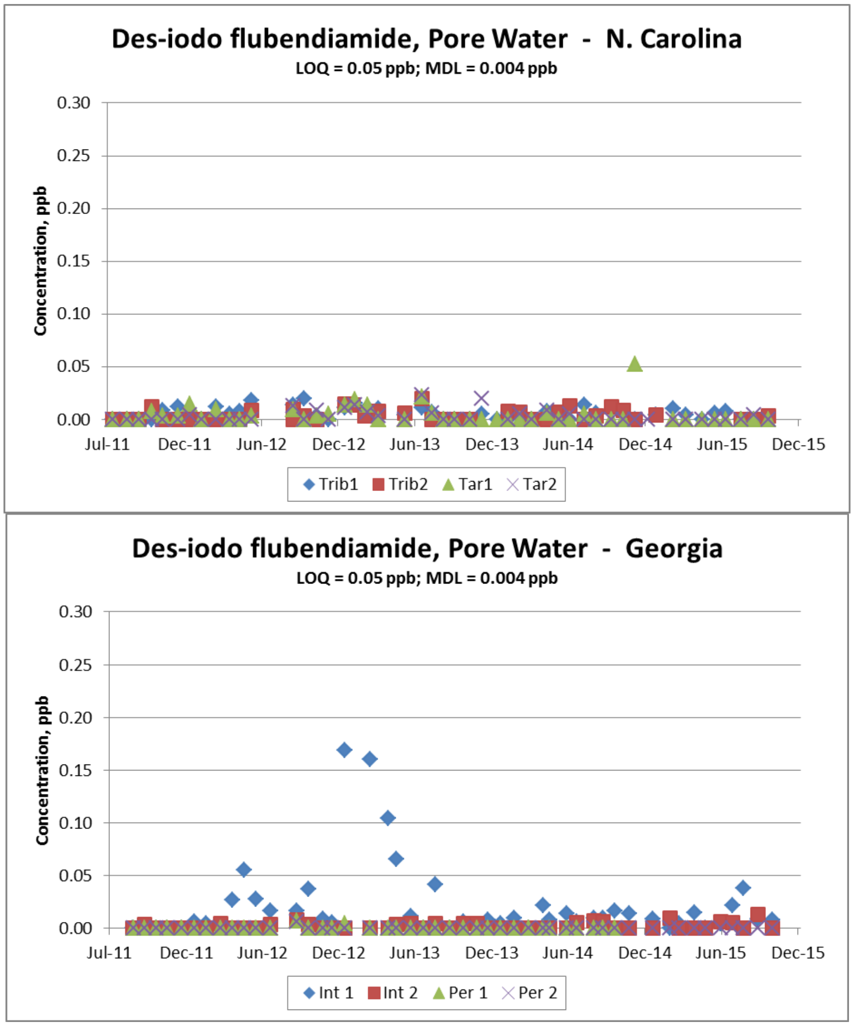


Figure 2. Des-iodo concentrations in samples taken from upstream intermittent creeks (Trib 1 / Int 1), downstream intermittent creeks (Trib 2 / Int 2), upstream perennial creeks / rivers (Tar 1 / Per 1) and downstream perennial creeks / rivers (Tar 2 / Per 2).

Q: In your opinion, what do the samples from the intermittent creeks and perennial creeks/rivers indicate?

A: Samples taken before and after pond water flows into intermittent creeks or tributaries, and finally into larger perennial creeks and rivers confirm no evidence of accumulation; are well below any risk endpoint defined by EFED; and confirm my opinion that chemical residues will move from collection points, such as ponds, through the agricultural watershed in concentrations that do not challenge the environment.

C. <u>The USGS Data Do Not Show That Flubendiamide or Des-Iodo Are Ubiquitous or Accumulating.</u>

Q: What is your understanding of the available United States Geological Service ("USGS") data for flubendiamide and des-iodo?

A: At EPA's request, the USGS has tested for flubendiamide and des-iodo as part of its nationwide water monitoring program. As part of my review, I downloaded the flubendiamide and des-iodo concentration data for rivers and streams from the USGS website on March 12, 2016. The USGS data include nearly four years of monthly observations for these constituents from the fall of 2012 through the summer of 2015 for more than 90 stations, and include additional stations with smaller numbers of observations. Analyses of 5,004 samples were reported. Review of the USGS river and stream monitoring data do not suggest that flubendiamide and des-iodo are ubiquitous or accumulating. Observed levels are well below the "no effect" level.

Q: Please describe EFED's analysis of the USGS data.

A: EFED previously analyzed USGS data for the period of fall 2012 to October 2014; approximately one year of observations fewer than are currently available. Based on their review of the USGS data, EFED indicated that "California, Georgia, North Carolina, Mississippi, and Louisiana had multiple sites with frequent detections (Figure 1)," and referred to "widespread, non-targeted, filtered USGS detections."[3] EPA's figure showing these detections is provided as Figure 3 below. A copy of Figure 3 is included at PBNX 82.

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[3] PBNX 31 at 16 (EFED Flubendiamide Ecological Risk Assessment Addendum (Jan. 28, 2016)).

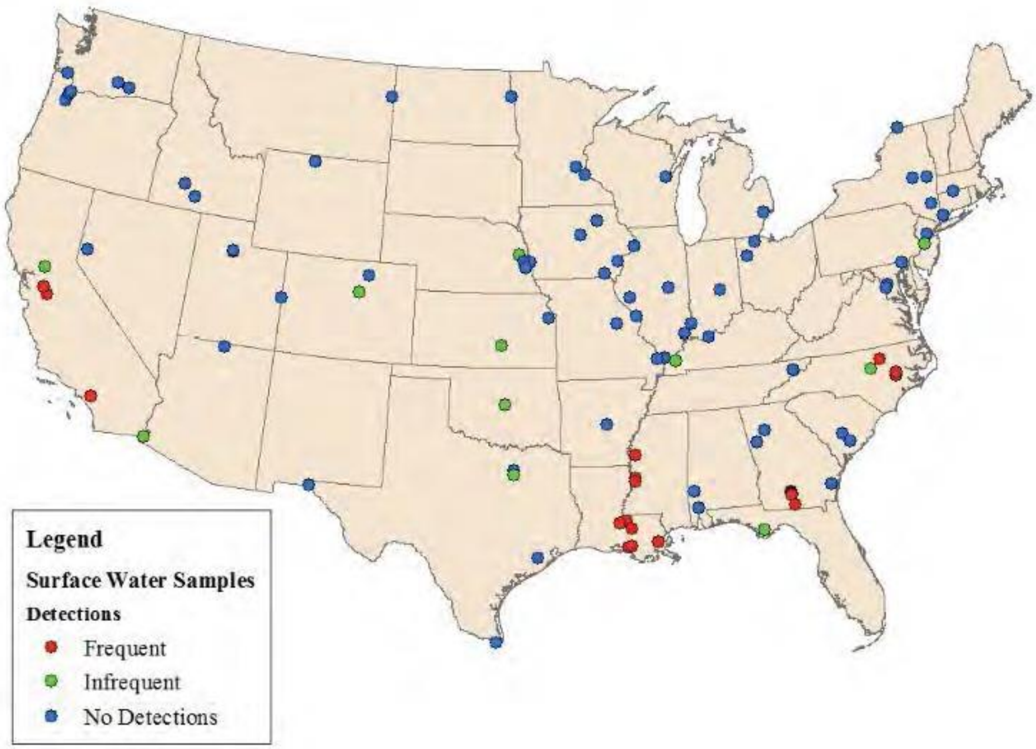

Figure 3. Flubendiamide detections in surface water samples collected by the USGS and registrant (from EFED Ecological Risk Assessment Addendum (Jan. 28, 2016), PBNX 31 at 16).

Q: What is your opinion on EFED's characterization of the geographical distribution of flubendiamide detections in the USGS data?

A: While the sites with what EFED termed "frequent detections" are widespread geographically, characterizing this as "widespread detections" is misleading. The three North Carolina sites that are identified as having frequent detections include two tributaries to the Neuse River and a downstream Neuse River site. The sites in Louisiana include three locations on the Mississippi River and three sites on the Atchafalaya River. Two sites with frequent detections in Mississippi are on the Yazoo River and the third is on the Mississippi River. The sites labeled with frequent detections in Georgia are small streams sampled by Bayer as part of its monitoring study, and not USGS as the supporting EPA text for the figure suggests. For the sites labeled as having infrequent detections, many of the detections were labeled by USGS as "below the reporting level but at or above the detection level" or "below the detection level."

Q: How does the geographical distribution of flubendiamide detections compare to the geographical use of flubendiamide products?

A: Figure 4 below shows the estimated agricultural use of flubendiamide for 2013 (sourced from the USGS website referenced in the figure caption). A copy of Figure 4 is included at PBNX 82. Stream and river sites in Figure 3 characterized by EPA as having frequent detections of flubendiamide occur in areas with the greatest flubendiamide application. Note also that not all sites in areas of highest application on Figure 4 were characterized by EPA on Figure 3 as having frequent detections.

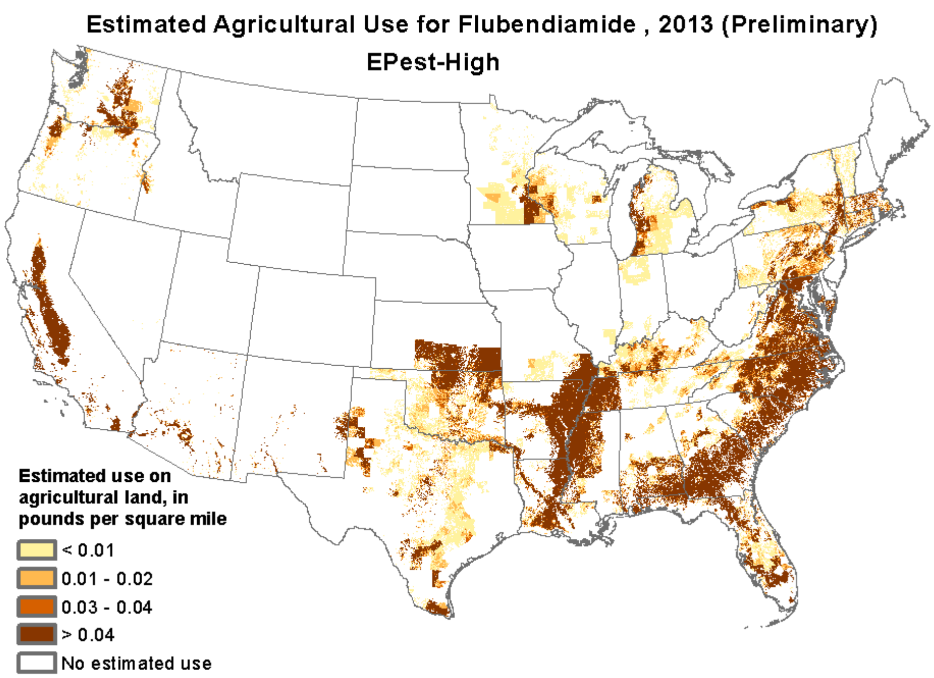

Figure 4. Estimated flubendiamide application in 2013 (from http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2013&map=FLUBENDIAMIDE&hilo=H).

Q: Were the USGS samples filtered?

A: Yes. EFED correctly describes the USGS samples as being filtered prior to analysis and acknowledges this will attenuate the residue levels by removing sediment-bound residue. While the extent of the residue attenuation due to filtering cannot be established, the reported USGS results are similar to those reported by Bayer where filtering did not occur, suggesting the impact of filtering is small.

Q: Please describe EFED's conclusions from its analysis of the USGS data.

A: EFED incorrectly concludes that the flubendiamide and des-iodo concentrations measured in flowing water by USGS are evidence for upstream accumulation in lentic (non-flowing) water bodies.[4] This conclusion cannot be drawn from the USGS data, as one should more reasonably assume the constituent detections in the USGS data illustrate the transport of residues through the watersheds under the influence of hydrologic cycling previously described. The more reasonable source of the residues is the treated fields in the watershed, not the lentic water bodies as EFED concludes. While some fields on which flubendiamide is applied would flow into ponds before the water from the ponds flows into streams, the majority of fields in watersheds would typically flow into channels and small streams.

Q: In your opinion, what conclusions can be drawn from a review of the USGS data?

A: In summary, review of the USGS river and stream monitoring data show limited, low-level detections consistent with areas of product use, but do not suggest that flubendiamide and des-iodo are ubiquitous or accumulating. The data analyzed contain an additional year of data beyond those available when EFED conducted an analysis of USGS data, providing further evidence that flubendiamide and des-iodo are not accumulating and exceedances are not

[4] PBNX 36 at 2 (EFED Response to Bayer CropScience LP Flubendiamide Aquatic Risk Email Submission (July 8, 2015)).

occurring. All values observed are below levels of regulatory concern. Further, EFED's characterization of the USGS data is misleading.

D. EPA Takes Contradictory Positions on the Effect of Buffers on Flubendiamide and Des-Iodo Runoff.

Q: Please describe EPA's position on how buffers affect flubendiamide and des-iodo runoff.

A: EFED attempts to simultaneously take the position that buffers do not work in reducing losses of flubendiamide to small ponds and that the grassed waterway works too well to consider the Georgia pond data. It is not possible to logically adhere to both of these positions simultaneously.

As discussed above, EFED largely discounts and ignores the data from the Georgia monitoring site, where application rates each year are consistent and the resulting concentrations of flubendiamide and des-iodo are more uniform, based on the presence of a grassed waterway that was installed in the watershed.[5]

On the other hand, EFED has taken the position that buffers are not effective in mitigating movement of flubendiamide off fields and out of watersheds. For example, one of their "key findings" from the pond monitoring study was that "Vegetative Filter Strips (VFSs) are ineffective in preventing this accumulation in downstream waterbodies."[6] If this is EFED's position, ignoring the results from the Georgia pond site is logically inconsistent. The grassed waterway is a standard conservation practice in watersheds such as the study site in Georgia. They are used to safely convey runoff that accumulates in concentrated flow areas. Grassed

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[5] *See, e.g.*, PBNX 35 at 4-5, 13-14 (EFED Review of Water Monitoring Project (Feb. 20, 2015) (contending that the presence of grassed waterways would "reduce the accumulation of flubendiamide and des-iodo" and "confounded" the interpretation of the Georgia data).

[6] PBNX 25 at 4.

waterways have some similarity to buffers in that both conservation practices are commonly used in addressing runoff issues. If anything, a grassed waterway would be expected to be less effective than a buffer in reducing flubendiamide reaching the pond, as grassed waterways are primarily designed to safely convey runoff while preventing significant soil erosion in the concentrated flow path or channel, thereby preventing gullies from forming.

Elsewhere, while largely ignoring the Georgia data, EPA asserts that "[b]ecause the Agency's modeling does not account for the effect of VFSs, but still largely matches the monitoring data, we believe the effect of VFSs is not large enough to mitigate the ecological risks posed by flubendiamide applications."[7] This contradicts EPA's position that the grassed waterway at the Georgia site precludes use and interpretation. Moreover, as discussed below, EFED's modeling does not "largely match" monitoring data at the Georgia or the North Carolina site.

E. EPA's Modeling Does Not Perform in Predicting Flubendiamide and Des-Iodo Concentrations.

1. EPA Relies on Unsupported Assertions That Its Modeling Performs Well.

Q: How does EFED characterize the performance of its model?

A: EFED's review documents consistently indicate EFED's model performs well relative to the observed data. For example, EFED's February 20, 2015 review of the reports from Bayer's monitoring study includes several statements asserting that the model performs well:

- "Overall, the Agency believes the monitoring data tracks reasonably well with the modeled data."
- "The Agency believes the SWCC predictions fit the water column data quite well (Figure 6a and b)."

[7] PBNX 30 at 4 (EPA Decision Memorandum (Jan. 29, 2016)).

- "The NC pond data provide a good match to the SWCC modeling (Figures 6a and b)."[8]

In addition, EFED's July 15, 2015 response to Bayer's June 30, 2015 white paper states:

- "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; . . . Continued monitoring at these sites are unlikely to change this understanding."

- "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."[9]

Finally, EFED's January 28, 2016 Ecological Risk Assessment Addendum indicates the following regarding the Georgia monitoring data:

- "The accumulation measured in the first three years of the pond data least impacted by the identified issues largely matched the initial 3 years of concentration predictions of EFED's aquatic exposure modeling."[10]

Q: What is your opinion on EFED's characterization of its model?

A: EFED concludes that its model "performs quite well," despite conducting no statistical analysis to identify how well the EFED model performed with respect to monitoring data. This is contrary to the guidance in the EPA document on Guidance on the Development, Evaluation, and Application of Environmental Models that suggests comparison of modeled results with monitoring data when feasible and provides a number of quantitative methods for assessing such comparisons.[11]

Furthermore, EFED's belief that its model performs well relative to observed field data is incorrect, as demonstrated in the next section.

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[8] PBNX 35 at 12, 18.

[9] PBNX 25 at 3-4.

[10] PBNX 31 at 12.

[11] PBNX 51 (EPA, Guidance on the Development, Evaluation, and Application of Environmental Models (Mar. 2009) (excerpts).

2. <u>Statistical Analysis Shows That EFED's Model Does Not Perform Well.</u>

Q: Did you perform any statistical analyses of the performance of EFED's model?

A: Yes.

Q: Please describe the statistical measures you used in your analyses.

A: Several statistical analyses are commonly used in assessment of hydrologic and water quality models such as the model used by EFED. These commonly used statistical measures are briefly introduced, followed by their computation for the North Carolina and Georgia monitoring sites.

The Coefficient of Determination, or R^2, describes how well observed outcomes are replicated by the model, based on the proportion of total variation in observed data explained by the model. An R^2 of 1 indicates that the regression line or model perfectly fits the data, while an R^2 of 0 indicates that the line or model does not fit the data at all.

A common statistic used to understand the performance of hydrologic/water quality models is the Nash-Sutcliffe Efficiency (NSE).[12] The NSE indicates how well the plot of observed versus simulated data fits the 1:1 line (a line of perfect fit between a model and observed data). This is the same as the Coefficient of Determination (R^2) when the intercept is forced to be 0. NSE ranges from $-\infty$ to 1.0, with NSE = 1 being the optimal value. Values between 0.0 and 1.0 suggest the model has some predictive ability, whereas values < 0.0 indicate that the mean observed value is a better predictor than the modeled values. This would indicate that simply taking the average of the observed data would be a better predictor than applying the model, which indicates unacceptable performance of the model.

[12] D.N. Moriasi et al., *Model Evaluation Guidelines for Systematic Quantification of Accuracy in Watershed Simulations*, 50(3) Transactions ASABE 885-900 (2007).

Percent bias (PBIAS) is another measure used to assess model performance and measures average tendency of the simulated data to be larger or smaller than their observed counterparts.[13] PBIAS is the deviation of data being evaluated, expressed as a percentage. The optimal value of PBIAS is 0.0, with small values indicating accurate model simulation. Positive values indicate model underestimation bias, and negative values indicate model overestimation bias.

Q: What ranges of statistical performance measures are considered acceptable for hydrologic/water quality models?

A: Ranges of statistics considered acceptable for hydrologic/water quality models are highlighted in Engel et al. (2007)[14] and Santhi et al. (2001).[15] Engel et al. (2007) reviewed ranges of statistical performances for hydrologic/water quality models. Santhi et al. (2001) suggested the following NSE, R^2, and P_{BIAS} values as acceptable ranges for hydrologic/water quality model performance:

NSE > 0.50

$R^2 > 0.50$

P_{BIAS} ±25%.

Q: Please describe your statistical analysis of EFED's modeling of flubendiamide and des-iodo concentrations for the North Carolina site.

A: The NSE, PBIAS, and R^2 were computed for EFED's modeling of flubendiamide and des-iodo concentrations in the water column and in sediment pore water at the North Carolina site using the observed data from the site. EFED modeled two cases – their standard model and

[13] *Id.*

[14] B. Engel et al., *A Hydrologic/Water Quality Model Application Protocol*, 43(5) J. Am. Water Res. Ass'n 1223-36 (2007).

[15] C. Santhi et al., *Validation of the SWAT Model on a Large River Basin With Point and Nonpoint Sources*, 37(5) J. Am. Water Res. Ass'n 1169-88 (2001).

an updated model considering flow through the pond. Statistics were computed for both. The results are summarized in the table below (Table 1). A copy of Table 1 is included at PBNX 83.

Table 1. NSE, PBIAS, and R^2 for North Carolina site EFED models and monitoring data.

	North Carolina Site		
Model	**NSE**	**PBIAS (%)**	R^2
Flubendiamide in Water Column	-0.17	66	0.15
Flubendiamide in Water Column with Flow Through	-0.24	72	0.11
Des-iodo in Water Column	-0.22	-22	0.29
Des-iodo in Water Column with Flow Through	0.10	24	0.22
Flubendiamide in Pore Water	-0.41	-89	0.16
Flubendiamide in Pore Water with Flow Through	-0.14	-59	0.11
Des-iodo in Pore Water	-11.92	-227	0.42
Des-iodo in Pore Water with Flow Through	-3.37	-127	0.35

Q: Are the statistical performance measures for the North Carolina site within the acceptable range?

A: No. All but one of the NSE values are negative, indicating the mean of the observed data is a better predictor than the EFED model. The only model with a positive NSE is for des-iodo in the water column with flow through. However, based on suggested NSE values for hydrologic/water quality models performance, this value is well below the level for acceptable model performance (NSE > .50). Further, the PBIAS values indicate that the model greatly over predicts des-iodo in pore water even when water flow through the pond is considered.

Q: Based on your statistical analysis, what are your conclusions regarding EFED's model for the North Carolina site?

A: In short, statistical analysis of the EFED model and monitoring data for the North Carolina site indicates that the model does not perform well. The mean of the monitoring data is a better estimate of the observed data than the model, indicating the model has no value as a predictive tool for future conditions. Given that the mean of observed data is a better predictor of observed data than both EFED models, the mean of the observed data is the best predictor of future conditions. This supports continued collection of monitoring data to evaluate future trends and to address and clarify concerns of accumulation and the use of observed monitoring data rather than EPA's modeling to guide regulatory determinations.

Q: Please describe your statistical analysis of EFED's modeling of flubendiamide and des-iodo concentrations for the Georgia site.

A: A similar analysis was conducted for the Georgia monitoring site, which had two ponds at the site. The results are summarized in the table below (Table 2). A copy of Table 2 is included at PBNX 83.

Table 2. NSE, PBIAS, and R^2 for Georgia site EFED models and monitoring data.

	Pond 1			**Pond 2**		
Model	**NSE**	**PBIAS (%)**	**R^2**	**NSE**	**PBIAS (%)**	**R^2**
Flubendiamide in Water Column	-4.52	-286	0.24	-2.81	-255	0.12
Flubendiamide in Water Column with Flow Through	-0.51	-121	0.28	-0.15	-103	0.10
Des-iodo in Water Column	-41.27	-661	0.50	-40.15	-748	0.32
Des-iodo in Water Column with Flow Through	0.64	-52	0.55	0.36	-70	0.30
Flubendiamide in Pore Water	-215.65	-2100	0.57	-494.69	-2888	0.34
Flubendiamide in Pore Water with Flow Through	-63.42	-1164	0.43	-149.67	-1616	0.29
Des-iodo in Pore Water	-428.14	-2310	0.59	-2478.93	-5694	0.29
Des-iodo in Pore Water with Flow Through	-21.78	-596	0.51	-152.07	-1574	0.24

Q: Are the statistical performance measures for the Georgia site within the acceptable range?

A: No. Similar to the North Carolina site, all but one of the NSE values are negative for each pond, indicating the mean of the observed data is a better predictor than the model, and the only model with a positive NSE (des-iodo in the water column with flow through) is still well below the level for acceptable performance. The very large, negative PBIAS values indicate that the model vastly over predicts des-iodo in pore water, even when water flow through the pond is considered.

Q: How did the statistical measures for the Georgia site compare to those for the North Carolina site?

A: The NSE and PBIAS values for the Georgia site were much more negative generally than those for the North Carolina site, suggesting the model deviates more from observed values in Georgia than North Carolina. On the other hand, the R^2 values for the Georgia site were comparable or larger than values for the North Carolina site. The lower NSE values and larger negative PBIAS values at the Georgia site may be due to the grassed waterway at the site. However, the data are insufficient to reach this conclusion.

Q: What are your overall conclusions regarding your statistical analysis of EFED's model for the North Carolina and Georgia sites?

A: The statistical analysis of the EFED model performance at both the North Carolina and the Georgia monitoring sites indicates the model performs very poorly. Based on statistical values used by hydrologic/water quality modelers, there is no possibility of the model performance being considered to perform "reasonably well" or "quite well" as the EFED concludes. The only conclusion that should be reached for the EFED models is that they do not perform well. It does not inform the exposure analysis better than the mean of the available field data and should not be used to predict future trends.

F. <u>EFED's Models Should Be Improved as a Long-Term Objective.</u>

Q: Did EFED change its modeling approach in the modeling conducted and presented in connection with EPA's recent cancellation determination?

A: Yes. Responding to longstanding criticism from the registrants, EFED updated its modeling to consider variable volume and allow outflow from the modeled farm ponds.

Q: What effect, if any, did this have on the performance of EFED's modeling?

A: EFED's effort to improve the representation of pond conditions by considering variable volume (flow through the pond) in the model is a step in the right direction. Model performance was so poor, however, that the statistics do not indicate the model's ability to simulate the monitored data was improved as compared to the model that did not consider variable volume.

Q: What does this mean for EFED's modeling approach going forward?

A: Further refinements are needed for representation of reality. Comparison of the modeled concentrations with observed data indicate a significant over-prediction of observed data. Continued refinement in representation of agricultural production and water systems within the model is consistent with EFED's tiered modeling approach.

Q: Have you identified any other issues in EFED's modeling approach?

A: Yes. For some locations and situations, the current modeling approach does not represent situations that are ecologically relevant. For example, modeling small ponds in arid regions such as the Central Valley in California that dry up and using constituent concentrations at time steps shortly before the ponds become dry do not represent situations that are of ecological relevance given the severe stresses on the aquatic systems due to the ponds becoming dry. Such ponds are unlikely to even exist given irrigation management practices.

Q: Please describe what additional data and studies are needed in order to improve the modeling for flubendiamide and des-iodo concentrations.

A: Pore water data are critical to assessing the impacts of flubendiamide and des-iodo in the environment. In general, pore water concentrations of constituents in the environment are not widely studied, which is reflected in little scientific literature on this issue. Additional study of pore water concentrations of constituents, including those of concern in this report, are needed. Further, few models that predict pore water concentrations are available, and those that are available have not been widely tested. Additional study of pore water and its constituents is needed as is the further development and testing of models for predicting pore water constituents.

G. <u>Monitoring Results Show That Flubendiamide and Des-Iodo Have Not Accumulated to Levels of Concern.</u>

Q: In your opinion, how useful is EFED's model as a basis for risk assessments and regulatory determinations?

A: Because the EFED model does not accurately estimate flubendiamide and des-iodo concentrations, it is not useful in assessing expected des-iodo concentrations to support a science-based risk assessment. Thus, EFED should rely on the available monitoring data only in reaching its regulatory determinations.

Q: What do those data show?

A: The best available monitoring data for exposure or risk evaluation come from the North Carolina and Georgia pond studies, where both water column and pore water concentrations were measured with product usage confirmed in the adjacent field. The following table (Table 3) compares the toxicity endpoints identified by EFED and Bayer (as summarized in EPA's risk assessment documents) to the maximum values observed in each location for the Bayer monitoring study. The USGS data are included in the summary table for comparative and confirmatory purposes. A copy of Table 3 is included at PBNX 84.

Table 3. Maximum observed flubendiamide and des-iodo concentrations compared to toxicity endpoints.

Water Body		**Water Column <u>maximum</u> concentration, ppb**		**Pore Water <u>maximum</u> concentration, ppb**	
	Sampling	**Flubendiamide**	**Des-iodo flubendiamide**	**Flubendiamide**	**Des-iodo flubendiamide**
Toxicity Endpoints (NOEC / NOAEC)	*EFED*	*15.5*	*1.9*	*1.5*	*0.28*
	Bayer	*33*	*4.0*	*2.6*	*19.5*
Pond	Pond Studies	1.95	0.32	0.30	0.10
Intermittent Stream		0.62	0.05	0.19	0.17
Perennial Stream/River		0.09	0.01	0.19	0.05
Stream / River	USGS	0.93	0.07	not sampled	not sampled

Bayer NC and GA pond studies sampled monthly for 4.5 years; USGS – 5,004 samples from national monitoring network, over 3 years, approx. monthly (not all sites for full duration)

As shown in Table 3, the maximum observed concentrations of flubendiamide and des-iodo in ponds, intermittent streams, and perennial streams in the water column and the pore water are all below the endpoints identified by EFED and Bayer. The real-world data, including more than 1,000 overlying and pore water pond samples, do not show any concentrations indicating accumulation to or near identified toxicity endpoints.

Q: What, if anything, do the data in Table 3 indicate with respect to the merits of EPA's cancellation determination?

A: As Dr. Moore explains in his testimony, the critical factor driving EPA's cancellation decision is EPA's determination that des-iodo levels in pore water will increase beyond the 0.28 ppb endpoint that EPA has identified. As Dr. Moore further explains, EPA's reliance on the 0.28 ppb level of concern derived from the spiked water study is not scientifically sound, and the more relevant and scientifically sound endpoint is the 19.5 ppb level of concern from the spiked sediment study. As shown in the table above, after almost five years of product use in pond settings similar to EFED's modeled pond scenario, not a single sample has exceeded even the incorrect 0.28 ppb level of concern.

The maximum measured concentration of des-iodo in pore water was 0.17 ppb, which is below EPA's incorrect 0.28 ppb level of concern, and 115 times lower than the proper 19.5 ppb des-iodo pore water level of concern based on the spiked sediment study. The maximum 0.17 ppb pore water concentration was measured at a single site, with concentrations decreasing in subsequent sampling taken at the same site. Moreover, out of 509 pore water samples from Bayer's monitoring studies, only five samples were measured at or above 0.10 ppb.

H. Monitoring of Flubendiamide and Des-Iodo Concentrations Should Continue.

Q: What is your opinion on the continuation of Bayer's monitoring studies?

A: Given the currently available data and the poor performance of the current models in explaining monitored data, data collection efforts should continue. Currently, the mean of the data is a better predictor than EFED's models of actual observations in the Bayer monitoring sites. While the data do not suggest that flubendiamide or des-iodo is accumulating to levels of concern, continuation and potential expansion of the monitoring studies would provide the most reliable data on this question. It is my opinion, therefore, that the monitoring study should continue for perhaps 2-4 additional years and expansion to additional sites should be considered.

If the monitoring is continued for a sufficiently long period, I would expect concentrations in the pond sediment and pore water to eventually reach a plateau resulting from the dynamic equilibrium of residues entering and leaving the watershed as described above and confirmed by the monitoring data available to date.

Q: Are there other data that should be considered on an ongoing basis?

A: The USGS data set for flubendiamide and des-iodo in streams and rivers continues to grow. This data set should continue to be explored to understand the concentrations of flubendiamide and des-iodo under actual conditions as well as their spatial and temporal distribution. Data from other sources may also be available that provide insight into the concentrations and distributions of these constituents in the water environment.

V. EXHIBITS

Q: Dr. Engel, in your testimony you referenced the following exhibits: PBNX 25, 30-31, 35-36, 50-51, and 80-84. PBNX 25, 30-31, 35-36, and 50-51 were previously produced as attachments to Bayer and Nichino's Motion for Accelerated Decision. PBNX 80-84 are copies of figures and tables introduced in your testimony and are being produced as part of Bayer and Nichino's Prehearing Submission. Are these exhibits true and correct copies of the documents you referenced?

A: Yes.

Q: Thank you, Dr. Engel.

Bayer and Nichino move to enter PBNX 25, 30-31, 35-36, 50-51, and 80-84 into evidence.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this __21st__ day of ____April_______, 2016.

____
Bernard Engel, Ph.D.