UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

VERIFIED WRITTEN STATEMENT OF DWAYNE R. J. MOORE, PH.D. ON BEHALF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

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I. PROFESSIONAL EXPERIENCE

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

A: My name is Dr. Dwayne R. J. Moore. I am a Senior Vice President and Senior Scientist at Intrinsik Environmental Sciences (US) Inc., located at 41 Campus Drive, Suite 202, New Gloucester, Maine 04260.

Q: Please describe your education background.

A: I hold a Bachelor's of Science degree in Plant Sciences from the University of Western Ontario, and Masters of Science and Doctor of Philosophy degrees in community ecology from the University of Ottawa.

Q: Please summarize your occupational history.

A: I have served as an ecological risk assessor for the past 25 years, the first seven years with Environment Canada (the Canadian analogue to the U.S. Environmental Protection Agency (EPA)), the next seven years as a Senior Associate with The Cadmus Group, and the last 11 years as a Senior Vice President and Senior Scientist with Intrinsik Environmental Sciences. During my career, I have led and conducted numerous refined risk assessments on the effects of industrial chemicals and pesticides to aquatic life and wildlife.

While at Environment Canada, I developed guidance for conducting ecological risk assessments of priority industrial substances, led and participated in priority substance assessments, and developed water quality guidelines for toxic chemicals that ensure protection of aquatic life. For the last 17 years, I have served as a consultant and ecological risk assessor to private firms, non-government organizations, and various government agencies in Canada, the United States, Europe and Australia. The agencies have included Environment Canada, Health Canada, Canadian Nuclear Safety Commission, Canadian Department of Fisheries and Oceans, Provinces of British Columbia and Ontario, Canadian Council of Ministers of the Environment, U.S. Army Corps of Engineers, U.S. Department of Energy, U.S. Environmental Protection Agency, Australian Pesticides and Veterinary Medicines Authority, and Department for Environment in the United Kingdom.

PBNX 43 is a copy of my curriculum vitae further detailing my qualifications, experience, publications and presentations.

Q: Please describe your professional publications and your involvement in academic and professional institutions.

A: I have authored over 50 peer-reviewed publications and 11 book chapters, edited a book, been a member of editorial boards for two major journals in the area of ecological risk assessment and toxicology, and helped organize many Society of Environmental Toxicology and Chemistry (SETAC) Pellston workshops on specialized topics in risk assessment.

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

A: Yes, I served on Scientific Advisory Panels convened under FIFRA in 1999, 2000, and 2004, addressing issues related to the ecological risks posed by chlorfenapyr, implementation of probabilistic ecological assessments, and development of refined terrestrial and aquatic models for assessments of pesticides. I have also served as a member of the US EPA Scientific Advisory Board in 2006 and 2008, where I participated in a panel on the state of the practice for ecological risk assessment, and provided advice on advancing the science and application of ecological risk assessment in environmental decision making. In 1999, I served on the Terrestrial Peer Input Panel that reviewed the refined terrestrial assessment methods report developed by the Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM). In 2005, I reviewed the report prepared by the National Research Council of the National

Academies that convened to determine lessons learned from the Superfund Site Assessment for the Coeur d'Alene River Basin in Idaho.

Q: Please describe your areas of expertise.

A: I am an expert in, among other areas, ecological risk assessments for pesticides and industrial chemicals, wildlife exposure modeling, development of water quality guidelines and criteria for protection of aquatic life, community ecology, statistics, uncertainty analysis, and analysis of toxicity data. Since becoming a consultant in 1996, I have developed probabilistic exposure and risk models for birds and mammals exposed to bait, granular, seed treatment and flowable pesticides. I have also led and participated in many refined aquatic and wildlife exposure and risk assessments for pesticides, including insecticides such as aldicarb, azinphos methyl, bifenthrin, brodifacoum, carbofuran, carbosulfan, chlorpyrifos, clothianidin, dimethoate, diphacinone, imidacloprid, malathion, and methyl parathion.

Q: Please provide a sampling of the work you have performed on behalf of regulatory agencies in Canada and the United States.

A: For Environment Canada, I led a team that developed the guidance manual for deriving Ideal Performance Standards (IPS, equivalent to environmental quality criteria) for pesticides in Canada. Subsequent to preparation of the guidance manual, my team completed development of IPS for protection of aquatic life for 8 priority pesticides in Canada. For the Pest Management Regulatory Agency, I developed their first probabilistic ecological risk assessment for a pesticide, chlorpyrifos. I have also taught several courses on statistics and probabilistic methods to regulatory agencies including Canadian Council of Ministers of the Environment, Canadian Pest Management Regulatory Agency, Ontario Ministry of the Environment, US EPA Office of Pesticide Programs and others. For the Canadian Nuclear Safety Commission, I developed a guidance manual for statistical analysis of monitoring data and for the Canadian Department of Fisheries and Oceans, I reviewed available methods for conducting quantitative uncertainty analyses. I led the ecological risk assessment for the polychlorinated biphenyl (PCBs)-contaminated Housatonic River in Massachusetts on behalf of EPA, and the mercury-contaminated East Fork Poplar Creek in Tennessee on behalf of the US Department of Energy. I also co-led the ecological risk assessment of the Calcasieu Estuary in Louisiana, also on behalf of EPA.

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 ecological risk assessments conducted by EPA for benthic invertebrates potentially exposed to flubendiamide. Specifically, I was asked: 1) to review the studies, data, guidelines, and risk assessments for benthic invertebrates potentially exposed to flubendiamide and the degradation metabolite, des-iodo flubendiamide (hereafter "des-iodo"), 2) to determine whether EPA had properly evaluated the studies and data and had selected the correct toxicity study results (endpoints) for its risk determination, and 3) to determine whether EPA's proposed cancellation of flubendiamide due to potential risks to benthic invertebrates was based on sound science.

In my analysis, I have considered the ecological risk assessments published by EPA, including recent assessments issued in support of its January 29, 2016 Decision Memorandum, the benthic invertebrates toxicity study reports for flubendiamide and des-iodo, and the guidelines, publications, and other materials cited in this Written Statement.

Q: Bayer and Nichino offer Dr. Moore as an expert in the areas of ecotoxicology; ecological risk assessments for pesticides and industrial chemicals; and related areas

including development of water quality guidelines and criteria for protection of aquatic life and analysis of toxicity data.

III. SUMMARY OF CONCLUSIONS

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

A: My analysis focused on the issue of the potential chronic risk posed by flubendiamide and des-iodo in sediment pore water to benthic invertebrates, which is the only significant risk issue identified by EPA in its Notice of Intent to Cancel the flubendiamide registrations and the Decision Memorandum explaining its cancellation determination. After review of the relevant documents, studies, and data, and for the reasons described in this testimony, it is my opinion that EPA's assessment of the risk posed to benthic aquatic invertebrates is fundamentally flawed. Therefore, the Agency's decision to cancel on that basis is not supported by the science.

More specifically, based on my analysis I conclude that:

- The toxicity endpoint that EPA uses to justify cancellation of the flubendiamide registrations is not appropriate. The toxicity endpoint for benthic invertebrates of 0.28 µg/L of des-iodo in sediment pore water (i.e., the water in the spaces between sediment particles) was derived from a spiked water study that is not relevant for des-iodo and was superseded by a subsequently conducted and more relevant spiked sediment study.
- The des-iodo spiked water study assesses the potential impacts of an exposure route, spray drift, which is not a significant route of exposure for flubendiamide, and is irrelevant for des-iodo.
- The spiked water study has other flaws, including a flawed statistical analysis that, if corrected, would lead to a higher endpoint.
- Prior EPA statements, OECD guidance, and sound scientific considerations confirm that the spiked sediment study is more relevant and the preferred approach to analyzing the potential impacts of flubendiamide and des-iodo on benthic invertebrates.
- The spiked sediment study mimics the potential gradual buildup of des-iodo that could occur over time in sediment and sediment pore water, as a result of flubendiamide partitioning to sediment and degrading to des-iodo.

- EPA's decision documents provide no explanation or rationale for their decision to regulate flubendiamide based on the des-iodo spiked water endpoint, rather than the more relevant and scientifically sound des-iodo spiked sediment endpoint.

- The des-iodo pore water chronic toxicity endpoint based on the spiked sediment study was calculated by EPA to be 19.5 µg/L, which is 70 times higher than the spiked water endpoint EPA wrongly relies on.

- Observed des-iodo pore water concentrations in water bodies close to flubendiamide-treated fields after five years of monitoring and seven years of product use are well below the sediment pore water endpoint of 19.5 µg/L and thus, flubendiamide application poses no risks of concern.

- EPA's risk assessments for flubendiamide and des-iodo provide no reliable scientific basis to conclude that benthic invertebrates are at significant risk from the continued registration and use of flubendiamide products.

IV. BACKGROUND

Q: What is flubendiamide and how is it used?

A: Flubendiamide is a selective, non-systemic insecticide that has been approved by EPA for a variety of uses, including alfalfa, Brassica leafy vegetables, Christmas trees, corn, cotton, cucurbit vegetables, fruiting vegetables, grapes, leafy vegetables, legume vegetables, low-growing berries, peanuts, pistachio, pome fruit (e.g., apple, pear), sorghum, stone fruit (e.g., apricot, cherry, peach), sugarcane, sunflower, safflower, tobacco, tree nut crops (e.g., almond, cashew, pecan, walnut), and others. Flubendiamide is used to control lepidopteran pests at the larval and adult stages, including armyworms, bollworms, corn borers, cutworms, fruitworms, hornworms, leaf rollers, loopers, moths, and many others. Flubendiamide may be applied by ground spray, aerial spray and/or chemigation (i.e., application through an irrigation system) depending on the formulation and use pattern.

Q: How does flubendiamide work?

A: Flubendiamide is a member of the diamide class of chemistry. Flubendiamide targets the insect ryanodine receptor binding site, a site of little importance in mammals, and interferes with the calcium release channel.[1] As a result, flubendiamide is selectively toxic to insect pests, but has very low toxicity to humans and other mammals.

Q: What is the focus of your analysis and testimony?

A: On March 1, 2016, EPA announced its intent to cancel the registration of four pesticide products containing the active ingredient flubendiamide.[2] In its Notice of Intent to Cancel (NOIC), EPA explained that it was seeking cancellation based on a determination that continued registration of flubendiamide products "will result in unreasonable adverse effects on the environment."[3] The NOIC and the January 29, 2016 Decision Memorandum cite concerns about flubendiamide's mobility, persistence, and potential to accumulate, and "the extremely toxic nature of the primary degradate NNI-001-des-iodo [des-iodo] to invertebrates of aquatic systems."[4] My analysis is focused on the potential toxicity of flubendiamide and des-iodo to aquatic invertebrates, particularly benthic invertebrates, and whether EPA's assessment of toxicity endpoints is consistent with sound science.

Q: What topics will you cover in your testimony?

A: In the text that follows, I begin with a general overview of how EPA conducted its aquatic invertebrates assessment for flubendiamide and des-iodo. I then proceed with specific comments on the available sediment toxicity studies for benthic invertebrates and EPA's rationale for selecting the effects metrics for their assessment from these studies.

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[1] J.E. Casida, *Golden Age of RyR and GABA-R Diamide and Isoxazoline Insecticides: Common Genesis, Serendipity, Surprises, Selectivity, and Safety*, 28(4) Chem. Res. Toxicology 560-66 (2015).

[2] PBNX 19.

[3] PBNX 20 at 11,559.

[4] *Id.*; *see also* PBNX 30 at 1.

V. EPA'S AQUATIC INVERTEBRATE RISK ASSESSMENTS

A. EPA's Ecological Risk Assessments Have Focused on Potential Risks to Benthic Aquatic Invertebrates.

Q: Please describe the ecological risk assessments that EPA has conducted for flubendiamide.

A: EPA's Environmental Fate and Effects Division (EFED) assessed the ecological risks of flubendiamide and des-iodo in three risk assessments conducted in support of the original flubendiamide registrations in June 2008 and in support of the expansion of the registrations to cover new crops and uses in May 2010 and December 2010.[5] In connection with its January 29, 2016 cancellation determination, EPA issued an ecological risk assessment addendum to address new studies and data that had been received and discussions and evaluations of flubendiamide that had occurred since the December 2010 risk assessment.[6]

Q: In its ecological risk assessments, has EPA identified areas where flubendiamide does not pose any regulatory risks of concern?

A: In its flubendiamide risk assessments, EPA has repeatedly confirmed that there are no direct risks of regulatory concern with respect to mammals, birds, fish, crustaceans, estuarine and marine mollusks, beneficial insects, bee pollinators, and plants.[7]

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[5] PBNX 27 (EFED Risk Assessment for the Section 3 New Chemical Registration of Flubendiamide (June 23, 2008)); PBNX 28 (EFED Risk Assessment for Legume Vegetable and Christmas Tree New Uses for the Insecticide Flubendiamide); PBNX 29 (EFED Ecological Risk Assessment for the New Use of Flubendiamide on Alfalfa and Certain Other Crops).

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

[7] PBNX 27 at PDF p. 2; PBNX 28 at 3-8 (PDF pp. 22-27); PBNX 29 at 38-41.

Q: What risk of concern has EPA identified as the basis for the Agency's flubendiamide cancellation determination?

A: The ecological concern behind EPA's January 29, 2016 cancellation determination and the March 4, 2016 NOIC is the potential for chronic risk to aquatic invertebrates.[8] More specifically, EPA's concern is that flubendiamide and des-iodo would "accumulate in aquatic systems" over time, "eventually exceeding Agency LOCs [levels of concern]" and creating "a potential for risk to benthic invertebrates."[9]

Q: What are benthic aquatic invertebrates?

A: Benthic aquatic invertebrates are a class of small organisms that includes insects, crustaceans, mollusks, and worms that are aquatic (live in water), lack backbones (invertebrate), and live in or on the sediment at the bottom of the water body (benthic), for part or all of their life cycle.

Q: Please describe the framework EPA used for assessing the ecological risks of flubendiamide.

A: In its original three ecological risk assessments, EPA assessed potential risk to aquatic invertebrates with a screening-level (Level 1) risk assessment in which acute and chronic estimated environmental concentrations (EECs) in overlying and benthic pore water and bulk sediment were compared to corresponding effects endpoints (e.g., LC50 [concentration causing 50% mortality] for acute effects, NOEC[10] [No observed effects concentration] for chronic

[8] PBNX 30 at 10; PBNX 20 at 11,559.

[9] PBNX 30 at 3.

[10] In its assessments and data evaluation records, EPA uses the terms "No Observed Effect Concentration" (NOEC) and "No Observed Adverse Effect Concentration" (NOAEC) interchangeably. The two terms have slightly different meanings as a NOEC may also be derived for beneficial effects. To avoid confusion herein, I will use the NOEC nomenclature throughout.

effects) for aquatic invertebrates. This analysis results in a risk quotient (RQ, i.e., Acute RQ = EEC/LC50 and chronic RQ = EEC/NOEC) to quantify the potential risk. EPA compares each risk quotient to the corresponding Level of Concern (LOC, e.g., LOC for acute restricted use for aquatic species = 0.05, LOC for chronic risk to all species = 1). Separate analyses were conducted for flubendiamide and des-iodo.

EPA's January 28, 2016 ecological risk addendum provided in connection with its cancellation determination (PBNX 31) was conducted after the generation of higher-tier, more relevant data, including five years of real-world monitoring data and more environmentally relevant toxicity data.

Q: What is your understanding of EPA's approach to estimating environmental exposures in its latest risk assessment and cancellation determination?

A: As described in Dr. Engel's testimony, EPA's most recent risk assessment addendum fails to properly reflect the higher-tier, real-world monitoring data, and its environmental exposure estimates are based on overly conservative, theoretical modeling that does not accurately reflect or predict real-world exposures.

Q: What is your opinion on the toxicity endpoints EPA relies on to support its cancellation determination?

A: As discussed below, EPA's most recent risk assessment addendum (PBNX 31) and the reasoning EPA provided in support of its cancellation determination (PBNX 30) ignore the results of more relevant toxicity studies. EPA's ecological risk assessment relies on a toxicity endpoint that is far lower than the science supports. For the reasons discussed below, EPA's proposed cancellation of flubendiamide based on the spiked water toxicity endpoint for des-iodo is not supported by the current science.

B. EPA Has Identified No Regulatory Risks of Concern for Aquatic Invertebrates Other Than Potential Chronic Risks to Benthic Invertebrates.

Q: What studies, if any, have been conducted to assess risks to aquatic invertebrates?

A: Acute and chronic toxicity tests involving aquatic invertebrates have been conducted for flubendiamide and des-iodo. Studies were conducted using water-only systems and on systems containing water and sediment.

Q: Please summarize the results of studies conducted using water-only study systems.

A: Testing was conducted on *Daphnia magna*, a small crustacean also known as a water flea, to evaluate the potential impacts on water column dwelling (i.e., non-sediment dwelling) aquatic invertebrates to an acute exposure to flubendiamide and des-iodo and chronic exposure to flubendiamide. These studies all showed no observed adverse effects at concentrations up to their limits of solubility (29.9 µg/L for flubendiamide and 187 µg/L for des-iodo).[11] Similarly, the following sediment dwelling species experienced no adverse effects to flubendiamide exposure concentrations of 30 µg/L (the solubility limit for flubendiamide) or des-iodo concentrations of 200 µg/L (slightly higher than the solubility limit for des-iodo) following acute exposures in water only trials: *Lumbriculus variegatus*, *Hyalella azteca*, *Centroptilum triangulifer*, *Chironomus tentans* and *Chironomus riparius*.[12] Because concentrations of flubendiamide and des-iodo in water in the environment are limited by their solubility, these studies indicate that the tested species could not be at acute risk in the environment as a result of exposure to flubendiamide or des-iodo in the overlying water.

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[11] PBNX 29 at 24.

[12] S. Thomas and H.O. Krueger, Wildlife International, Ltd., Benthic Organism Acute Toxicity Screens for Flubendiamide and NNI-0001 des-iodo, Bayer Study No. EBAMY010 (2010).

Acute and chronic toxicity testing of *D. magna* using formulated products showed risk quotients that exceeded EPA's LOCs for some use patterns.[13] However, as EPA has recognized, chronic exposure is not a concern for the formulated products because the products do not persist in their formulations in the aquatic environment. Acute exposure to formulated products is likewise not a source of significant regulatory concern. As EPA confirmed in the January 29, 2016 Decision Memorandum, "[t]he acute risk issue is relatively minor and refers to enhanced toxicity of the formulations" which is "applicable only to direct application to aquatic environments through spray drift."[14] However, spray drift exposure from flubendiamide is not a significant concern, because "most of the contributions to aquatic environments are from means other than spray drift (runoff and erosion)."[15]

Q: What is the significance of these studies?

A: As *D. magna* is the standard and well vetted surrogate for water column invertebrates in ecotoxicity testing for pesticides, the above indicates that flubendiamide and des-iodo pose no risks to water column dwelling (i.e., non-sediment dwelling) invertebrates. The lack of acute effects on additional species at the solubility limits for flubendiamide and des-iodo further supports the conclusion that these compounds pose no risk to water column invertebrates.

Q: Please describe the studies conducted using water and sediment test systems.

A: Studies of the potential chronic effects of flubendiamide and des-iodo on a benthic aquatic invertebrate (*Chironomus riparius*, a type of midge also known as the harlequin fly) were conducted using methods that included both water and sediment phases in one test system. The first set of studies conducted and submitted to EPA were spiked water studies of flubendiamide

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[13] PBNX 27 at 53-54; PBNX 28 at 42-43; PBNX 29 at 29-30.

[14] PBNX 30 at 3.

[15] PBNX 27 at 68.

and des-iodo, in which the test material is introduced directly into the overlying water and equilibrates between the overlying water, sediment, and sediment pore water during the test. The second set of studies conducted and submitted to EPA were spiked sediment studies, in which the test material is introduced into the sediment and the system is allowed to equilibrate before the study begins.

Q: Why are these studies significant?

A: My analysis focuses on these studies because chronic risks to benthic aquatic invertebrates have been identified by EPA as the only significant ecological risks of concern and are the risks that EPA relies on to justify its cancellation determination.[16] EPA's effects endpoints for benthic aquatic invertebrates are lower for des-iodo than for flubendiamide, and EPA's calculated RQs for des-iodo are higher.

Q: How did EPA use these studies in its ecological risk assessment and cancellation determination?

A: In estimating chronic risk of flubendiamide and des-iodo to sediment dwelling aquatic invertebrates, EPA relied on the results of spiked water studies for the midge, *Chironomus riparius*. For the reasons I will discuss, it is my opinion that EPA's reliance on the results of the spiked water studies to evaluate chronic risk to benthic aquatic invertebrates, rather than the subsequent, more relevant spiked sediment studies, is not scientifically justified. As a result, EPA's risk assessments for flubendiamide and des-iodo are flawed, and provide no reliable scientific basis to conclude that benthic invertebrates are at significant risk from the continued registration and use of flubendiamide products.

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[16] *See, e.g.*, PBNX 30 at 10.

VI. DERIVATION OF BENTHIC AQUATIC ENDPOINTS FROM THE SPIKED WATER AND SPIKED SEDIMENT STUDIES

A. Background

Q: Let's discuss in more detail the chronic sediment studies conducted in support of flubendiamide. Why were studies conducted with des-iodo as well as flubendiamide?

A: Bayer CropScience conducted chronic toxicity testing on the degradation metabolite des-iodo because initial toxicity studies suggested that des-iodo might be more toxic than the parent compound flubendiamide for some receptor groups, e.g., sediment dwelling invertebrates.

Q: What guidelines, if any, are there for conducting the chronic sediment tests?

A: Following a standardized guideline for toxicity testing is important to ensure that the results of the study are accurate and of the highest quality. To date, EPA has not published guidelines for the conduct of chronic sediment testing.[17] The Organisation for Economic Co-operation and Development (OECD) has published guidelines for the conduct of standardized toxicity studies, including chronic sediment studies.[18]

Q: Please describe the chronic sediment tests conducted by Bayer in further detail.

A: Bayer CropScience generated two chronic sediment toxicity studies involving exposure of the midge, *C. riparius*, to des-iodo: one in which overlying water was spiked (hereafter referred to as "the spiked water study"), which was submitted in support of the original registrations,[19] and one in which sediment was spiked (hereafter referred to as "the spiked

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[17] PBNX 44 at 11 (EFED Memorandum re Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates (Apr. 10, 2014)).

[18] OECD Guidelines for the Testing of Chemicals, Section 2, available at http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_chem_guide_pkg-en (last visited Apr. 8, 2016).

[19] Bayer CropScience AG, *Chironomus riparius* 28-Day Chronic Toxicity Test With NNI-001-des-iodo in a Water-Sediment System Using Spiked Water, Report No. DOM 23069 (2004) ("Spiked Water Study Report").

sediment study"), which was conducted and submitted in 2010.[20] Similar studies were submitted for flubendiamide.

The spiked water study followed the OECD guideline for sediment-water chironomid toxicity tests using spiked water.[21] OECD guidelines state that spiked water studies are "intended to simulate a pesticide spray drift event."[22]

The spiked sediment study followed the OECD guideline for sediment-water chironomid toxicity tests using spiked sediment.[23] The OECD guideline document for the spiked sediment study states that such tests are "intended to simulate accumulated levels of chemicals persisting in the sediment."[24]

The spiked water and spiked sediment studies both exposed *C. riparius* individuals from their first instar through emergence and monitored time to emergence and survival of both males and females. Because the chronic RQs are higher for des-iodo compared to the parent compound, and because the des-iodo RQs are driving EPA's cancellation decision, the remainder of this section focuses on des-iodo. Many of the points, however, also apply to the flubendiamide studies.

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[20] S. Thomas et al., Wildlife International, Ltd., [14C]NNI-0001-desiodo: A Prolonged Sediment Toxicity Test With *Chironomus riparius* Using Spiked Sediment, Final Report, Bayer Study No. EBAMY006 (2010) ("Spiked Sediment Study Report").

[21] PBNX 45 (OECD Guidelines, Test No. 219: Sediment-Water Chironomid Toxicity Test Using Spiked Water (Apr. 13, 2004)).

[22] *Id.* at 1.

[23] PBNX 46 (OECD Guidelines, Test No. 218: Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (Apr. 13, 2004)).

[24] *Id.* at 1.

Q: What were the reported results from the des-iodo spiked water study?

A: In the spiked water study for des-iodo, the reported No Observed Effect Concentration (NOEC) for the most sensitive endpoint (percent emergence) was 4 µg/L des-iodo in the overlying water. This value is based on the nominal concentrations of des-iodo added to the overlying water.

Q: Did EPA adopt the 4 µg/L NOEC for des-iodo for the spiked water study?

A: No. EPA chose to use the analytical data from the spiked water study to calculate a time-weighted average (TWA) NOEC for des-iodo in sediment pore water of 0.28 µg/L.[25] The NOEC of 0.28 µg/L for des-iodo in sediment pore water derived from the spiked water study is the most sensitive endpoint for aquatic invertebrates, and EPA's cancellation determination is based on predicted exceedances of this NOEC.

Q: What is your opinion on EPA's calculation of the 0.28 µg/L des-iodo sediment pore water NOEC?

A: The calculation of a TWA NOEC for des-iodo in sediment pore water for a spiked water study is not supported by sound science. As noted by the European Commission, spiked water NOECs should be calculated for overlying water and then compared to estimated concentrations in that compartment.[26] This is because at the outset of the test, concentrations in overlying water vastly exceed the concentrations in pore water and thus any observed toxicity is likely the result of exposure to overlying water. Including the largely irrelevant, very low initial concentrations in sediment pore water in the TWA calculation skews the NOEC downward. Analytical data from the spiked water study may be used to study partitioning behavior over time from overlying

[25] PBNX 33 at 15 (Des-iodo Spiked Water Study Data Evaluation Record (May 21, 2008)).

[26] PBNX 47 at 18 (European Commission, Working Document: Guidance Document on Aquatic Toxicology (Oct. 17, 2002)).

water to sediment and sediment pore water, but it was never intended to derive toxicity endpoints for sediment and pore water.

Q: What were the reported results of the des-iodo spiked sediment study?

A: As noted above, the spiked sediment study was conducted specifically to assess potential toxicity to sediment dwelling invertebrates in sediment pore water due to the potential accumulation of des-iodo residues over time. The reported NOEC for des-iodo in the spiked sediment study based on measured concentrations (consistent with OECD guidance and standard practice) was 22 µg/L of des-iodo in sediment pore water, which was the highest level tested. The actual level at which impacts on benthic invertebrates begin to occur was not determined in the study and could be significantly higher.

Q: Did EPA adopt the 22 µg/L NOEC for des-iodo for the spiked sediment study?

A: No. In reviewing this study, EPA again chose to calculate a TWA endpoint, resulting in a somewhat lower NOEC of 19.5 µg/L of des-iodo in sediment pore water.[27] The difference from this value to the reported result is not as significant as for the spiked water study, because for the spiked sediment study the system is allowed to equilibrate before the study begins.

Notably, the EPA-calculated NOEC of 19.5 µg/L is approximately 70 times higher than the NOEC of 0.28 µg/L EPA derived from the less relevant spiked water study.

Q: What is your opinion on EPA's reliance on the 0.28 µg/L des-iodo sediment pore water endpoint in its risk assessment?

A: The spiked water study has major flaws that should have precluded its use in the des-iodo risk assessment for benthic invertebrates. As discussed in Section B below, the flaws include, most significantly, the use of an exposure route quite different from what would occur in real-

[27] PBNX 34 at 14 (Des-iodo Spiked Sediment Study Data Evaluation Record (July 19, 2011)).

world conditions, resulting in significant overestimation of toxicity and risk. The spiked water study also used inappropriate statistical analyses and laboratory conditions that differ from those specified in OECD guidelines. As discussed below, a more appropriate and scientifically relevant spiked sediment study is available and should have been used in the benthic invertebrates risk assessment for des-iodo.

B. EPA's Reliance on the Pore Water NOEC from the Spiked Water Study Is Not Scientifically Sound.

1. The spiked water study is not the most relevant study to determine potential effects on benthic invertebrates for des-iodo.

Q: Which type of study is considered more relevant to the risk of concern identified by EPA?

A: As noted above, the OECD guideline document for spiked water studies states that such tests are "intended to simulate a pesticide spray drift event," whereas the OECD guideline for spiked sediment studies states that those tests are "intended to simulate accumulated levels of chemicals persisting in the sediment."[28] Because the primary concern identified by EPA is the potential accumulation of flubendiamide and its degradate des-iodo in sediment and sediment pore water, the spiked sediment study is the more relevant and scientifically correct study to measure potential effects to sediment dwelling invertebrates.

EPA previously agreed with this point. For example, in its May 2008 review of the spiked water study, EPA identified as a "Major Guideline Deviation" the fact that "[o]verlying water was spiked," noting that EPA "prefer[s] that the sediment is spiked."[29] As a result, Bayer conducted a study using the preferred and more relevant spiked sediment approach, resulting in a sediment pore water NOEC of 19.5 µg/L (EPA calculated) or 22 µg/L (derived in the study

[28] PBNX 45 at 1; PBNX 46 at 1.

[29] PBNX 33 at 2.

report). However, EPA decided in its final risk assessment addendum supporting the cancellation decision to revert to the superseded and scientifically less sound NOEC of 0.28 µg/L from the spiked water study.

Q: Why is the spiked sediment study more relevant?

A: The greater relevance and reliability of the spiked sediment study is confirmed when one considers the characteristics of flubendiamide and des-iodo and their behavior in the environment. Flubendiamide degrades slowly under laboratory and field conditions.[30] The two major degradation routes, aquatic and soil photolysis and anaerobic aquatic metabolism, could not occur during spray drift. Using the pesticide spray drift route of exposure for des-iodo is inappropriate because flubendiamide cannot degrade to des-iodo during spray drift prior to entering the aquatic environment.

Further, runoff of des-iodo to aquatic systems in large spikes is highly unlikely given the very slow degradation rate from the flubendiamide parent compound to des-iodo in soil. Des-iodo has, in fact, only been detected in minor amounts in the top soil layers in three field dissipation studies.[31] Thus, runoff is likely to contribute small pulses of des-iodo to water bodies over extended periods of time rather than large, short-term spikes. As described in Dr. Engel's testimony, monitoring studies conducted by Bayer CropScience in a Georgia pond demonstrated that des-iodo concentration maxima occurred several months after flubendiamide concentrations peaked. Such a result is a strong indication that des-iodo in the sediment was the

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[30] PBNX 27 at 12 (PDF p. 17); PBNX 28 at 10 (PDF p. 29).

[31] P. Babczinski, Bayer CropScience AG, Outdoor Soil Degradation of 14C-NNI-0001, Study No. M1251280-9 (2004); H. Reiner, Bayer CropScience AG, Metabolism of [phthalic acid ring-UL-14C]NNI-0001 in Confined Rotational Crops, Report MEF-008/03, DOMA Edition No. MO-04-009109 (2004); H. Reiner, Bayer CropScience AG, Metabolism of [aniline ring-UL-14C]NNI-0001 in Confined Rotational Crops, Study No. M 1301192-7 (2004).

result of slow degradation of the parent compound in sediment rather than transport to aquatic systems by spray drift or runoff events shortly after application.

Q: Please summarize your opinions on EPA's use of the spiked water study endpoint instead of the spiked sediment study endpoint.

A: OECD guidance, EPA's own assessments, and sound science dictate that the spiked sediment study is the most relevant and scientifically sound study for measuring potential toxic effects of des-iodo through agricultural runoff and degradation. EPA's reliance on the NOEC of 0.28 µg/L from the spiked water study to justify its cancellation determination is not scientifically sound.

2. <u>The des-iodo pore water endpoint derived from the spiked water study seriously overestimates potential effects on sediment dwelling invertebrates.</u>

Q: What is the practical effect of EPA's use of the spiked water study endpoint?

A: The use of a simulated spray drift event to derive a sediment pore water NOEC for *C. riparius* larvae exposed to des-iodo in pore water seriously overestimates potential toxicity.

Spiking water with a pesticide results in high concentrations in the overlying water immediately following test initiation. The concentrations in overlying water then decline as the compound moves into the sediment compartment. Indeed, measured concentrations in the spiked water study demonstrated highest concentrations of des-iodo in overlying water on Day 0 of the spiked water study followed by a steady decline to roughly one third of initial concentrations by Day 28.[32] Conversely, concentrations in sediment pore water were low initially, followed by a peak on Day 7 and slow decline to Day 28.[33]

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[32] Spiked Water Study Report at 19-20.

[33] *Id.*

This is significant because sediment-water studies evaluate overall toxicity of the system and are not designed to provide toxicity endpoints for each of the overlying water, pore water, and bulk sediment media. The exposure route in sediment-water studies dictates which toxicity endpoint is the most meaningful. In the case of spiked water studies, the exposure route being evaluated is spray drift added to the overlying water. Thus, for this type of study and according to the OECD guidelines, it is the overlying water NOEC that is the most meaningful endpoint. Analytical pore water measurements are useful to help understand the partitioning behavior of pesticides over time from the overlying water to sediment and sediment pore water. However, pore water NOECs in spiked water studies are of little relevance and not based on sound science. Not surprisingly, when overlying water is a much less important route of exposure, as in the spiked sediment study, the sediment pore water NOEC increased at least 70-fold to ≥19.5 µg/L.[34] Previous studies, e.g., Lydy et al. (1990) with carbaryl, parathion and aldicarb,[35] have similarly found much increased toxicity for pesticides introduced via spiked water rather than spiked sediment in sediment bioassays with *C. riparius*.

Q: How does EPA's use of the spiked water study endpoint affect its risk assessment?

A: EPA's reliance on the pore water NOEC derived from the spiked water study significantly overestimates the toxicity of des-iodo by measuring the wrong route of exposure, and results in an endpoint that is not relevant to the exposure that would occur in the real world.

[34] PBNX 34 at 2.

[35] M.J. Lydy et al., *Effects of Sediment and Route of Exposure on the Toxicity and Accumulation of Neutral Lipophilic and Moderately Water Soluble Metabolizable Compounds in the Midge, Chironomus riparius*, *in* 13 Aquatic Toxicology and Risk Assessment 140-64 (W.G. Landis and W.H. van der Schalie eds., 1990).

3. The spiked water study has methodological flaws that further undermine its usefulness and reliability.

Q: Did you reach any other opinions based on your analysis of the spiked water study?

A: Yes. In addition to an inappropriate route of exposure and EPA's use of the wrong medium (i.e., sediment pore water) to calculate the NOEC, the spiked water study contains methodological errors that further undermine the reported toxicity endpoints.

Q: Please describe the methodological errors you noted.

A: First, the statistical analysis reported in the study incorrectly combined data from two sets of controls to increase the statistical power of the study. Two control treatments are necessary when a chemical is poorly soluble in water and must be dissolved in a solvent to reach experimental concentrations. The purpose of the solvent control is to verify that the solvent did not have an additional effect on exposed organisms.[36]

OECD guidelines do not allow combining of data from no-solvent and solvent-control treatments. This type of post hoc data manipulation is unacceptable in statistics, wherein hypotheses must be stated before data are collected.[37] Statistical modifications must be made to the level at which significance is determined when post hoc comparisons are made, due to the increased likelihood of falsely rejecting the null hypothesis. In this case, a Holm-Bonferroni correction should have been applied to the p-value.[38] This correction using the William's multiple sequential t-test (i.e., the test used by the study authors) would have doubled the NOEC for des-iodo in overlying water in the spiked water study to be 8 µg/L, rather than the 4 µg/L NOEC reported in the study.

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[36] PBNX 45 at 4-6.

[37] J.H. Zar, Biostatistical Analysis (5th ed. 2010).

[38] H. Abdi, *Holm's Sequential Bonferroni Procedure*, *in* 2 Encyclopedia of Research Design 573-77 (N. Salkind ed., 2010).

Second, the control treatments, which each had 4 replicates, were combined after statistical comparison with the Student's t-test. OECD guidelines state that a Student's t-test must include at least 6 replicates for each treatment for the test to be valid. With fewer than the recommended number of replicates, statistical power is reduced, thus reducing the likelihood of finding a significant difference between no-solvent and solvent-control treatments.

Third, in the original analyses, the no-solvent and solvent-control results were inappropriately statistically compared to exposure treatment results using William's multiple sequential t-test. This test allows multiple means to be compared to a single value (i.e., the control), but requires that all results trend in a monotonic manner (i.e., magnitude of effect increases as treatment concentration increases).[39] However, the spiked water study with des-iodo did not have a monotonic concentration-response relationship for the most sensitive endpoint (i.e., percent emergence), and therefore using William's test to analyze the data was inappropriate.[40] A more appropriate statistical test for this scenario is Dunnett's test.[41] When the data are analyzed using Dunnett's test, with the control treatments separated, the NOEC for des-iodo in overlying water is 8 µg/L, twice the NOEC in the original analyses.

Fourth, the OECD guidelines provide specific instructions regarding study conditions in sediment toxicity studies, e.g., sediment composition and provision of food to test organisms. The spiked water study had several issues in this regard. For example, the OECD guidelines

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[39] F. Bretz and L.A. Hothorn, *A Powerful Alternative to William's Test With Application to Toxicological Dose-Response Relationships of Normally Distributed Data*, 7(2) Envtl. & Ecological Stat. 135-54 (2000).

[40] *Id.*

[41] PBNX 48 at 37, 42, 58 (OECD, Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application (May 9, 2006)).

specify that the peat in the sediment must have a pH of 5.5-6.0 and be air dried.[42] The spiked water study used peat that had a pH of 2-4, and no mention was made of how the peat was dried. In addition, the OECD guidelines specify provision of 0.25-0.5 mg of fish food/day/chironomid larvae for the first 10 days of the test and 0.5-1 mg of fish food/day/chironomid larvae for days 11 to 28.[43] In the spiked water study, feeding rates were 1 mg of fish food/day/chironomid larvae each day of the study. The impact of the departures from OECD guidelines with regard to sediment pH and feeding rate are unknown, but it is possible that the behavior, bioavailability and toxicity of des-iodo to chironomids may have been affected.

C. <u>The Spiked Sediment Study Is the Correct Study to Gauge Potential Toxic Effects to Benthic Aquatic Invertebrates.</u>

Q: What study should have been used to assess the potential impact of des-iodo on benthic aquatic invertebrates?

A: As discussed above, the OECD guideline for sediment-water chironomid toxicity tests using spiked sediment states that these tests are "intended to simulate accumulated levels of chemicals persisting in the sediment," and EPA previously identified the spiked sediment study as its preferred approach for these purposes as well.[44] The spiked sediment study for des-iodo followed the appropriate exposure regime for des-iodo because the degradate would potentially accumulate slowly over time in the sediment rather than arriving as a pulse in the overlying water from spray drift or runoff events shortly after application. Sediment pore water exposure would cease following adult emergence to the terrestrial environment.

[42] PBNX 45 at 3.

[43] *Id.* at 7.

[44] PBNX 46 at 1; PBNX 33 at 2.

Q: What are the relevant toxicological endpoints from the spiked sediment study?

A: According to EPA, the TWA NOECs for the des-iodo spiked sediment study were 7.18 µg/L in overlying water, and 19.5 µg/L in sediment pore water.[45] The study report, consistent with the OECD reporting guidelines, reports a slightly higher NOEC of 22 µg/L in sediment pore water based on mean, measured concentrations. However, the actual NOECs in the spiked sediment study are likely higher than all of these values because no effects were observed at *any* test concentration for any endpoint including mortality, mean development time, mean emergence ratio or development rate.[46]

Q: Did you note any methodological flaws with respect to the spiked sediment study?

A: The spiked sediment study for des-iodo, like the spiked water study, also pooled the data from blank and solvent controls for the statistical analyses.[47] However, when the proper statistical tests – either a Holm-Bonferroni p-value correction or a Dunnett's test with separate control groups – are used, the results are unchanged, i.e., no statistically significant effects occur with any endpoint for any test concentration. Thus, the time-weighted average NOEC of 19.5 µg/L calculated by EPA for des-iodo in sediment pore water[48] is unaffected.

The spiked sediment study for des-iodo had several minor deviations from the OECD guideline[49]: 1) ground rabbit food was used instead of flaked fish food, 2) the light intensity was 446 lux, which is below the 500 – 1000 lux range specified in the guideline, and 3) the pH of the

[45] PBNX 34 at 2.

[46] Spiked Sediment Study Report at 21.

[47] *Id.* at 16.

[48] PBNX 34 at 2.

[49] PBNX 46 at 6, 9.

peat component was not reported and the moisture content of the sediment was below recommended levels.

Control mortality in the spiked sediment study for des-iodo was less than 30%, and thus acceptable. In addition, the authors observed that unusual chironomid behaviors "were few in number and occurred in the controls as well as the treatment groups . . . [any unusual behaviors observed] were not considered to be treatment-related."[50]

Q: How do these flaws impact the spiked sediment study results?

A: Although the spiked sediment study has minor flaws, the flaws do not detract from the results of the study. This sentiment was echoed in the EPA's reviewer comments, i.e., "there were no significant deviations from OECD Guideline 218 that would affect the scientific soundness of this study."[51] Furthermore, the exposure route in the spiked sediment study, i.e., potential accumulation in sediment pore water as a result of degradation of the parent compound, mirrors the exposure route for benthic invertebrates in aquatic systems near treated areas.

Q: What is the toxicity endpoint EPA calculated based on the spiked sediment study?

A: The time-weighted average NOEC in sediment pore water for *C. riparius* exposed to des-iodo in the spiked sediment study is 19.5 µg/L,[52] which is 70-fold higher than the corresponding NOEC of 0.28 µg/L[53] in the spiked water study. The difference may in fact be greater because no effects were observed in the spiked sediment study and thus the Lowest Observed Effect Concentration (LOEC) is unknown and the NOEC is a lower bound.

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[50] Spiked Sediment Study Report at 20.

[51] PBNX 34 at 19.

[52] *Id.* at 2.

[53] PBNX 33 at 15.

D. EPA's Decision Documents Do Not Justify or Explain the Use of the Endpoint from the Spiked Water Study.

Q: Did EPA provide an explanation for its decision to base its cancellation decision on the spiked water study endpoint?

A: The documents EPA has produced in support of its cancellation decision do not justify or explain in any transparent fashion the Agency's decision to rely on the scientifically incorrect pore water NOEC of 0.28 µg/L for des-iodo to support its cancellation determination.

EFED's January 28, 2016 Ecological Risk Assessment Addendum suggests that the NOEC of 0.28 µg/L was EPA's consistent position, by comparing EPA's current use of that endpoint to the June 2008, May 2010, and December 2010 risk assessments.[54] Yet those assessments were all conducted before EPA completed and released its July 2011 review of the spiked sediment study, which EPA "prefer[s]" and which results in a more scientifically relevant and much higher 19.5 µg/L endpoint.[55]

Although EPA's reversion to the NOEC of 0.28 µg/L in December 2015 was the subject of significant discussion between the registrants and EPA leading up to the January 29, 2016 cancellation determination, the January 28, 2016 EFED Addendum and the January 29, 2016 Decision Memorandum do not mention, let alone provide an explanation for, EPA's decision to regulate flubendiamide based on the superseded spiked water study. Instead, both documents simply present the 19.5 µg/L endpoint from the spiked sediment study as among the "final suite" of available effects toxicity endpoints.[56]

[54] PBNX 31 at 8.

[55] PBNX 33 at 2; PBNX 34 at 2.

[56] PBNX 30 at 5; PBNX 31 at 9.

Only by examining the underlying data and modeling and comparing them to EPA's statements regarding the exceedances is it clear that EPA selected the 0.28 µg/L endpoint as an "Agency LOC" [level of concern] and the basis for its cancellation determination, while rejecting and incorrectly characterizing the 19.5 µg/L endpoint as a "[Bayer/Nichino]-suggested" endpoint with which EPA did not agree.[57] As a former regulator, and as a scientist who has spent years conducting and assessing ecotoxicological risk assessments, I found EPA's lack of discussion of this point striking. Given how critical EPA's choice of endpoint was to its cancellation determination, the Agency's lack of transparency about how and why that endpoint was selected is troubling.

E. <u>EPA Did Not Follow Its Own Guidance in Extrapolating Risk Between Aquatic Compartments.</u>

Q: Have you reviewed the January 29, 2016 Addendum to Clarify Invertebrate Terminology that EPA provided in connection with its cancellation determination?

A: Yes.

Q: Was there a part of that Addendum that struck you as relevant to EPA's selection and use of aquatic invertebrate toxicity endpoints?

A: Yes. In the "Invertebrate Terminology" Addendum, EPA makes the following statement: "As a second policy check, EFED consulted guidance entitled 'Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates' (USEPA 2014), which suggests that endpoints from water-only toxicity tests with invertebrates are important risk evaluation tools to ascertain potential risk to sediment organisms because bioavailability into benthic organisms is largely mediated by dissolved concentrations of the toxicant in sediment pore waters or

[57] PBNX 30 at 7.

overlying water."[58] The Addendum then goes on to state, "It then follows that risk estimates based on water column environmental exposures compared with overlying water expressed endpoints from sediment toxicity tests with invertebrates would have reasonable applicability as a surrogate for risks to aquatic invertebrates existing in the water column because the dissolved water concentration of the toxicant remains the important source of exposure."[59]

Q: What do you understand this to mean?

A: What EPA is stating in a convoluted way is that dissolved pesticide concentrations control toxicity to both sediment dwelling and water column dwelling invertebrates and thus risk can be extrapolated between the two receptor groups.

Q: Does this type of extrapolation make sense for flubendiamide and des-iodo?

A: No, it does not. What the Invertebrate Terminology Addendum fails to note is that EPA's 2014 guidance document states that "pesticides with higher sorption [to sediment] (partitioning) values are expected to result in greater exposure of benthic-dwelling invertebrates compared to pesticides with lower sorption values."[60] Because invertebrates that only occur in the water column (i.e., pelagic invertebrates) are not exposed to sediment, they would have lower exposures than benthic invertebrates for pesticides that readily sorb to sediment particles. Flubendiamide and des-iodo readily bind to sediment.[61] Thus, risks cannot be extrapolated between water column dwelling and sediment dwelling invertebrates because the former have lower exposures than do the latter for pesticides that readily bind to sediment such as flubendiamide and des-iodo.

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[58] PBNX 32 at 2-3.

[59] *Id.* at 3.

[60] PBNX 44 at 4-5.

[61] *See, e.g.*, PBNX 27 at 28.

F. Use of the Spiked Sediment Endpoint Results in No Risks of Concern to Benthic Aquatic Invertebrates.

Q: Do the exposure data indicate any risks of concern based on the 19.5 µg/L sediment pore water endpoint from the spiked sediment study?

A: As described in Dr. Engel's testimony, environmental exposures to des-iodo are properly evaluated using the higher-tier, real-world monitoring data generated by the registrants at EPA's direction. The results after almost five years of monitoring in water bodies near areas with seven years of product use and the analysis of more than 1,000 overlying and pore water samples, all measured concentrations are well below even the NOEC of 0.28 µg/L for des-iodo that EPA wrongly relies on. The highest measured concentration was 0.17 µg/L, measured at a single site, which subsequently declined in later sampling at the same site. Only five pore water samples had concentrations of des-iodo at or above 0.10 µg/L. The 0.17 µg/L maximum concentration is 115 times lower than the scientifically justified NOEC of 19.5 µg/L for des-iodo in pore water from the spiked sediment study.

In short, when the correct NOEC from the spiked sediment study is used, chronic risk to benthic invertebrates from exposure to des-iodo in sediment pore water is far less of a concern than portrayed by EPA in recent documents. Observed concentrations in water bodies close to treated fields after five years of monitoring and seven years of product use do not come close to approaching a properly determined sediment pore water NOEC of 19.5 µg/L.

Q: Do the exposure data show any exceedances of any of the toxicological endpoints identified by EPA or Bayer?

A: No. As shown in Table 3 to Dr. Engel's written testimony, the maximum observed concentrations of flubendiamide and des-iodo in overlying water and sediment pore water are below all of the toxicity endpoints identified by EPA or Bayer.

In light of these results, it is questionable whether further monitoring is even necessary. The observed levels of flubendiamide and des-iodo do not suggest any risks of concern that could provide a scientific basis to justify a cancellation determination.

VII. CONCLUSION

Q: Please summarize your opinions with respect to EPA's use of the 0.28 µg/L des-iodo sediment pore water toxicity endpoint to justify its determination that flubendiamide products pose unreasonable adverse effects and should be cancelled.

A: Based on the above, I conclude that EPA has no scientific basis for using the chronic pore water NOEC of 0.28 µg/L that was derived for des-iodo from the spiked water study. Instead, the chronic NOEC of 19.5 µg/L derived from the spiked sediment study should have been used. When the correct NOEC is used along with the results from the multi-year monitoring studies, chronic risk to benthic invertebrates is not a concern. Thus, EPA has no scientific basis for canceling the flubendiamide registrations.

VIII. EXHIBITS

Q: Dr. Moore, in your testimony you referenced the following exhibits: PBNX 19-20, 27-34, and 43-48. PBNX 19-20, 27-34, and 43-48 were previously produced as attachments to Bayer and Nichino's Motion for Accelerated Decision. Are these exhibits true and correct copies of the documents you referenced?

A: Yes.

Q: Thank you, Dr. Moore.

Bayer and Nichino move to enter PBNX 19-20, 27-34, and 43-48 into evidence.

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

Executed on this 22nd day of April, 2016.

Dwayne R. J. Moore, Ph.D.