EXHIBIT 18

U. S. ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: June 23, 2008
Chemical: Flubendiamide
PC Code: 027602
DP Barcode: 329594, 329613, 329606, 329599

MEMORANDUM

SUBJECT: **Environmental Fate and Effects Division Risk Assessment for the Section 3 New Chemical Registration of Flubendiamide**

TO: Richard Gebken, Risk Manager
Carmen Rodia, Risk Manager Reviewer
Registration Division (7505P)

FROM: Holly Galavotti, Biologist
Robert Miller, Environmental Protection Specialist
Stephen Wente, Biologist
Lewis R Brown, Environmental Biologist
Environmental Risk Branch I
Environmental Fate and Effects Division (7507P)

THROUGH: Nancy Andrews, Branch Chief
Faruque Khan, Senior Scientist
Environmental Risk Branch I
Environmental Fate and Effects Division (7507P)

Please find the attached Environmental Fate and Effects Division's (EFED) environmental risk assessment for the proposed new chemical registration of flubendiamide. The proposed formulations are NNI-0001 480 SC (EPA Reg. 264-XXX) and NNI-0001 24 WG (EPA Reg. 264-XXX). Application of the flubendiamide formulation 480 SC is proposed for corn, cotton, tobacco, grapes, pome fruit, stone fruit, and tree nut crops. 24 WG is proposed for use on cucurbit vegetables, fruiting vegetables, leafy vegetables, and brassica (cole) leafy vegetables. The maximum proposed single foliar application rate is 0.156 lb a.i./A with annual maximum of 0.468 lb a.i./A for use on pome fruit.

A screening-level (Level I) risk assessment suggests that both flubendiamide and its des-iodo degradate will accumulate to concentrations in aquatic environment that will pose risks to freshwater benthic invertebrates. The available mesocosm data does not provide evidence to

refute these conclusions. No degradation pathway was identified for the des-iodo degradate. Flubendiamide's technical product is not acutely toxic at its water solubility limit (29.9 µg/L) to freshwater or estuarine/marine organisms. The formulated products 480 SC and 24 WG do result in direct acute and chronic risk to freshwater invertebrates. Based on the potential direct effects to these taxa, there may be potential indirect effects to species of concern that depend on these taxa as a source of food and pollination. The screening assessment suggests that there is no potential risk to freshwater fish, marine fish and invertebrates, marine crustaceans, marine mollusks, and aquatic plants at the limit of solubility for parent flubendiamide. There is no potential acute risk or reproductive effects to birds and mammals for all of the proposed uses. In addition, there is no potential risk to earthworms, beneficial insects including bees and natural Lepidoptera predators, and terrestrial plants. There is some potential for risk to adult ladybird beetles due to ingestion of food items (aphids and pollen) containing flubendiamide residues. In addition, there is a potential direct risk to non-target Lepidoptera species, including endangered species.

Listed Species

Aquatic and terrestrial invertebrates (non-target Lepidoptera species and beetles) were identified as being of potential concern for direct effects for listed species for the proposed uses (**Table 1**). There is potential for flubendiamide to exert indirect effects upon the listed organisms by, for example, perturbing forage or prey availability, altering pollination and/or dispersal, etc. With additional refinement, such as exploring more detailed use patterns and species biology (*e.g.*, geographic location, specific feeding habits, time of year likely to utilize crop fields), it may be determined that some (or all) listed species may not be affected.

Table 1. Listed species risks associated with direct or indirect effects due to applications of flubendiamide

Listed Taxonomy	Direct Effects	Indirect Effects
Terrestrial and semi-aquatic plants – monocots	No	Yes[a]
Terrestrial and semi-aquatic plants – dicots	No	Yes[a]
Terrestrial invertebrates	Yes[a]	No
Birds (surrogate for terrestrial-phase amphibians and reptiles)	No	Yes [a]
Mammals	No	Yes[a]
Aquatic vascular plants	No	No
Aquatic non-vascular plants [a]	No	No
Freshwater fish (surrogate for aquatic-phase amphibians)	No	Yes[b]
Freshwater Invertebrates	Yes – due to exposure to formulations [b]	Yes[b]
Freshwater Benthic Invertebrates	Yes – due to exposure to both flubendiamide and the des-iodo degradate [c]	Yes[b]
Estuarine/Marine Fish	No	No
Estuarine/Marine Crustaceans	No	No
Estuarine/Marine Mollusks	No	No

[a] Potential risk to non-target insects (Lepidoptera) and adult ladybird beetles due to ingestion of food items (aphids and pollen) containing flubendiamide residues

[b] Acute and Chronic LOC exceeded for daphnids exposed to the formulations

[c] Potential risk to benthic invertebrates exposed to the des-iodo degradate

Key Uncertainties and Information Gaps

The following uncertainties, limitations, and assumptions were identified in this environmental risk assessment:

- The 480 SC and 24 WG proposed labels restrict use per season; however, there are crops, such as brassica leafy vegetables, that often have more that one season in a year. In this risk assessment, RQs are based on one season per year and risk is underestimated for crops that have more than one growing season per year.

- Registrant-submitted toxicity testing shows that both the SC and WG flubendiamide formulations to be more toxic to freshwater invertebrates than the parent compound on an acute and chronic basis. While on the surface, these observed differences in toxicity might constitute a source of uncertainty in risk conclusions, the risk assessment, in accordance with Overview Document methods performs a separate assessment for formulations difting directly to surface waters. Therefore, the risk assessment team is not recommending any further toxicity studies and feels the current assessment methods adequately address this issue.

- Two 28-day chronic toxicity studies indicate that flubendiamide and its des-iodo degradate are toxic to the midge, *Chironomus riparius*, in an overlying-water spiked system. It is evident that there is a potential for direct effects to benthic invertebrates exposed to the parent and degradate. Neither of the two chronic toxicity midge studies followed sediment toxicity guidelines which require the sediment to be spiked as opposed to the overlying water. Regardless of the route of administration in the studies, there were measured pore water concentrations and these combined with available mesocosm data suggest that there is sufficient information to reach a risk conclusion for bethic invertebrates.

- Data gaps in the environmental fate database for flubendiamide and NNI-0001-des-iodo exist. In order to refine the ecological risk assessment for flubendiamide and NNI-0001-des-iodo, EFED recommends submitting the following guideline and non-guideline studies:

  Flubendiamide

  (Non-guideline) **Small-scale Runoff/Vegetative buffer strip Study** – The runoff study is requested to determine the magnitude of the parent, flubendiamide, retained in buffer strips of various widths. EFED believes that the efficacy of buffers for flubendiamide use are uncertain. It appears that a program of monitoring receiving waters and storm water conveyances under varying conditions of use would greatly benefit any evaluation of potential utility of buffers to reduce flubendiamide loadings to receiving waters. Additionally, EFED has provided the registrant with a description of a framework for an acceptable runoff monitoring protocol as well as comments on proposed monitoring protocols (Memorandum from Sidney Abel, 5/15/01; Memorandum from Hetrick, Odenkirchen, Evans, and Abel, 5/6/02 (D282366 and D281864).

Des-iodo Degradate

(161-1) **Hydrolysis** – The hydrolysis study is requested to establish the significance of chemical hydrolysis as a route of degradation for NNI-0001-des-iodo and to identify, if possible, the hydrolytic products formed which may adversely affect non-target organisms.

(161-2) **Photodegradation in Water** – Pesticides introduced into aqueous systems in the environment can undergo photolytic transformation by sunlight. Data on rates of photolysis are needed to establish the importance of this transformation process and the persistence characteristics of the photoproducts formed.

162-3) **Anaerobic Aquatic Metabolism** – The anaerobic aquatic metabolism is needed to assess the effects the nature and extent of formation of NNI-0001-des-iodo residues in water and in hydrosoil since anaerobic conditions are more likely to exist in aquatic environments.

(162-4) **Aerobic Aquatic Metabolism** – The requested study is needed to determine the effects on NNI-0001-des-iodo to aerobic conditions in water and sediments during the period of dispersal of NNI-0001-des-iodo throughout the aquatic environment and to compare rates and formation of metabolites. The data from this study would provide the aerobic aquatic input parameter for PRZM/EXAMS reducing modeling uncertainty.

(164-1) **Terrestrial Field Dissipation Studies** – NNI-0001-des-iodo is persistent and moderately mobile which increases the likelihood for run-off and leaching. No definitive studies on the field dissipation and degradation properties of the major degradate have been submitted to the Agency.

Labeling Recommendations

According to the Label Review Manual, the following label statements are recommended:

Environmental Hazards

This pesticide is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Surface Water and Ground Water Advisory

Flubendiamide and its degradate NNI-0001-des-iodo have properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow.

Flubendiamide and its degradate may also impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. These chemicals are classified as having a medium potential for reaching both surface water and aquatic sediment via runoff several months or more after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of flubendiamide and its degradate NNI-0001-des-iodo from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

EXHIBIT 19

From: Dana Sargent
Sent: Wednesday, December 16, 2015 10:35 PM
To: jones.jim@epa.gov
Cc: Housenger.jack@Epa.gov; 'Lewis, Susan'
Subject: Flubendiamide

Dear Mr. Jones:

I would like to confirm that you are aware of a new development that warrants your attention. In communications today with OPP, as follow up to our meeting with you yesterday, and our subsequent proposed label mitigation, we were informed that EFED used a new ecotoxicity endpoint in the risk assessments it presented to you today. It is our understanding that EPA is using this new endpoint as the basis for determining the acceptability of our proposed label mitigation and to inform your pending decision about extending the registration of flubendiamide. Given the importance of this endpoint and resulting modeling scenarios to our ongoing conversations, we have asked that OPP promptly provide a copy of the EFED summary and modeling scenarios (including any changes to underlying assumptions).

The timing of the notification of this change, at such a critical point in the registration process, lacks appropriate transparency at a minimum. This benthic organism endpoint was the basis of our many meetings and discussions thus far. It was the foundation for all the risk analyses Bayer prepared and EPA reviewed and discussed with Bayer. EPA never told Bayer that it was changing the endpoint or even that EPA was reevaluating the endpoint. Even in yesterday's meeting with you and the CEO's of both Bayer CropScience and Nichino America, EPA failed to inform us of this critical change. This lack of clarity and disclosure undercuts the integrity of our prolonged scientific discussions and renders them useless.

In our conversations today, OPP proposed to meet with us as early as next week. It is important that we understand the relationship of that meeting and its relevance to our ongoing discussions, as well as its impact, if any, on your decision and its timing.

Freundliche Grüße / Best regards,

Dana Sargent
VP, NA Regulatory Affairs

Bayer CropScience

Science For A Better Life

Bayer CropScience LLP
2 T.W. Alexander Drive
Research Triangle Park
Tel: +1 919 549 5323
Mobile: +1 919 949 0695
Fax: +1 919 549 2514
E-mail: dana.sargent@bayer.com
Web: http://www.bayercropscience.com

EXHIBIT 20

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Friday, December 18, 2015

Mrs. Nancy Delaney
Regulatory Manager
Authorized Agent for Nichino America, Inc.
c/o Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Subject: **Corrected Extension of Registration Expiration Date for Flubendiamide**
BELT™ SC Insecticide, EPA Reg. No. 264-1025
SYNAPSE™ WG Insecticide, EPA Reg. No. 264-1026
FLUBENDIAMIDE Technical, EPA Reg. No. 71711-26
VETICA® Insecticide, EPA Reg. No. 71711-32
TOURISMO® Insecticide, EPA Reg. No. 71711-33

Dear Mrs. Delaney:

Bayer CropScience LP (BCS), on its behalf and as an agent for Nichino America, Inc., submitted a request to the U.S. Environmental Protection Agency (EPA) on December 16, 2015, requesting an extension of certain time-limited registrations to include a new expiration date of January 8, 2016. These products are currently time-limited conditional registrations under Section 3(c)(7) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) with an expiration date of December 18, 2015.

In response to the BCS' request, and to accommodate the necessary time needed for discussions regarding the registrations, EPA is extending the expiration date of December 18, 2015 to January 15, 2016. All of the original conditions of registration for these flubendiamide products as outlined in the preliminary acceptance letter for flubendiamide dated July 31, 2008 (copy attached) are still in effect.

Yesterday I sent you a letter extending the flubendiamide registrations, but there were a few errors in that letter. In that letter we extended the expiration dates for the following registrations: EPA Reg. No 264-1025; EPA Reg. No 264-1026; EPA Reg. No 264-1107; EPA Reg. No 71711-26; EPA Reg. No 71711-32; EPA Reg. No 71711-33. It has come to our attention that Bayer submitted a request for Voluntary Cancellation under FIFRA section 6(f) for the Synapse WG Insecticide, EPA Reg. No. 264-1026 on December 12, 2014. Because EPA has not acted on that request, we will extend the expiration date to January 15, 2016 for EPA Reg. No. 264-1026 along with all the other flubendiamide registrations listed above. It is also our understanding that Synapse 480 Insecticide EPA Reg. No. 264-1107 expired on January 6, 2015 and that Bayer is not currently marketing this product. We will follow up with a cancellation order for EPA Reg. No 264-1107 in the near future.

If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov* or Mr. Richard J. Gebken by phone at (703) 305-6701 or via e-mail at *Gebken.Richard@epa.gov*.

Sincerely,

Richard Gebken
Product Manager 10
Invertebrate & Vertebrate Branch 2
Office of Pesticide Programs

Attachments: *Copy of Preliminary Acceptance Letter for Flubendiamide, dated July 31, 2008*
Copy of BCS Request for Extension of Registration Expiration Date for Flubendiamide, dated December 16, 2015

cc: *Ms. Lydia Cox, Nichino America, Inc.*

000264-01025 BELT™ SC Insecticide
000264-01026 SYNAPSE™ WG Insecticide
071711-00026 FLUBENDIAMIDE Technical
071711-00032 VETICA® Insecticide
071711-00033 TOURISMO® Insecticide

EXHIBIT 21

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Friday, January 29, 2016

Ms. Nancy Delaney, Regulatory Manager
Authorized Agent for Nichino America, Inc.
c/o Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

SUBJECT: **Flubendiamide**
BELT™ SC Insecticide, EPA Reg. No. 264-1025
SYNAPSE™ WG Insecticide, EPA Reg. No. 264-1026
FLUBENDIAMIDE Technical, EPA Reg. No. 71711-26
VETICA® Insecticide, EPA Reg. No. 71711-32
TOURISMO® Insecticide, EPA Reg. No. 71711-33

Dear Ms. Delaney:

Bayer CropScience LP, on its behalf and as an agent for Nichino America, Inc., hereafter jointly identified as BCS/NAI, was granted a time-limited/conditional registration under section 3(c)(7) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for flubendiamide on August 1, 2008, with an original registration expiration date of July 31, 2013. The expiration date was included in the registration in large part because of EPA's initial concerns regarding flubendiamide's mobility, stability/persistence, accumulation in soils, water columns and sediments, and the extremely toxic nature of the primary degradate NNI-001-des-iodo (des-iodo) to invertebrates of aquatic systems. As a condition of registration as established in the preliminary acceptance letter (PAL) for flubendiamide, dated July 31, 2008 (copy attached), if the Agency were to make a determination that further registration of the flubendiamide technical and end-use products would result in unreasonable adverse effects to the environment, within (1) week of notification of this finding, BCS/NAI will submit a request for the voluntary cancellation of the flubendiamide technical and all end-use products.

BCS/NAI's original release for shipment of the flubendiamide products constituted acceptance of the conditions of registration as outlined in the PAL. As stated in the notices of registration for each flubendiamide product, if the conditions of registration are not complied with, the registration for all flubendiamide products would be subject to cancellation in accordance with section 6(e) of FIFRA. In addition, as part of these conditions of registration, BCS/NAI agreed to generate and submit a vegetative buffer strip and water monitoring studies. These two studies were submitted to the Agency and have been reviewed.

A series of meetings between EPA scientists and BCS/NAI scientists have occurred since March 2015, where the Agency and BCS/NAI have continued to engage in dialogue about the referenced conditional data, various label mitigation proposals, and all the Agency's conclusions regarding the same. EPA has not altered its original conclusion that flubendiamide and its des-iodo degradate are mobile, stable/persistent, accumulate in soils, water columns and sediments and are toxic to aquatic invertebrates. In fact, EPA's most recent analysis suggests that the continued use of flubendiamide is expected to have significant negative impact on invertebrates of aquatic systems, which could lead to negative impacts on other taxa as well. For a complete Agency regulatory conclusion, please refer to

the following attached document: "*EPA Recommendation to Cancel All Currently Registered Flubendiamide Products.*"

The benefits of flubendiamide are that it plays a role in integrated pest management and insecticide resistance management based upon the following characteristics: (1) specificity to Lepidopteran larvae; (2) non-systemic but translaminar properties; and (3) no to low impacts on beneficial arthropods. Overall, EPA concludes that there are efficacious alternatives for flubendiamide. For a complete Agency benefits conclusion, please refer to the following attached document: "*Review of Bayer CropScience Benefits Document Supporting the Continued Registration of Flubendiamide (Belt SC) and BCS White Paper.*"

The Agency has made a determination that the continued use of the currently registered flubendiamide products will result in unreasonable adverse effects on the environment. These conclusions are contained within the attached documents: "*Flubendiamide: Ecological Risk Assessment Addendum Summarizing All Submissions and Discussions to Date*" and "*EPA Recommendation to Cancel All Currently Registered Flubendiamide Products.*"

BCS/NAI understood and agreed by signing the PAL that if, after review of the referenced conditional data, EPA makes a determination of unreasonable adverse effects on the environment, that BCS/NAI would within one (1) week of notification of this finding submit a request for voluntary cancellation of all the flubendiamide registrations. We are hereby notifying you that we have made such a finding and under the terms of the time-limited/conditional registration, you are obligated to submit an appropriate request for voluntary cancellation to EPA by or before Friday, February 5, 2016. This request for voluntary cancellation must include a statement that BCS/NAI recognizes and agrees that the cancellation request is irrevocable. Failure to submit a timely voluntary cancellation request will result in the Agency initiating cancellation of all currently registered flubendiamide products under section 6(e) of FIFRA.

If you have any questions about anything contained in this letter, please contact either Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov* or Mr. Richard J. Gebken by phone at (703) 305-6701 or via e-mail at *Gebken.Richard@epa.gov*. If there are any legal concerns, you may contact the Office of General Counsel's Ariadne Goerke by phone at (202) 564-5471 or via e-mail at *Goerke.Ariadne@epa.gov*.

Sincerely yours,

Jack E. Housenger, Director
Office of Pesticide Programs

Attachments: *Copy of Preliminary Acceptance Letter for Flubendiamide, dated July 31, 2008*
Copy of Decision Memorandum "EPA Recommendation to Cancel All Currently Registered Flubendiamide Products," dated January 29, 2016
Copy of BEAD "Review of Bayer CropScience Benefits Document Supporting the Continued Registration of Flubendiamide (Belt SC) and BCS White Paper," dated July 24, 2015
Copy of EFED Memorandum "Flubendiamide: Ecological Risk Assessment Addendum Summarizing All Submissions and Discussions to Date," dated January 28, 2016
Copy of EFED "Addendum to Clarify Invertebrate Terminology in January 28,2016 Ecological Risk Assessment Addendum Summarizing all Submissions and Discussions to Date" dated January 29, 2016

cc: *Ms. Lydia Cox, Nichino America, Inc.*

EXHIBIT 22

Jack E. Housenger, Director
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Date: 2016 February 5
Bayer CropScience LP
2 T.W. Alexander Drive
P. O. Box 12014
RTP, NC 27709

Subject: Response to Request to Submit Voluntary Cancellation Requests for Flubendiamide Technical Registration and Associated End Use Products:
Flubendiamide Technical, EPA Reg. No. 71711-26
Belt SC Insecticide, EPA Reg. No. 264-1025
Synapse WG Insecticide, EPA Reg. No. 264-1026
Vetica Insecticide, EPA Reg. No. 71711-32
Tourismo Insecticide, EPA Reg. No. 71711-33

Dear Mr. Housenger:

Bayer CropScience LP (Bayer), on its behalf and as regulatory agent for Nichino America, Inc. (Nichino), provides the following response to the January 29, 2016 letter from Director Housenger requesting Bayer and Nichino to submit requests to voluntarily cancel all registrations issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for products containing flubendiamide, as identified above.

As noted in Bayer's December 21, 2015 letter to EPA, Bayer stopped using the Synapse WG Insecticide (EPA Reg. No. 264-1026) registration in 2012 and submitted a voluntary cancellation request for that registration by letter dated December 12, 2014. Bayer stands by its cancellation request for Synapse WG Insecticide, which has been pending for more than a year, and does not plan to resubmit a cancellation request for that registration. For the reasons stated below, Bayer and Nichino decline to issue voluntary cancellation requests for the remaining flubendiamide registrations.

First, EPA's demand that Bayer and Nichino issue immediate, forced "voluntary" cancellation requests for the flubendiamide registrations in response to EPA's just-issued, January 29, 2016 Recommendation to Cancel All Currently Registered Flubendiamide Products is unlawful. In making this demand, EPA relies on an unlawful condition of registration that EPA devised in an effort to bypass required statutory cancellation proceedings, deny Bayer and Nichino due process rights in their registrations granted by Congress, and shield EPA's future scientific and regulatory determinations from required interagency and scientific peer review. In granting the first flubendiamide registrations on August 1, 2008, EPA determined, as required under FIFRA Section 3(c)(7)(C), that conditional registration of flubendiamide would not cause "any unreasonable adverse effect on the environment" and served the public interest given flubendiamide's many benefits and its excellent human health and environmental safety profile. In the eight years since, EPA has expanded flubendiamide registrations to approximately 200 crops, each time applying the FIFRA registration standard. Yet EPA refused in 2008 to issue the flubendiamide

registrations without an unlawful condition purporting to require Bayer and Nichino to "voluntarily" cancel their registrations if at some future point EPA changed its mind and concluded that the registrations posed unreasonable adverse effects. EPA cannot grant itself the right to bypass required cancellation proceedings and deny registrants the due process rights they possess by statute.

Second, if EPA has now determined that further registration of flubendiamide will cause unreasonable adverse effects and wishes to cancel the registrations, EPA must initiate the normal cancellation process under FIFRA Section 6(b). The full Section 6(b) cancellation process requires EPA, among other things, to submit its findings for interagency and scientific peer review before initiating cancellation proceedings, and to provide registrants and other interested stakeholders the right to contest the substance of EPA's findings in an administrative hearing. Congress imposed these requirements to ensure that the benefits of the product to the agricultural community and the potential agricultural and commercial harms cancellation could cause are fully considered, and that the scientific grounds for the proposed cancellation are subject to and can withstand independent scientific peer review before a cancellation order issues. EPA, apparently concerned that its determinations would not withstand this required scrutiny, seeks to bypass the Section 6(b) cancellation process by demanding that Bayer and Nichino "voluntarily" cancel the registrations, and by threatening to seek cancellation under the streamlined Section 6(e) process if Bayer and Nichino do not comply with the unlawful cancellation demand. Bayer and Nichino decline to request that their registrations be cancelled and will challenge any effort by EPA to cancel the registrations without the required Section 6(b) process.

Third, and most significantly, Bayer and Nichino do not agree that continued registration of flubendiamide poses unreasonable adverse effects on the environment. EPA's concerns are focused solely on the possibility that flubendiamide and a metabolite might accumulate in ponds and water systems to levels that may be toxic to aquatic invertebrates that dwell in sediment. In July 2013, EPA confirmed that Bayer had submitted all data required in support of the original conditions of registration as of July 2012, and granted the first of several extensions of the registrations to allow for EPA's further review and discussion of the submitted data. In addition, during 2015, Bayer and EPA engaged in scientific exchanges, which included Bayer submitting pertinent new data and information, including an aqueous photolysis study showing the first identified degradation pathway for the des-iodo metabolite of flubendiamide, flubendiamide benefits information requested by EPA, and detailed responses and scientific critiques of EPA's assumptions on the accumulation of flubendiamide and the des-iodo metabolite. In meetings and discussions from July through November 2015, EPA identified a list of additional data that could be useful to address any remaining uncertainty regarding potential accumulation and indicated that it planned to extend the registration for three years while Bayer generated the additional data.

However, in early December, EPA abruptly shifted course and expressed its intent to discount the real world monitoring data, conducted as EPA directed and required, and to rely on overly conservative and unrealistic theoretical modeling to argue that flubendiamide is accumulating in the environment at or beyond levels of concern. This approach culminated in EPA's issuance of the January 29, 2016 Recommendation that all flubendiamide registrations should be cancelled.

To support its finding, EPA suddenly shifted back to a toxicity endpoint that is 70 times lower than the endpoint that had been the basis of EPA's and Bayer's 2015 scientific and regulatory analyses and discussions. According to EPA's guidance, the appropriate study to evaluate potential toxicity to sediment dwelling organisms is a spiked sediment study. Bayer conducted and submitted the appropriate spiked sediment study. Yet EPA is now ignoring that study in favor of a less appropriate study with a different endpoint. Notably, after seven years of flubendiamide use and monitoring, not one of the water monitoring samples that EPA required and that was collected has met or exceeded even this lower endpoint.

EPA also relies on theoretical modeling that is based on highly unrealistic assumptions – including a farm pond model that assumes 30 years of substantial agricultural runoff carrying flubendiamide residues into the pond without any outflows. In fact, the real world monitoring data that Bayer collected as required and as directed by EPA, as well as substantial real world data gathered by the United States Geological Survey (USGS), also at the request of EPA, show that when flubendiamide and its metabolite are found, it is in minute quantities well below levels of concern.

Moreover, although the unreasonable adverse effects registration standard requires consideration of benefits as well as risks, EPA downplays or ignores the significant benefits flubendiamide provides compared to alternatives, including its excellent safety profile and its targeted control. EPA has repeatedly concluded that use of flubendiamide raises no human health or safety concerns, and EPA has identified no environmental concerns with respect to fish, birds, mammals, crustaceans, mollusks, beneficial insects, and plants. Flubendiamide provides highly effective and selective control of lepidopteran insects (caterpillar pests and worms), is compatible with Integrated Pest Management (IPM) techniques that focus on natural predation and minimization of impact to beneficial insects, and provides an alternative mode of action that is important to resistance management efforts. The scientific and regulatory record strongly supports the continued registration of flubendiamide. Removal of this important tool will have negative impacts on growers, the nation's food supply, and the environment.

For all these reasons, Bayer and Nichino decline EPA's request to voluntarily cancel all flubendiamide registrations. We remain available to address the science in a transparent and methodical way, consistent with the FIFRA registration standard and process. If this is done as Congress envisioned, the products should remain registered.

Sincerely,

Dana Sargent
Vice President of North American Regulatory Affairs
Bayer CropScience LP

cc: Susan Lewis, Division Director, Registration Division (RD)
Lydia Cox, Director, Regulatory Affairs, Nichino America

EXHIBIT 23

DATA EVALUATION RECORD
FRESHWATER SEDIMENT *Chironomus riparius* EMERGENCE TEST

1. **CHEMICAL:** Flubendiamide PC Code: 027602

2. **TEST MATERIAL:** [^{14}C]Flubendiamide-desiodo Purity: 99%

3. **CITATION:**

Authors: Thomas, S., *et al.*
Title: [^{14}C]NNI-0001-desiodo: **A** Prolonged Sediment Toxicity Test with *Chironomus riparius* Using Spiked Sediment.
Study Completion Date: July 28, 2010
Laboratory: Wildlife International Ltd.
8598 Commerce Drive
Easton, MD 21601
Sponsor: Bayer CropScience
P.O. Box 12014, 2T.W. Alexander Drive
Research Triangle Park, NC 27709
Laboratory Report ID: 149A-235
MRID No.: 48175605

4. **REVIEWED BY:** Christie E. Padova, Staff Scientist, Dynamac Corporation

Signature: Christie E. Padova **Date:** 01/31/11

APPROVED BY: Teri S. Myers, Senior Scientist, Cambridge Environmental Inc.

Signature: Teri S Myers **Date:** 02/16/11

5. **APPROVED BY:** Robin Sternberg, EPA

Signature: Robin Sternberg **Date:** 7/19/11

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Chironomus riparius*
Age of Test Organism: 1st instar larvae, 1 to 4 days post-hatch
Definitive Test Duration: 28 days
Study Method: Static, with aeration
Type of Concentrations: TWA sediment, pore water, and overlying water

7. CONCLUSIONS:

Results Synopsis:

Time-Weighted Average (TWA) Sediment Concentrations:
28-day LC_{50}: >52.6 µg TRR/kg
28-day NOAEC: 52.6 µg TRR/kg
28-day LOAEC: >52.6 µg TRR/kg

Time-Weighted Average (TWA) Pore Water Concentrations:
28-day LC_{50}: >19.5 µg TRR/L
28-day NOAEC: 19.5 µg TRR/L
28-day LOAEC: >19.5 µg TRR/L

Time-Weighted Average (TWA) Overlying Water Concentrations:
28-day LC_{50}: >7.18 µg TRR/L
28-day NOAEC: 7.18 µg TRR/L
28-day LOAEC: >7.18 µg TRR/L

Assessment endpoints: percent emergence (survival), emergence ratio, development rate, and development time
Most sensitive endpoints: none

8. ADEQUACY OF THE STUDY:

A. Classification: Supplemental

B. Rationale: This study was conducted according to OECD Guideline 218: *Sediment-Water Chironomid Toxicity Test Using Spiked Sediment* (April 2004), and does not fulfill any current U.S. EPA data requirement.

C. Reparability: N/A

9. MAJOR GUIDELINE DEVIATIONS (from OECD Guideline 218):

It was not reported if aeration of the overlying water was stopped for a 24-hour period during and immediately following the insertion of the larvae.

10. SUBMISSION PURPOSE: RS Non-PRIA 575 data

11. MATERIALS AND METHODS

Stability of Compound Under Test Conditions: The stability of flubendiamide-desiodo was not specifically assessed. However, overlying water, pore water, and sediment samples were analyzed for total radioactive residues (TRR) of the test substance using LSC analyses on Days 0, 7, and 28. In general, the concentrations of TRR were variable but showed an overall decrease in sediment, while concentrations of TRR decreased in pore water and increased in overlying water. The majority of radioactivity remained associated with the sediment.

In the treated sediment, recoveries of TRR ranged from 55.2 to 71.3% of nominal concentrations at 0 Days, 40.5 to 83.2% of nominal at 7 Days, and 43.4 to 57.7% of nominal at 28 Days. In overlying water samples, concentrations of TRR increased 71 to 146% of initial measured levels from Days 0 to 28 at all levels (reviewer-calculated). In pore water, concentrations of TRR decreased 43 to 52% of initial measured levels from Days 0 to 28 at all levels. For all matrices, time-weighted averaged (TWA) concentrations were reviewer-calculated (using Excel software; copy provided in Appendix II).

Mass balance approximations were provided by the study authors. The TRR recovered ranged from 71.7 to 112% of the applied for all levels and intervals.

Physicochemical properties of flubendiamide-desiodo.

Parameter	Values	Comments
Water solubility at 20°C	Not reported	
Vapor pressure	Not reported	
UV adsorption	Not reported	
pKa	Not reported	
Kow	Not reported	

OECD requires water solubility, stability in water and light, pK_a, P_{ow}, and vapor pressure of the test compound.

A. Test Organisms/Acclimation

Guideline Criteria	Reported Information
Species *Chironomus riparius*	*Chironomus riparius*, identity verified by supplier
Source	Egg masses were supplied by Environmental Consulting and Testing, Superior, Wisconsin
Culture Conditions A reproduction and oviposit chamber should consist of an adult area, sufficiently large to allow swarming (minimum 30 x 30 x 30 cm), and an oviposit area. Crystallizing dishes or larger containers with a thin layer of quartz sand (5 to 10 mm) or Kieselgur (thin layer to a few mm) spread over the bottom and containing suitable water to a depth of several cm are suitable as an oviposit area. Environmental conditions: temperature 20±2°C; 16:8 hours light:dark (intensity ca. 1000 lux); air humidity ca. 60%	N/A
Egg Mass Acclimation Period Four to five days before test initiation freshly laid egg masses should be taken from cultures and maintained separately in culture medium, temperature change should not exceed 2°C per day.	The organisms were held for 5 days prior to the start of the test at approximately the same temperature used during testing and in water from the same source as used during testing. During the 5-day holding period preceding the test, water temperatures ranged from 19.9 to 20.4°C, the pH ranged from 8.3 to 8.5, and the dissolved oxygen ranged from 7.8 to 8.9 mg/L (≥86% saturation).
Age of Test Larvae First instar (1 to 4 days post-hatch with confirmation)	1st instar, 1 to 4 days post-hatch The hatched midges from at least three separate egg masses were used to initiate the test.

Guideline Criteria	Reported Information
Food Green algae (e.g., *Scenedesmus subspicatus, Chlorella vulgaris*) or flaked fish food as a ground powder, suspension, or filtrate	Ground Hartz® pet rabbit food
Health of parent culture stock Were parent chironomids in good health during the culture period?	N/A

B. Test System

Guideline Criteria	Reported Information
Type of Test System Static (static-renewal or flow-through of overlying water is evaluated on a chemical-specific basis). Distilled or deionized water may be added to overlying water once daily as needed to maintain volume.	Static with aeration. Additional vessels were prepared at each level for analytical sampling; thus, the method for analytical sampling did not affect volume, biological load, or test concentration.
Test Material	Identity: [^{14}C]flubendiamide-desiodo Batch No.: Not reported Description: solid Radiochemical purity: 99% Specific activity: 79.26 mCi/mmol Label position: uniformly on the phthalic acid ring Storage: frozen conditions

Guideline Criteria	Reported Information
Test Water Soft reconstituted water or water from a natural source is preferred. Dechlorinated tap water may be used if the test organism will survive in it for the duration of the culturing and testing without showing signs of stress.	Moderately-hard freshwater obtained from an on-site well *ca.* 40-m deep was sand-filtered, aerated, and filtered again (0.45 µm) and UV-sterilized prior to use. During the 4-week period immediately preceding the study, the specific conductance of the well water ranged from 338 to 366 µS/cm, the hardness ranged from 140 to 144 mg/L as $CaCO_3$, the alkalinity ranged from 180 to 182 mg/L as $CaCO_3$, and the pH ranged from 8.1 to 8.2.
Test Sediment Formulated (reconstituted, artificial, or synthetic) sediment is recommended. Content of sediment by dry weight: 5% peat (dry) (pH 5.5-6.0) or alpha-cellulose, 75% quartz sand (>50% in size range of 50-200 microns), 20% kaolinite clay (kaolinite content ca. 30%), $CaCO_3$ 0.05-0.1%). Moisture content 30-50%, TOC 2% (±0.5%) and pH 6.5 - 7.5. Natural sediment can be used if it is fully characterized, unpolluted, and free of organisms that might compete with or consume chironomids. (If solvent other than water will be used, sand content of artificial sediment is adjusted accordingly.)	Formulated (artificial) sediment consisted of 75% industrial quartz sand, 20% kaolin clay, and 5% sphagnum peat moss. The dry ingredients were mixed in a PK Twinshell® mixer for 40 minutes and stored under ambient conditions until use. The amount of peat added to the batch sediment was adjusted for the moisture content in the peat suspension (70%). The laboratory-determined pH of the sediment was 7.2. The soil was characterized by Agvise Laboratories (Northwood, ND). The following characteristics were provided: Composition: 77% sand, 9% silt, and 14% clay USDA textural class: sandy loam Bulk density: 1.24 g/cm^3 CEC: 9.3 meq/100 g Moisture at 1/3 bar: 11.5% Organic carbon: 1.9% Organic matter: 3.2% pH (1:1 soil:water ratio): 7.5

Guideline Criteria	Reported Information
Sediment Spiking	A 0.140 mg/mL primary stock solution was prepared by dissolving the radio-labeled test material in acetone. Secondary stocks (10.0, 5.00, 2.50, 1.30, 0.63, and 0.31 µg/mL) were prepared by proportional dilution and mixed by inversion. The primary and secondary stock solutions appeared clear and colorless. A 15-mL aliquot of the appropriate stock solution was added to 150 g of formulated sediment and mixed by hand, and the acetone was allowed to partially evaporate. The 150-g premix was added to 600 g of untreated sediment and mixed for an unspecified period of time, and then 750 g of untreated sediment was added and the final batches (1500 g final weight) mixed using a rotary mixer for *ca.* 40 hours. Batches of negative and solvent control sediment were also prepared. No adjustments were made for the purity of the test material.
Sediment Conditioning Artificial sediment: 7 days in flowing dilution water prior to test initiation, chambers may be aerated	Test systems (spiked-sediment:overlying water) were prepared and acclimated for *ca.* 50 hours prior to the introduction of the test organisms. The systems were gently aerated and maintained in an environmental chamber.
Introduction of Test Organisms Twenty-four hours prior to test initiation aeration of chambers is stopped and organisms are added to the chambers. Aeration should not resume for at least 24 hours. At test initiation, the test substance is spiked into the overlying water column.	At test initiation, midge larvae were impartially added one and two at a time to the test chambers. It was not reported if aeration was discontinued during and 24 hour immediately following the insertion of larvae.

Guideline Criteria	Reported Information
Solvents If used, minimal (i.e., ≤0.1 ml/l) and same concentration in all treatments. Suitable solvents are acetone, ethanol, methanol, elthylene glycol monoethyl ether, ethylene glycol dimethyl ether, dimethylformamide or triethylene glycol. (OECD guidelines also allows use of dispersants: Cremophor RH40, Tween 80, methycellulose 0.01%, and HCO-40)	Acetone, 15 mL/1500 g sediment The reviewer-calculated maximum possible concentration of acetone in the sediment (assuming no evaporation occurred) was equivalent to 0.8% (where ρ of acetone = 0.79 g/mL).
Water Temperature 20°C ± 2°C (Should not deviate between vessels by more than 1°C.)	Daily: 19.8 to 20.8°C Continuous: 19 to 20°C
pH Sediment: 7.0 ± 0.5 Interstitial Water: Overlying Water: 6.0 to 9.0 (Should not vary by more than 1 unit during test)	Sediment: 7.2 to 7.5 (initial analysis) Interstitial Water: Not determined Overlying Water: 8.0 to 8.6
TOC Sediment: 2 ± 0.5% Overlying Water: 2 mg/L	Sediment: 1.9% (initial analysis) Overlying Water: Not determined
Ammonia Interstitial Water: Overlying Water:	Interstitial Water: Not determined Overlying Water: Day 0: <0.17 mg/L Day 28: ≤1.57 mg/L
Total Water Hardness 200 mg/L as $CaCO_3$ (prefer 160 to 180 mg/L as $CaCO_3$)	156 to 164 mg/L as $CaCO_3$
Dissolved Oxygen 60% air saturation value throughout test	≥5.6 mg/L (≥62% of saturation)

Guideline Criteria	Reported Information
Aeration (ca. one bubble/sec) is allowed except for when larvae are being added and for at least 24 hours after introduction of test organisms to a test chamber. If one test chamber is aerated all test chambers must be treated the same.	Gentle aeration (>1 bubble/sec) was provided to each vessel through a glass pipette that did not extend to a depth closer than 2 cm from the sediment's surface. It was not reported if aeration was stopped during the addition of larvae.
Test Vessels or Compartments 1. Material: Glass, No. 316 stainless steel, teflon or perfluorocarbon plastics 2. Size: Sediment depth of 1.5- 3 cm and the depth ratio of sediment to water should be ca. 1:4, must not be >1:4; 600 ml beaker with 8 cm diameter	Test vessels were 1-quart glass jars containing 2 cm of sediment and 600 mL of overlying water. The measured depth in sediment and overlying water from one representative chamber was 2.1 and 8.3 cm, respectively. Thus, the sediment:water ratio was ≈1:4.
Covers Test vessels should be covered with a glass plate.	Vessels were loosely covered with plastic dishes.
Photoperiod 16 hours light, 8 hours dark (Light intensity 500 to 1000 lux)	16 hours light:8 hours dark, with 30-minute low light transition periods Light intensity was 446 lux at the surface of one representative test chamber.
Food Green algae (e.g., *Scenedesmus subspicatus, Chlorella vulgaris*) or flaked fish food as a ground powder, suspension, or filtrate	Ground Hartz® pet rabbit food
Food Concentration and Frequency Preferably feed daily but at least 3 times per week. day 1 to 10: 0.25-0.5 mg per larvae per day remainder of test: 0.5-1 mg per larvae per day (keep to a minimum, should not accumulate on sediment surface, cause overlying water to be cloudy or cause drop in DO)	Three times per week 10 to 30 mg per vessel per feeding

C. Test Design

Guideline Criteria	Reported Information
Duration *Chironomus riparius*: 28 days (if midges emerge early the test can be terminated after a minimum of 5 days after emergence of the last adult in the control).	28 days
Nominal Concentrations Negative control, solvent control (if a solvent was used) and at least 5 test concentrations. (Note exception to dilution factors described below can be made for shallow slope responses but minimum number of test concentrations may need to be increased) ECx endpoint: test concentrations should bracket ECx and span the environmental concentration range. Dilution factor should not be greater than two between exposure concentrations. NOEC/LOEC endpoint: factor between concentrations must not be greater than 3.	Negative control, solvent control, 3.1, 6.3, 13, 25, 50, and 100 µg/kg dw sediment (not corrected for purity) ECx endpoint: N/A NOAEC/LOAEC endpoint: A nominal factor rate of 2 was used.
Number of Test Organisms** ECx endpoint: 60 larvae per treatment level; 3 replicates per treatment level NOAEC/LOAEC endpoint: at least 80 larvae per treatment level with at least 4 replicates per treatment level (adequate power to detect a 20% difference, Type I error rate 5%) *(Optional) If data on 10-day growth and survival are needed additional replicates (number based on ECx or NOEC/LOEC endpoint determination) should be included at test initiation..	ECx endpoint: N/A NOAEC/LOAEC endpoint: 80 larvae per treatment level divided evenly into four replicates (each containing 20 organisms). **(Optional) 10-day growth data were not collected.

Guideline Criteria	Reported Information
Test organisms randomly or impartially assigned to test vessels?	Yes
Overlying Water Parameter Measurements 1. Dissolved oxygen should be measured daily in all test chambers. 2. Temperature and pH should be measured in all test chambers at the start and end of the test and at least once a week during the test. 3. Temperature should be monitored at least hourly throughout the test in one test chamber. 4. Hardness and ammonia should be measured in the controls and one test chamber at the highest concentration at the start and end of the test.	1. – 3. DO and temperature were measured daily in one alternating replicate chamber for each level. Temperature was also continuously monitored in a beaker of water adjacent to the test chambers. The pH was measured at test initiation, weekly during the test, and at test termination in one alternating replicate chamber for each level. 4. Hardness, ammonia, specific conductance, and alkalinity were measured in a composite sample of overlying water from the control groups and from the highest treatment level (i.e., 100 µg/kg) at study initiation and termination.
Chemical Analysis-Overlying Water At a minimum must be analyzed at test initiation (i.e., one hour after introduction of test substance into the test chamber) and at the end of the test in at least the highest concentration and one lower concentration.	Surrogate samples (three per level) were collected for analysis on Days 0, 7, and 28. Overlying water was decanted and 10-mL aliquots analyzed for total radioactive residues of [^{14}C]flubendiamide-desiodo using LSC. The limit of quantitation (LOQ) was 0.0133 µg/L.
Interstitial Water and Sediment Isolation Method Centrifugation (e.g., 10,000 g and 4 EC for 30 min) is recommended. If test substance is demonstrated not to adsorb to filters, filtration may be acceptable.	Not reported

Guideline Criteria	Reported Information
Chemical Analysis-Interstitial Water At a minimum must be analyzed at the end of the test in at least the highest concentration and one lower concentration.	Surrogate samples (three per level) were collected for analysis on Days 0, 7, and 28; 10-mL aliquots were analyzed for total radioactive residues of [^{14}C]flubendiamide-desiodo using LSC. The limit of quantitation (LOQ) was 0.0133 µg/L.
Chemical Analysis-Bulk Sediment At a minimum must be analyzed at the end of the test in at least the highest concentration and one lower concentration.	Surrogate samples (three per level) were collected for analysis on Days 0, 7, and 28. Isolated sediment was dried overnight and analyzed for total radioactive residues of [^{14}C]flubendiamide-desiodo using LSC following combustion. The limit of quantitation (LOQ) was 0.293 µg/kg.

12. REPORTED RESULTS

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes. This study was conducted in compliance with U.S. EPA 40 CFR, Parts 160 and 792, with the following exceptions: periodic analysis of well water and sediment for potential contaminants, and the stability of the test substance under conditions of storage at the testing facility. It was reported that the periodic analysis (of water and sediment) was performed using a certified laboratory and standard U.S. EPA analytical methods.
Control Mortality <30%	Negative control – 29% Solvent control – 30%
Did chironomids emerge in controls between day 12 and 23?	Negative controls – Days 15 to 28 Solvent control – Days 15 to 28

Guideline Criteria	Reported Information
Control Emergence Mean emergence between 50-70%	Negative control – 71% emergence Solvent control – 73% emergence
Data Endpoints Emergence Test (28 day) - Number alive - Time to emergence - Number of emerged male and female midges - Number of visible pupae that have failed to emerge - Number of egg masses deposited - Observations of other effects, abnormal behavior, or appearance or clinical signs (e.g., leaving sediment, unusual swimming) Growth and Survival (10-day) (Optional) - Number alive - Instar level of surviving larvae - Dry weight (ash free) per test chamber of surviving larvae by instar level	Emergence Test (28 days) - Mortality - Time to emergence - Number of emerged male and female midges - Emergence rate - Development rate - Development time Growth and Survival (10-day) (Optional) N/A
Raw data included?	Yes

Effects Data

Table 1. Summary of [^{14}C]Flubendiamide-desiodo effects on *Chironomus riparius* emergence success and sex ratio

Toxicant Concentration				Initial No.	Mean Number Emerged			Mean Sex Ratio[b] (%)		% Emergence (Day 28)
Mean-measured (and Nominal) Sediment (µg/kg dw)	TWA Measured[a]				♂	♀	Total	♂	♀	
	Sediment (µg TRR/ kg dw)	Overlying Water (µg TRR/L)	Pore Water (µg TRR/L)							
Negative control	<LOQ	<LOQ	<LOQ	80	34	23	57	60	40	71
Solvent control	<LOQ	<LOQ	<LOQ	80	36	22	58	62	38	73
1.7 (3.1)	1.75	0.195	0.551	80	27	22	49	55	45	61
4.3 (6.3)	4.44	0.453	1.10	80	27	24	51	53	47	64
7.8 (13)	7.31	0.895	2.44	80	25	32	57	44	56	71
13 (25)	12.2	1.72	4.28	80	32	27	59	54	46	74
30 (50)	28.5	3.50	9.06	80	23	32	55	42	58	69
55 (100)	52.6	7.18	19.5	80	35	29	64	55	45	80

[a] TWA concentrations were determined by the reviewer using Excel software (copy of worksheet in Appendix II). The limit of quantitation (LOQ) was 0.293 µg TRR/kg for sediment and 0.0133 µg TRR/L for overlying and pore water. TRR = Total Radioactive Residues of [^{14}C]flubendiamide-desiodo.

[b] Equivalent to the number of emerged males (or females)/number of emerged larvae x 100; reviewer-calculated.

Table 2. Summary of [^{14}C]Flubendiamide-desiodo effects on *Chironomus riparius* development time and rate.

Toxicant Concentration				Mean Emergence Ratio	Mean Development Rate[b]	Mean Development Time
Mean-measured (and Nominal) Sediment (µg/kg dw)	TWA Measured[a]					
	Sediment (µg TRR/ kg dw)	Overlying Water (µg TRR/L)	Pore Water (µg TRR/L)		(1/days)	(days)
Negative control	<LOQ	<LOQ	<LOQ	0.71	0.0471	22.5
Solvent control	<LOQ	<LOQ	<LOQ	0.73	0.0482	21.9
1.7 (3.1)	1.75	0.195	0.551	0.61	0.0466	22.6
4.3 (6.3)	4.44	0.453	1.10	0.64	0.0490	21.7
7.8 (13)	7.31	0.895	2.44	0.71	0.0494	21.1
13 (25)	12.2	1.72	4.28	0.74	0.0495	21.4
30 (50)	28.5	3.50	9.06	0.69	0.0469	22.4
55 (100)	52.6	7.18	19.5	0.80	0.0480	21.9

[a] TWA concentrations were determined by the reviewer using Excel software (copy of worksheet in Appendix II). The limit of quantitation (LOQ) was 0.293 µg TRR/kg for sediment and 0.0133 µg TRR/L for overlying and pore water. TRR = Total Radioactive Residues of [^{14}C]flubendiamide-desiodo.

[b] Mean development rate $= \sum_{i=1}^{m} \frac{f_i x_i}{n_e}$ where: i = index of inspection interval; m = maximum number of inspection intervals; f_i = number of midges emerged in the inspection interval i; n_e = total number of midges emerged; and $x_i = 1/\left(day_i - \frac{l_i}{2}\right)$ which is the development rate of the midges emerged in interval i; day_i = inspection day (days since application); and l_i = length of inspection interval i (days, 1 day in this study).

Toxicity Observations: Emergence was first noted on Day 15, and adults that emerged appeared normal. There were a few observations of organisms climbing the walls of the test chamber, on the surface of the sediment, and/or swimming in the water column prior to adult maturation; occasional partial emergence; and adults that emerged and subsequently died during the maturation period. The observations were few in incidence and occurred in the controls as well as the treatment levels, and were thus not considered to be related to treatment.

Mean mortality at Day 28 was 29, 30, 39, 39, 29, 29, 31, and 20% for the negative control, solvent control, and mean-measured 1.7, 4.3, 7.8, 13, 30, and 55 µg TRR/kg test levels, respectively (TRR = total radioactive residues of [^{14}C]flubendiamide-desiodo). The observed EC_{50} for mortality of midges was >55 µg TRR/kg based on mean-measured sediment concentrations. Conversely, percent emergence averaged 71, 73, 61, 64, 71, 74, 69, and 80% for the negative control, solvent control, and mean-measured 1.7, 4.3, 7.8, 13, 30, and 55 µg TRR/kg test levels, respectively. No statistically-significant differences were indicated at any treatment level compared to the pooled control, and the NOAEC for percent emergence was 55 µg TRR/kg.

Mean development time was 22.5 and 21.9 days in the negative and solvent control groups, respectively, compared to 22.6, 21.7, 21.1, 21.4, 22.4, and 21.9 days for the mean-measured 1.7, 4.3, 7.8, 13, 30, and 55 µg TRR/kg test levels, respectively. There were no statistically-significant differences indicated for any treatment level compared to the pooled control. Thus, the NOAEC for development time was 55 µg TRR/kg, based on mean-measured sediment concentrations.

Based upon an ANOVA procedure looking at the interaction between sexes, no significant interaction was found between sex and treatments for development rates, and therefore the data for each sex were pooled for this endpoint. Mean development rates were 0.0471, 0.0482, 0.0466, 0.0490, 0.0494, 0.0495, 0.0469, and 0.0480 days^{-1} for the negative control, solvent control, and mean-measured 1.7, 4.3, 7.8, 13, 30, and 55 µg TRR/kg test levels, respectively; no statistically-significant differences were indicated for any treatment level compared to the pooled control. Thus, the NOAEC for development rate was 55 µg TRR/kg based on mean-measured sediment concentrations.

As previously described for development rates, the interaction between sexes was evaluated for emergence ratios (although it was noted that evaluations of the sensitivity for this endpoint are not meaningful as it is impossible to know the initial number of male and female 1- to 4-day old larvae). No significant interaction was found between sex and treatment. Emergence ratios averaged 0.71, 0.73, 0.61, 0.64, 0.71, 0.74, 0.69, and 0.80 for the negative control, solvent control, and mean-measured 1.7, 4.3, 7.8, 13, 30, and 55 µg TRR/kg test levels, respectively. No statistically-significant differences were indicated for any treatment

level compared to the pooled control. Thus, the NOAEC for emergence ratio was 55 µg TRR/kg based on mean-measured sediment concentrations.

B. Statistical Results (From Study Report)

Endpoints that were statistically evaluated included percent emergence (i.e., survival data), development time, emergence ratio, and development rate. The emergence ratio data were arcsine transformed prior to analysis. NOAEC and LOAEC values were determined by visual interpretation of the dose-response pattern and statistical significance of the data.

The data were analyzed using an appropriate t-test to determine any statistical differences between the negative and solvent control groups. No significant differences were indicated for any endpoint, and the control data were pooled for all subsequent comparisons. Data were analyzed using Dunnett's test, at the $p<0.05$ level of sensitivity. ANOVA was used to evaluate sensitivity between sexes.

The 28-day EC_{50} was determined by visual interpretation of the mortality data collected at study termination.

All statistical procedures were performed using SAS statistical software and were reported in terms of mean-measured sediment concentrations.

Most sensitive endpoint: none

Endpoint	Methods	LC_{50}/EC_{50} (95% CI) (µg TRR/kg)	NOAEC (µg TRR/kg)	LOAEC (µg TRR/kg)
Percent Emergence	Dunnett's t-test	>55	55	>55
Emergence Ratio	Dunnett's t-test	---	55	>55
Development Rate	Dunnett's t-test	---	55	>55
Development Time	Dunnett's t-test	---	55	>55

13. VERIFICATION OF STATISTICAL RESULTS

Summary of Statistical Methods used for NOAEC/LOAEC Analyses.

Endpoint	Solvent vs Dilution Control		NOAEC/LOAEC	
	Method	Diff [1] (%)	Method	Diff [2] (%)
28-d Emergence Rate	Student's t-test	-1.8	ANOVA, Dunnett's test	-12.7
28-d Survival	Student's t-test	1.4	ANOVA, Dunnett's test	-12.7
Development time	Student's t-test	3.1	ANOVA, Dunnett's test	2.9
28-d Development Rate	Student's t-test	-2.3	ANOVA, Dunnett's test	-2.0
10-d Survival (Optional)	---	---	---	---
10-day Dry Weight (Optional)	---	---	---	---

[1] Difference between the mean dilution water and solvent control responses; a negative number indicates a promoted response in the solvent control, relative to the negative control.
[2] Difference between the dilution water and NOAEC concentration treatment; a negative number indicates a promoted response in the NOAEC, relative to the negative control.

Most sensitive endpoint: none

Verification Statistical Endpoint Values[a].

Statistical Endpoint	28-day Emergence	28-day Survival	Development time	28-day Development Rate
NOAEC				
Sediment:	52.6 µg TRR/kg	52.6 µg TRR/kg	52.6 µg TRR/kg	52.6 µg TRR/kg
Overlying Water:	7.18 µg TRR/L	7.18 µg TRR/L	7.18 µg TRR/L	7.18 µg TRR/L
Pore Water:	19.5 µg TRR/L	19.5 µg TRR/L	19.5 µg TRR/L	19.5 µg TRR/L
LOAEC				
Sediment:	>52.6 µg TRR/kg	>52.6 µg TRR/kg	>52.6 µg TRR/kg	>52.6 µg TRR/kg
Overlying Water:	>7.18 µg TRR/L	>7.18 µg TRR/L	>7.18 µg TRR/L	>7.18 µg TRR/L
Pore Water:	>19.5 µg TRR/L	>19.5 µg TRR/L	>19.5 µg TRR/L	>19.5 µg TRR/L
IC_{50} (95% C.I.)				
Sediment:	>52.6 µg TRR/kg	>52.6 µg TRR/kg	>52.6 µg TRR/kg	>52.6 µg TRR/kg
Overlying Water:	>7.18 µg TRR/L	>7.18 µg TRR/L	>7.18 µg TRR/L	>7.18 µg TRR/L
Pore Water:	>19.5 µg TRR/L	>19.5 µg TRR/L	>19.5 µg TRR/L	>19.5 µg TRR/L
Slope (Standard Error)	N/A	N/A	N/A	N/A

[a] Results are based on TWA test concentrations.

14. REVIEWER'S COMMENTS:

The reviewer's conclusions agreed with the study authors'. There was no treatment-related toxicity in this study.

The study was designed to fulfill OECD Guideline 218 *Sediment-Water Chironomid Toxicity Test Using Spiked Sediment* (2004). Although this study does not fulfill any current U.S. EPA guideline requirement, there were no significant deviations from OECD Guideline 218 that would affect the scientific soundness of this study.

In order for the test to be valid, OECD 218 Guidance requires the following conditions: emergence in the controls must be at least 70% at the end of the test; *C. riparius* emergence to adults should occur between 12 and 23 days after their insertion into the vessels; at the end of the test, pH and dissolved oxygen should be measured in each vessel (the oxygen concentration should be at least 60% of the air saturation value at the temperature used, the pH of overlying water should be in the 6-9 range in all test vessels); and the water temperature should not differ by more than ±1.0°C. In this study, all validity requirements were considered to be fulfilled. Although emergence in controls occurred between Days 15 and 28 (both groups), this deviation did not have any effect on the scientific soundness of this study.

Although OECD 218 prefers that results are provided in terms of (initial) nominal sediment concentrations, TWA concentrations were reviewer-calculated (refer to associated Excel worksheet in Appendix II). As TWA concentrations are more indicative of exposure levels throughout the study, they were reported in the Statistical Verification and Conclusions sections of the DER. TWA concentrations were calculated using the following equation:

$$C_{TWA} = \frac{\left(\frac{C_1 + C_0}{2}\right)(t_1 - t_0) + \left(\frac{C_2 + C_1}{2}\right)(t_2 - t_1) + \left(\frac{C_{n-1} + C_2}{2}\right)(t_{n-1} - t_2) + \left(\frac{C_n + C_{n-1}}{2}\right)(t_n - t_{n-1})}{t_n}$$

where:
C TWA is the time-weighted average concentration,
C j is the concentration measured at time interval j (j = 0, 1, 2,...n)
t j is the number of hours (or days or weeks, units used just need to be consistent in the equation) of the test at time interval j (e.g., t 0 = 0 hours (test initiation), t 1 =24 hours, t 2 =96 hours).

At test initiation, the overlying water appeared slightly cloudy and light tan in all test chambers. At termination, it appeared cloudy and tan in all test chambers.

The mean recovery from LSC analysis of the primary stock solution (nominal 150 µg/mL) was 93.3% of nominal. Recoveries from LSC analyses of the working stock solutions (nominal 0.31, 0.63, 1.30, 2.50, 5.00, and 10.0 µg/mL) ranged from 106 to 108% of nominal concentrations.

Experimental test dates were November 17 to December 16, 2009.

15. REFERENCES:

OECD Guideline 218. 2004. *Sediment-Water Chironomid Toxicity Test Using Spiked Sediment.* Adopted April 2004.

APHA, AWWA, WPCF. 1998. *Standard Methods for the Examination of Water and Wastewater*. 20th Edition. American Public Health Association. American Waterworks Association. Water Pollution Control Federation, New York.

The SAS Sytem for Windows. 1999-2001. Release 8.2 (TS2M0). SAS Institute, Inc., Cary, North Carolina.

APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL ANALYSIS:

```
Title:  Percent Emergence
File:        5605e          Transform:          NO TRANSFORMATION

     t-Test of Solvent and Blank Controls          Ho: GRP1 Mean = GRP2 Mean
==========================================================================
GRP1 (Solvent cntl) Mean =      0.7125     Calculated t value =     -0.1777
GRP2 (Blank cntl) Mean   =      0.7250     Degrees of freedom =      6
Difference in means      =     -0.0125
==========================================================================
2-sided t value (0.05, 6) = 2.4469  No significant difference at alpha=0.05
2-sided t value (0.01, 6) = 3.7074  No significant difference at alpha=0.01

   WARNING:  This procedure assumes normality and equal variances!
Title:  Percent Emergence
File:              5605e              Transform:      ARC SINE(SQUARE ROOT(Y))

                   Shapiro - Wilk's Test for Normality
--------------------------------------------------------------------------

     D =   0.4953
     W =   0.9269

     Critical W  = 0.8960 (alpha = 0.01 , N = 28)
              W  = 0.9240 (alpha = 0.05 , N = 28)

--------------------------------------------------------------------------

Data PASS normality test (alpha = 0.01). Continue analysis.


Title:  Percent Emergence
File:              5605e              Transform:      ARC SINE(SQUARE ROOT(Y))

                   Levene's Test for Homogeneity of Variance

                                ANOVA Table
--------------------------------------------------------------------------

   SOURCE              DF              SS              MS            F
--------------------------------------------------------------------------
   Between              6              0.0451          0.0075        0.6245

   Within (Error)      21              0.2528          0.0120
--------------------------------------------------------------------------
   Total               27              0.2979
--------------------------------------------------------------------------
                                                      (p-value = 0.7088)

   Critical F  = 3.8117  (alpha = 0.01, df = 6,21)
               = 2.5727  (alpha = 0.05, df = 6,21)

   Since  F < Critical F  FAIL TO REJECT  Ho: All equal (alpha = 0.01)
```

Title: Percent Emergence
File: 5605e Transform: ARC SINE(SQUARE ROOT(Y))

ANOVA Table

SOURCE	DF	SS	MS	F
Between	6	0.1251	0.0208	0.8841
Within (Error)	21	0.4953	0.0236	
Total	27	0.6204		

(p-value = 0.5237)

Critical F = 3.8117 (alpha = 0.01, df = 6,21)
= 2.5727 (alpha = 0.05, df = 6,21)

Since F < Critical F FAIL TO REJECT Ho: All equal (alpha = 0.05)

Title: Percent Emergence
File: 5605e Transform: ARC SINE(SQUARE ROOT(Y))

Dunnett's Test - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	TRANS T STAT	SIG 0.05
1	Neg Control	1.0110	0.7125		
2	1.75	0.9079	0.6125	0.9498	
3	4.44	0.9266	0.6375	0.7773	
4	7.31	1.0068	0.7125	0.0389	
5	12.2	1.0684	0.7375	-0.5286	
6	28.5	0.9844	0.6875	0.2455	
7	52.6	1.1111	0.8000	-0.9218	

Dunnett critical value = 2.4600 (1 Tailed, alpha = 0.05, df [used] = 6,20)
(Actual df = 6,21)

Title: Percent Emergence
File: 5605e Transform: ARC SINE(SQUARE ROOT(Y))

Dunnett's Test - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	MIN SIG DIFF (IN ORIG. UNITS)	% OF CONTROL	DIFFERENCE FROM CONTROL
1	Neg Control	4			
2	1.75	4	0.2595	36.1	0.1000
3	4.44	4	0.2595	36.1	0.0750

4	7.31	4	0.2595	36.1	0.0000
5	12.2	4	0.2595	36.1	-0.0250
6	28.5	4	0.2595	36.1	0.0250
7	52.6	4	0.2595	36.1	-0.0875

Title: Percent Emergence
File: 5605e Transform: ARC SINE(SQUARE ROOT(Y))

William's Test - TABLE 1 OF 2 Ho: Control<Treatment

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSPORMED MEAN	ISOTONIZED MEAN
1	Neg Control	4	0.7125	1.0110	1.0110
2	1.75	4	0.6125	0.9079	1.0009
3	4.44	4	0.6375	0.9266	1.0009
4	7.31	4	0.7125	1.0068	1.0009
5	12.2	4	0.7375	1.0684	1.0009
6	28.5	4	0.6875	0.9844	1.0009
7	52.6	4	0.8000	1.1111	1.0009

Title: Percent Emergence
File: 5605e Transform: ARC SINE(SQUARE ROOT(Y))

William's Test - TABLE 2 OF 2 Ho: Control<Treatment

IDENTIFICATION	COMPARED MEANS	CALC. WILLIAMS	SIG 0.05	TABLE WILLIAMS	DEGREES OF FREEDOM USED
Neg Control	1.0110				
1.75	1.0009	0.0935		1.7200	k= 1, v=21
4.44	1.0009	0.0935		1.8000	k= 2, v=21
7.31	1.0009	0.0935		1.8300	k= 3, v=21
12.2	1.0009	0.0935		1.8400	k= 4, v=21
28.5	1.0009	0.0935		1.8500	k= 5, v=21
52.6	1.0009	0.0935		1.8500	k= 6, v=21

s = 0.1536

WARNING: Procedure has used isotonized means which differ from original (transformed) means.

Title: Percent Survival
File: 5605s Transform: NO TRANSFORMATION

t-Test of Solvent and Blank Controls Ho: GRP1 Mean = GRP2 Mean

GRP1 (Solvent cntl) Mean = 0.7125 Calculated t value = 0.1901

GRP2 (Blank cntl) Mean = 0.7000 Degrees of freedom = 6
Difference in means = 0.0125

2-sided t value (0.05, 6) = 2.4469 No significant difference at alpha=0.05
2-sided t value (0.01, 6) = 3.7074 No significant difference at alpha=0.01

WARNING: This procedure assumes normality and equal variances!

Title: Percent Survival
File: 5605s Transform: ARC SINE(SQUARE ROOT(Y))

Shapiro - Wilk's Test for Normality

D = 0.4496
W = 0.9478

Critical W = 0.8960 (alpha = 0.01 , N = 28)
W = 0.9240 (alpha = 0.05 , N = 28)

Data PASS normality test (alpha = 0.01). Continue analysis.

Title: Percent Survival
File: 5605s Transform: ARC SINE(SQUARE ROOT(Y))

Levene's Test for Homogeneity of Variance

ANOVA Table

SOURCE	DF	SS	MS	F
Between	6	0.0349	0.0058	0.6688
Within (Error)	21	0.1827	0.0087	
Total	27	0.2176		

(p-value = 0.6758)

Critical F = 3.8117 (alpha = 0.01, df = 6,21)
= 2.5727 (alpha = 0.05, df = 6,21)

Since F < Critical F FAIL TO REJECT Ho: All equal (alpha = 0.01)

Title: Percent Survival
File: 5605s Transform: ARC SINE(SQUARE ROOT(Y))

ANOVA Table

SOURCE	DF	SS	MS	F

Between	6	0.1254	0.0209	0.9763
Within (Error)	21	0.4496	0.0214	
Total	27	0.5750		

(p-value = 0.4654)

Critical F = 3.8117 (alpha = 0.01, df = 6,21)
= 2.5727 (alpha = 0.05, df = 6,21)

Since F < Critical F FAIL TO REJECT Ho: All equal (alpha = 0.05)

Title: Percent Survival
File: 5605s Transform: ARC SINE(SQUARE ROOT(Y))

Dunnett's Test - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	TRANS T STAT	SIG 0.05
1	Neg Control	1.0110	0.7125		
2	1.75	0.9079	0.6125	0.9969	
3	4.44	0.9015	0.6125	1.0590	
4	7.31	1.0068	0.7125	0.0409	
5	12.2	1.0274	0.7125	-0.1584	
6	28.5	0.9844	0.6875	0.2577	
7	52.6	1.1111	0.8000	-0.9674	

Dunnett critical value = 2.4600 (1 Tailed, alpha = 0.05, df [used] = 6,20)
(Actual df = 6,21)

Title: Percent Survival
File: 5605s Transform: ARC SINE(SQUARE ROOT(Y))

Dunnett's Test - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	MIN SIG DIFF (IN ORIG. UNITS)	% OF CONTROL	DIFFERENCE FROM CONTROL
1	Neg Control	4			
2	1.75	4	0.2469	34.4	0.1000
3	4.44	4	0.2469	34.4	0.1000
4	7.31	4	0.2469	34.4	0.0000
5	12.2	4	0.2469	34.4	0.0000
6	28.5	4	0.2469	34.4	0.0250
7	52.6	4	0.2469	34.4	-0.0875

Title: Percent Survival
File: 5605s Transform: ARC SINE(SQUARE ROOT(Y))

William's Test - TABLE 1 OF 2 Ho: Control<Treatment

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	Neg Control	4	0.7125	1.0110	1.0110
2	1.75	4	0.6125	0.9079	0.9898
3	4.44	4	0.6125	0.9015	0.9898
4	7.31	4	0.7125	1.0068	0.9898
5	12.2	4	0.7125	1.0274	0.9898
6	28.5	4	0.6875	0.9844	0.9898
7	52.6	4	0.8000	1.1111	0.9898

Title: Percent Survival
File: 5605s Transform: ARC SINE(SQUARE ROOT(Y))

William's Test - TABLE 2 OF 2 Ho: Control<Treatment

IDENTIFICATION	COMPARED MEANS	CALC. WILLIAMS	SIG 0.05	TABLE WILLIAMS	DEGREES OF FREEDOM USED
Neg Control	1.0110				
1.75	0.9898	0.2048		1.7200	k= 1, v=21
4.44	0.9898	0.2048		1.8000	k= 2, v=21
7.31	0.9898	0.2048		1.8300	k= 3, v=21
12.2	0.9898	0.2048		1.8400	k= 4, v=21
28.5	0.9898	0.2048		1.8500	k= 5, v=21
52.6	0.9898	0.2048		1.8500	k= 6, v=21

s = 0.1463

WARNING: Procedure has used isotonized means which differ from original (transformed) means.

Title: Development time
File: 5605t Transform: NO TRANSFORMATION

t-Test of Solvent and Blank Controls Ho: GRP1 Mean = GRP2 Mean

GRP1 (Solvent cntl) Mean = 22.5000 Calculated t value = 0.5932
GRP2 (Blank cntl) Mean = 21.8500 Degrees of freedom = 6
Difference in means = 0.6500

2-sided t value (0.05, 6) = 2.4469 No significant difference at alpha=0.05
2-sided t value (0.01, 6) = 3.7074 No significant difference at alpha=0.01

WARNING: This procedure assumes normality and equal variances!

Title: Development time
File: 5605t Transform: NO TRANSFORMATION

Shapiro - Wilk's Test for Normality

D = 36.8450
W = 0.9852

Critical W = 0.8960 (alpha = 0.01 , N = 28)
W = 0.9240 (alpha = 0.05 , N = 28)

Data PASS normality test (alpha = 0.01). Continue analysis.

Title: Development time
File: 5605t Transform: NO TRANSFORMATION

Levene's Test for Homogeneity of Variance

ANOVA Table

SOURCE	DF	SS	MS	F
Between	6	6.2521	1.0420	2.7268
Within (Error)	21	8.0250	0.3821	
Total	27	14.2771		

(p-value = 0.0405)

Critical F = 3.8117 (alpha = 0.01, df = 6,21)
= 2.5727 (alpha = 0.05, df = 6,21)

Since F < Critical F FAIL TO REJECT Ho: All equal (alpha = 0.01)

Title: Development time
File: 5605t Transform: NO TRANSFORMATION

ANOVA Table

SOURCE	DF	SS	MS	F
Between	6	8.6821	1.4470	0.8247
Within (Error)	21	36.8450	1.7545	
Total	27	45.5271		

(p-value = 0.5636)

Critical F = 3.8117 (alpha = 0.01, df = 6,21)
= 2.5727 (alpha = 0.05, df = 6,21)

Since F < Critical F FAIL TO REJECT Ho: All equal (alpha = 0.05)

Title: Development time
File: 5605t Transform: NO TRANSFORMATION

Dunnett's Test - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG 0.05
1	Neg Control	22.5000	22.5000		
2	1.75	22.6000	22.6000	-0.1068	
3	4.44	21.6500	21.6500	0.9075	
4	7.31	21.0750	21.0750	1.5214	
5	12.2	21.3500	21.3500	1.2278	
6	28.5	22.4250	22.4250	0.0801	
7	52.6	21.8500	21.8500	0.6940	

Dunnett critical value = 2.4600 (1 Tailed, alpha = 0.05, df [used] = 6,20)
(Actual df = 6,21)

Title: Development time
File: 5605t Transform: NO TRANSFORMATION

Dunnett's Test - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	MIN SIG DIFF (IN ORIG. UNITS)	% OF CONTROL	DIFFERENCE FROM CONTROL
1	Neg Control	4			
2	1.75	4	2.3041	10.2	-0.1000
3	4.44	4	2.3041	10.2	0.8500
4	7.31	4	2.3041	10.2	1.4250
5	12.2	4	2.3041	10.2	1.1500
6	28.5	4	2.3041	10.2	0.0750
7	52.6	4	2.3041	10.2	0.6500

Title: Development time
File: 5605t Transform: NO TRANSFORMATION

William's Test - TABLE 1 OF 2 Ho: Control<Treatment

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	Neg Control	4	22.5000	22.5000	22.5500
2	1.75	4	22.6000	22.6000	22.5500
3	4.44	4	21.6500	21.6500	21.6700
4	7.31	4	21.0750	21.0750	21.6700
5	12.2	4	21.3500	21.3500	21.6700
6	28.5	4	22.4250	22.4250	21.6700
7	52.6	4	21.8500	21.8500	21.6700

Title: Development time
File: 5605t Transform: NO TRANSFORMATION

William's Test - TABLE 2 OF 2 Ho: Control<Treatment

IDENTIFICATION	COMPARED MEANS	CALC. WILLIAMS	SIG 0.05	TABLE WILLIAMS	DEGREES OF FREEDOM USED
Neg Control	22.5000				
1.75	22.5500	-0.0534		1.7200	k= 1, v=21
4.44	21.6700	0.8862		1.8000	k= 2, v=21
7.31	21.6700	0.8862		1.8300	k= 3, v=21
12.2	21.6700	0.8862		1.8400	k= 4, v=21
28.5	21.6700	0.8862		1.8500	k= 5, v=21
52.6	21.6700	0.8862		1.8500	k= 6, v=21

s = 1.3246

WARNING: Procedure has used isotonized means which differ from original (transformed) means.

Title: Development rate
File: 5605d Transform: NO TRANSFORMATION

t-Test of Solvent and Blank Controls Ho: GRP1 Mean = GRP2 Mean

GRP1 (Solvent cntl) Mean = 4.7075 Calculated t value = -0.4155
GRP2 (Blank cntl) Mean = 4.8200 Degrees of freedom = 6
Difference in means = -0.1125

2-sided t value (0.05, 6) = 2.4469 No significant difference at alpha=0.05
2-sided t value (0.01, 6) = 3.7074 No significant difference at alpha=0.01

WARNING: This procedure assumes normality and equal variances!

Title: Development rate
File: 5605d Transform: NO TRANSFORMATION

Shapiro - Wilk's Test for Normality

D = 2.0659
W = 0.9843

Critical W = 0.8960 (alpha = 0.01 , N = 28)
W = 0.9240 (alpha = 0.05 , N = 28)

Data PASS normality test (alpha = 0.01). Continue analysis.

Title: Development rate
File: 5605d Transform: NO TRANSFORMATION

Levene's Test for Homogeneity of Variance

ANOVA Table

SOURCE	DF	SS	MS	F
Between	6	0.3531	0.0588	3.2532
Within (Error)	21	0.3799	0.0181	
Total	27	0.7330		

(p-value = 0.0202)

Critical F = 3.8117 (alpha = 0.01, df = 6,21)
= 2.5727 (alpha = 0.05, df = 6,21)

Since F < Critical F FAIL TO REJECT Ho: All equal (alpha = 0.01)

Title: Development rate
File: 5605d Transform: NO TRANSFORMATION

ANOVA Table

SOURCE	DF	SS	MS	F
Between	6	0.3711	0.0619	0.6288
Within (Error)	21	2.0659	0.0984	
Total	27	2.4370		

(p-value = 0.7056)

Critical F = 3.8117 (alpha = 0.01, df = 6,21)
= 2.5727 (alpha = 0.05, df = 6,21)

Since F < Critical F FAIL TO REJECT Ho: All equal (alpha = 0.05)

Title: Development rate
File: 5605d Transform: NO TRANSFORMATION

Dunnett's Test - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG 0.05
1	Neg Control	4.7075	4.7075		
2	1.75	4.6600	4.6600	0.2142	
3	4.44	4.8975	4.8975	-0.8567	
4	7.31	4.9450	4.9450	-1.0709	
5	12.2	4.9475	4.9475	-1.0821	
6	28.5	4.6875	4.6875	0.0902	
7	52.6	4.8025	4.8025	-0.4283	

Dunnett critical value = 2.4600 (1 Tailed, alpha = 0.05, df [used] = 6,20)
(Actual df = 6,21)

Title: Development rate
File: 5605d Transform: NO TRANSFORMATION

Dunnett's Test - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	MIN SIG DIFF (IN ORIG. UNITS)	% OF CONTROL	DIFFERENCE FROM CONTROL
1	Neg Control	4			
2	1.75	4	0.5456	11.6	0.0475
3	4.44	4	0.5456	11.6	-0.1900
4	7.31	4	0.5456	11.6	-0.2375
5	12.2	4	0.5456	11.6	-0.2400
6	28.5	4	0.5456	11.6	0.0200
7	52.6	4	0.5456	11.6	-0.0950

Title: Development rate
File: 5605d Transform: NO TRANSFORMATION

William's Test - TABLE 1 OF 2 Ho: Control<Treatment

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	Neg Control	4	4.7075	4.7075	4.8315

2	1.75	4	4.6600	4.6600	4.8315
3	4.44	4	4.8975	4.8975	4.8315
4	7.31	4	4.9450	4.9450	4.8315
5	12.2	4	4.9475	4.9475	4.8315
6	28.5	4	4.6875	4.6875	4.7450
7	52.6	4	4.8025	4.8025	4.7450

Title: Development rate
File: 5605d Transform: NO TRANSFORMATION

William's Test - TABLE 2 OF 2 Ho: Control<Treatment

IDENTIFICATION	COMPARED MEANS	CALC. WILLIAMS	SIG 0.05	TABLE WILLIAMS	DEGREES OF FREEDOM USED
Neg Control	4.7075				
1.75	4.8315	-0.5591		1.7200	k= 1, v=21
4.44	4.8315	-0.5591		1.8000	k= 2, v=21
7.31	4.8315	-0.5591		1.8300	k= 3, v=21
12.2	4.8315	-0.5591		1.8400	k= 4, v=21
28.5	4.7450	-0.1691		1.8500	k= 5, v=21
52.6	4.7450	-0.1691		1.8500	k= 6, v=21

s = 0.3136

WARNING: Procedure has used isotonized means which differ from original (transformed) means.

APPENDIX II. COPY OF REVIEWER'S TIME-WEIGHTED AVERAGE (TWA) CALCULATIONS USING EXCEL SOFTWARE:

SEDIMENT

Nominal Concentration (ug/kg)	Time (Day)	14C-Novaluron Equivalents Measured Concentration (ug/kg)	TWA (ug/kg)
3.1	0	1.73	
	7	2.06	
	28	1.35	
			1.75
6.3	0	3.98	
	7	5.24	
	28	3.53	
			4.44
13	0	9.26	
	7	6.9	
	28	7.21	
			7.31
25	0	13.8	
	7	10.1	
	28	14.4	
			12.2
50	0	35.2	
	7	29.3	
	28	25.2	
			28.5
100	0	60.1	
	7	50.6	
	28	52.8	
			52.6

EXHIBIT 24

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

PC Code: 027602
DP Barcodes: 412791 and 425073
Date: February 20, 2015

MEMORANDUM

SUBJECT: Review of Three Reports Related to a 3-year Flubendiamide Water Monitoring Project in Support of the Conditional Registration of Flubendiamide

FROM: Stephen Wente, Ph.D., Biologist 2/20/15
Environmental Risk Branch 1
Environmental Fate and Effects Division (7507P)

THROUGH: Sujatha Sankula, Ph.D., Branch Chief 2/20/15
Environmental Risk Branch 1
Environmental Fate and Effects Division (7507P)

Edward Odenkirchen, Ph.D., Senior Advisor
Immediate Office
Environmental Fate and Effects Division (7507P)

TO: Carmen Rodia, Risk Manager Reviewer
Richard Gebken, Risk Manager
Debbie McCall, Branch Chief
Invertebrate & Vertebrate Branch 2
Registration Division (7504P)

Introduction

Flubendiamide, an insecticide, was conditionally registered in 2008 for aerial and/or ground application to corn, cotton, tobacco, pome fruit, stone fruit, tree nuts, grapes, cucurbit vegetables, fruiting vegetables, leafy vegetables, and brassica leafy vegetables. Registrant-submitted effects studies indicate that both the parent (flubendiamide) and degradate (des-iodo) exhibit chronic toxicity to aquatic invertebrates[1]. Submitted fate data indicate flubendiamide slowly converts to its des-iodo degradate, which does not breakdown. EFED modeling (D329613+) predicts that

[1] Flubendiamide's mode of action is taxa-specific to an unknown degree (targets lepidopteran ryanodine receptors). EFED does not have endpoints specific to lepidopterans. There are numerous species of aquatic lepidopterans of which four are listed species.

flubendiamide and its degradate (des-iodo) will accumulate in aquatic systems eventually exceeding Agency levels of concern (LOCs).

The registrant has argued that: 1) vegetative filter strips (VFSs) would prevent accumulation from exceeding Agency LOCs (flubendiamide labels require a 15 ft VFS buffer around aquatic areas); and 2) the Agency overestimates aquatic exposure because EFED modeling cannot account for the effect of VFSs. According to the flubendiamide preliminary acceptance letter, the Registration Division stated, the "Agency believes that the efficacy of vegetative buffers for flubendiamide use is uncertain." The conditions of registration required a VFS study and, if the VFS study did not allay the Agency's concerns, a pond monitoring study. EFED identified a major modeling error in the VFS study (MRIDs 48175602, 48175604, and 48175606) and asked the registrant to correct it and re-submit (D382010). The VFS study was never re-submitted, therefore, the monitoring study was required. The 3-year monitoring study of water column, sediments, and pore water in 3 ponds (2 in Georgia and 1 in North Carolina) was submitted in December of 2014.

EFED has reviewed the monitoring data and associated studies and has identified several issues with this monitoring data. Despite these issues, EFED believes the monitoring data shows clear evidence that both flubendiamide and des-iodo accumulate in the ponds monitored. The accumulation measured in the first three years of the pond data least impacted by the identified issues largely matches the initial 3 years of concentration predictions of EFED's aquatic exposure modeling. Because EFED's modeling does not account for the effect of VFSs, but still largely matches the monitoring data, EFED believes the effect of VFSs is not large enough to mitigate the ecological risks posed by flubendiamide applications. Therefore, EFED concludes the original and subsequent ecological risk assessments performed by the Agency adequately reflect the risks posed by flubendiamide applications and rejects the registrant's argument that the label-required 15 ft VFSs would prevent accumulation from exceeding Agency LOCs.

The registrant submitted three reports related to this monitoring study: 1) "Monitoring for Flubendiamide and its Metabolite Des-iodo Flubendiamide in Sediment and Surface Water" (MRID 49415303), "Flubendiamide Aquatic Risk – Summary of Surface Water Monitoring and Toxicity Testing" (MRID 49415302), and "Aquatic Exposure Assessment for Flubendiamide and its Metabolite Des-iodo Flubendiamide based on a 3-Year Monitoring Study" (MRID 49415301). This memo provides EFED's analysis of the monitoring data provided in the 3-year monitoring study, summarizes the individual registrant reports, and responds to the major issues raised in these reports.

EFED's Analysis of the Monitoring Data

The residues of flubendiamide and its metabolite Des-iodo were monitored in three ponds in two locations: one pond in Louisburg, NC, and two adjacent ponds (attached by a culvert) in Omega, GA (MRID 49415303). The monitoring study ponds in North Carolina (NC) (Negley et al. 2011; MRID 48535201) and Georgia (GA) (Hanzas et al. 2011; MRID 48644901) were approved by the Agency (D394006 and D398132, respectively). The ponds were selected from areas with high flubendiamide use based on confidential 2009 U.S. sales data. Ponds were selected based on

the similarity of their surface area and watershed area to the standard pond that EFED uses in exposure modeling and the requirement that the entire watershed be planted to one crop. Additionally, an attempt was made to select ponds with watersheds that had similar characteristics to EFED standard scenarios for the crop planted in that watershed.

Although not requested by the Agency, the registrant also sampled intermittent and perennial streams near the monitored ponds. The *intermittent* stream sites were up and downstream of where the discharge of the pond(s) flowed into the intermittent stream, while the *perennial* stream sites were up and downstream of where the discharge of the intermittent stream flowed into the perennial stream. (Both Georgia ponds flowed into the same intermittent and perennial streams, so the total number of monitoring sites included 3 ponds, 4 intermittent stream sites (2 in GA and 2 in NC), and 4 perennial streams sites (2 in GA and 2 in NC).) Monthly water and sediment samples, with a few exceptions, were taken from each monitoring site for three years. Water quality parameters including pH, temperature, conductivity, dissolved oxygen, and oxidation/reduction potential (ORP) were measured on-site during each sampling event. Composite water and sediment (top 2 inches) samples were collected during each monthly sampling event. Applications of the flubendiamide product Belt™ were made to the watershed of the pond(s) at each location every year during the study period.

Pore water was separated from sediment samples by vacuum filtration at about 10 PSI to quantify the benthic water residue. Flubendiamide and des-iodo in the water column, pore water and sediment extracts were analyzed by LC/MS/MS, using isotopically-labelled internal standards for quantitation. The method detection limits were 0.004 μg/L for flubendiamide and des-iodo in water and pore water samples, and 0.02 μg/kg for flubendiamide and des-iodo in sediment samples.

Experimental Design and Data Quality Issues

EFED identified six major issues with the monitoring study that affect the interpretability of the study. The first four issues concern the experimental treatment of the watershed: 1) the variability in crops grown on the pond watersheds; 2) the variability in the date of application(s); 3) the variability in the application rates; and 4) the magnitude of the study application rates compared to the maximum annual label application rates (Table 1). Because the participation of the growers was voluntary, the registrant did not have much control over the treatment of the watersheds. The crops rotated in both watersheds – from tobacco (2011) to soybean (2012 and 2013) to tobacco (2014) in the NC pond watershed and from cotton (2011 and 2012) to peanut (2013) in the watershed of the GA ponds. The application dates were quite variable in the NC pond watershed with 15 months between the 1st and 2nd application, 12.5 months between the 2nd and 3rd, and 6.5 months between the 3rd and 4th application with a second application in 2014 occurring a month later. The application rates also varied in the NC pond watershed from 0.06 to 0.09 lb/A. Both the application dates (all in August) and rates (all 0.09 lb/A) in the watershed of the GA ponds were much more consistent.

Table 1. Timeline of applications within the watersheds of the monitoring study ponds and comparison to the maximum annual application rates allowed by flubendiamide labels.

Year	Crop	Application Date	Rate Applied (lb/A)	Label Maximum Annual Rate (lb/A)	Percent of Maximum Annual Rate (%)
North Carolina Pond Watershed					
2011	Tobacco	May 26	0.06	0.375	16
2012	Soybean	Aug 27	0.075	0.188	40
2013	Soybean	Nov 12	0.09	0.188	48
2014	Tobacco	May 31	0.0675	0.375	34
		June 28	0.06		
Georgia Ponds Watershed					
2011	Cotton	August 18 (25% of area) August 23, (75% of area)	0.09	0.282	32
2012	Cotton	August 13	0.09	0.282	32
2013	Peanut	August 30	0.09	0.375	24

The first three issues (variation in crops grown, application dates, and application rates) would be expected to add variability to the monitoring data; making it harder to detect trends in the data. The fourth issue (low application rates) reduces the magnitude of the trends, which makes it harder to detect trends from the noise in the data.

The fifth issue concerns the installation of maintained grass swales (grass waterways) in the watershed of the GA ponds. On page 15 of the GA Site selection Report (Hanzas, et al. 2011; MRID 48644901), it is stated "Primary entry points of runoff into the ponds originate from the southeast via two distinct, un-cropped (but not vegetated) drainage pathways." However the Interim Report 1 (MRID 48892501; after the first year of monitoring data) p. 13, the Interim Report 2 (MRID 49139801; after the second year of monitoring data) p. 13, and the Final Monitoring Report (MRID 49415303) p. 15, all state the same sentence "Primary entry points of runoff into the ponds originated from the southeast via three maintained grass swales." The Agency obtained aerial photography of the GA ponds and watershed from September 16, 2010 (Figure 5a) and September 13, 2013 (Figure 5b) from the National Agriculture Imagery Program (NAIP)[2].

[2] http://fsa.usda.gov/FSA/apfoapp?area=home&subject=prog&topic=nai

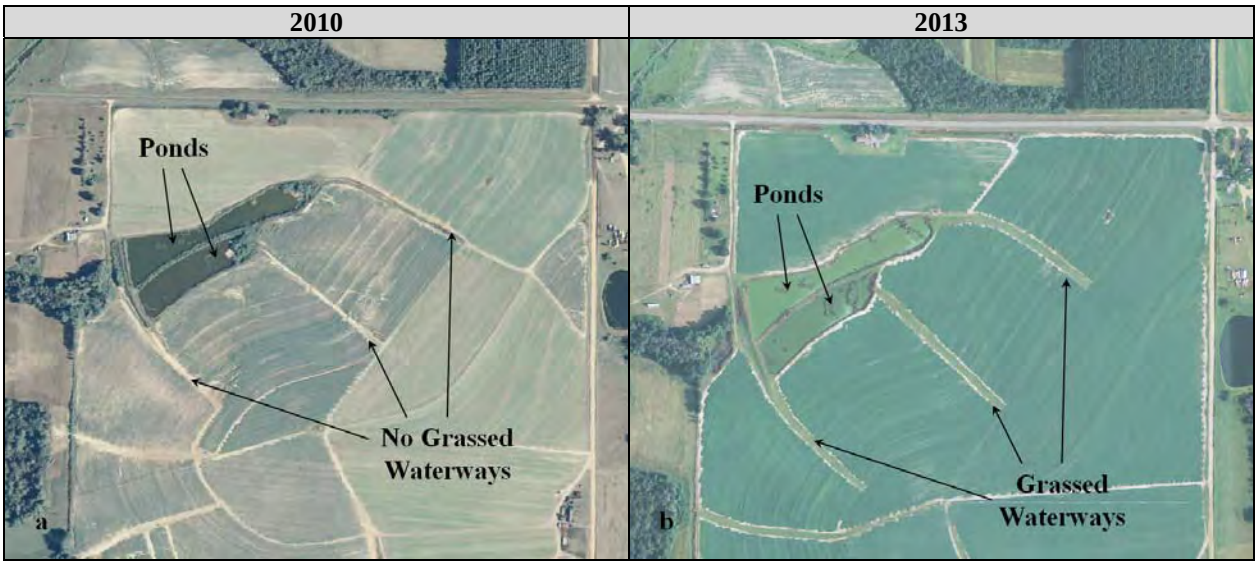


Figure 1. Aerial photography of the Georgia pond watershed taken before (a) and after (b) installation of grass waterways.

The purpose of grassed waterways is to reduce soil and chemical loadings to waterbodies. They occupy the main drainage pathways though which the majority of the pesticide in runoff and attached to eroded soil would travel. Grassed waterways are designed to trap eroded soil and allow runoff and the chemicals in the runoff to infiltrate into the ground. The flubendiamide labels require a 15 ft VFS between the treated field and waterbodies, but do *not* require grassed waterways. The presence of the grassed waterways would be expected to reduce the accumulation of flubendiamide and des-iodo in the GA ponds and therefore, make it more difficult to identify accumulation trends in the GA ponds. Additionally, the trends measured from water column, sediment, and pore water in the GA ponds would be diminished [*i.e.*, the magnitude (steepness) of those trends would be diminished relative to what would be expected in the absence of the grassed waterways].

The final issue with the submitted monitoring data concerns the magnitude of the pore water concentrations compared to the water column concentrations from samples collected from the same pond and at the same time. In the ponds, EFED expects the pore water and water column concentrations to equilibrate over time for both flubendiamide and des-iodo with only short-term excursions from nearly equal concentrations after drift and storm events. However, the observed pond pore water concentrations were typically much lower than the observed water column concentrations from samples collected from the same pond and at the same time.

To show the magnitude and pervasiveness of this discrepancy, the ratio of the pore water to water column concentration was plotted over time for all pond samples that had measured concentrations that were above the detection limit for both pore water and water column samples. If the pore water to water column concentration were equal, this ratio should equal 1. In the NC and GA pond samples (Figure 2a and c, respectively), almost all of the observed ratios plot below 1 (equilibrium) with many equal to, or less than, 0.1 indicating the pore water concentration is 10 times lower than the corresponding water column concentration for many of these samples. For comparison, similar ratios are plotted for samples from the up and downstream perennial stream sites (Figure 2b and d). The perennial stream site ratios tend to

straddle a ratio value of 1 indicating much more equality between pore water and water column concentrations.

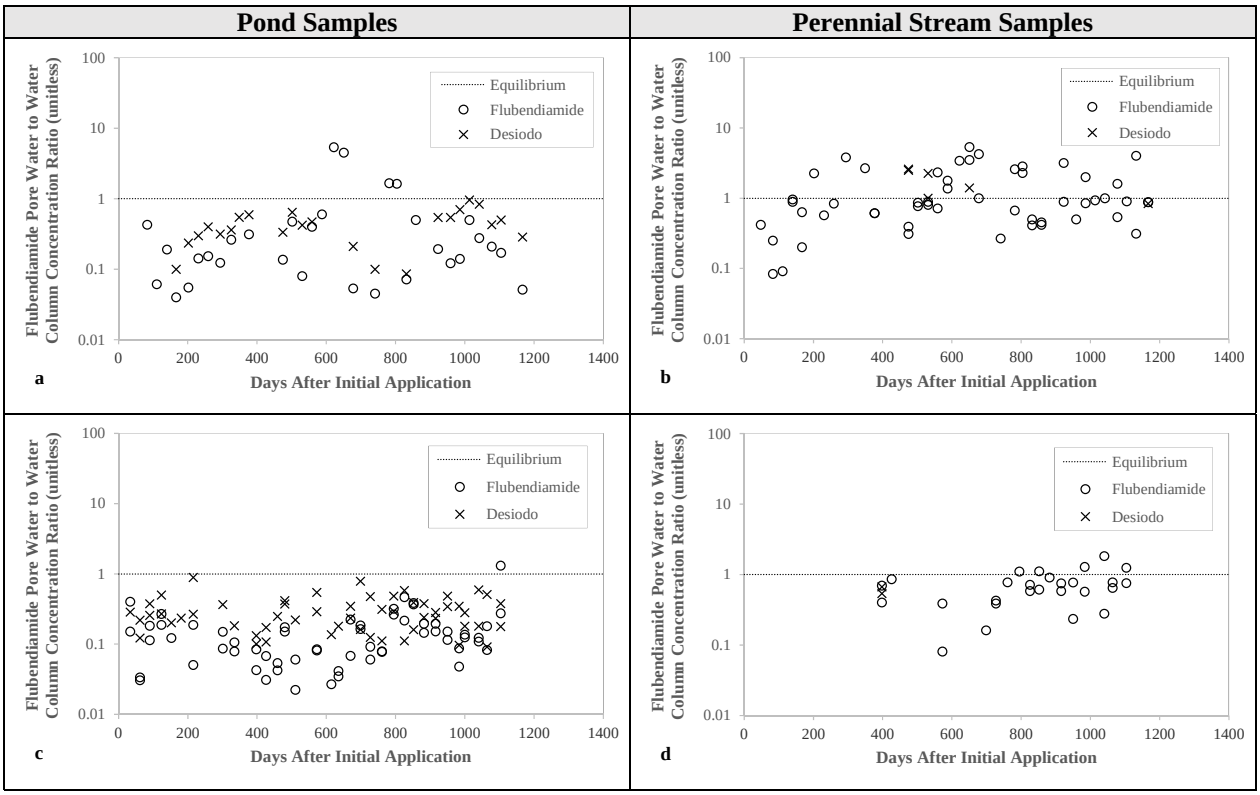


Figure 2. Comparison of observed pore water to water column concentration ratios for flubendiamide and des-iodo from the NC pond (a) the NC perennial stream (b) and GA ponds (c) the GA perennial stream (d) samples.

A potential explanation for why the pond pore water concentrations are so much lower relative to the pond water column concentrations may be that the depth of sediment and pore water contaminated with flubendiamide and des-iodo may be very shallow relative to the total depth of sediment and pore water extracted (~2 inches) during sample collection. Consequently, the pond sediment and pore water samples would constitute a mixture of flubendiamide/des-iodo and uncontaminated sediment and pore water, thus diluting the concentration flubendiamide and des-iodo in the sample.

The NC perennial stream exhibits pore water to water column concentration ratios that are much closer to 1 (Figure 2b). This stream (the Tar River) is a large river at the sites sampled. Sediment depths are likely deeper and better mixed due to turbulent flow in the river, which may make it easier to sample sediment and pore water sample from a surficial layer with less dilution from deeper uncontaminated sediment and pore water. The GA perennial stream water column and pore water concentrations were relatively low, so that early in the monitoring time frame, ratios could not be calculated because one or both concentrations fell below the detection limit. However, the later ratios from the GA perennial stream sites (Figure 2d) were distributed closer to 1 than the pond ratios, but further from 1 than the Tar River (NC perennial stream) ratios (the GA perennial stream is much smaller at the GA sample sites than the NC perennial stream is at

the NC sample sites). (Observed pore water to water column concentration ratios for flubendiamide and des-iodo for all stream sites are depicted in Appendix B.)

Assuming the measured sediment and pore water concentrations from the pond samples are biased low, it would be harder to detect trends in the sediment and pore water data because the observed rate of accumulation will have been diminished due to dilution with the uncontaminated layers. Additionally, these 'diluted' samples would be much lower than model predicted 'non-diluted' pore water concentrations.

Accumulation

EFED used the "LifeReg" regression procedure in SAS statistical software to fit trend lines to the pond concentration data because some of the data are only known to be less than the method detection limit (left-censored). This procedure better accounts for the presence of this left-censored data without biasing the fitted trend estimates. The fitted trends increase with time (accumulate) in all of the 18 time-series data sets collected from these ponds [3 ponds × 3 media (water column, sediments, and pore water) × 2 chemicals = 18 time series data sets]. Fitting these trends as exponential trends (*i.e.*, fitting a linear trend to the natural log of the concentration observations) indicated that 13 of these 18 trends were statistically significant at the $p = 0.05$ level of confidence (Figures 3, 4, and 5) despite the issues with this data described in the previous section. (The exponential trends appear as linear trends in these figures because the y-axis is presented as a log scale).

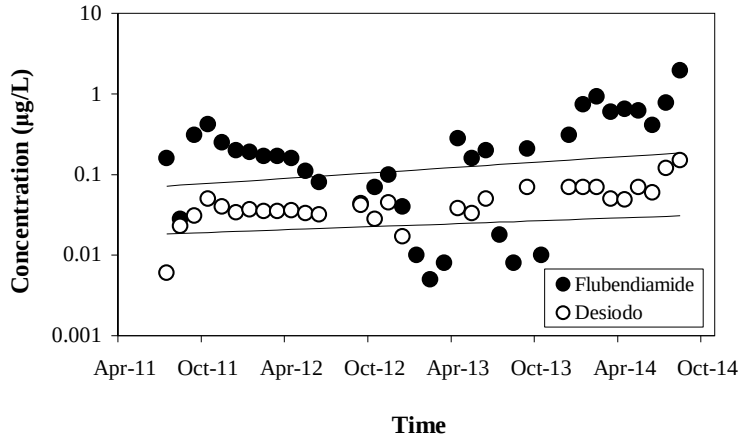
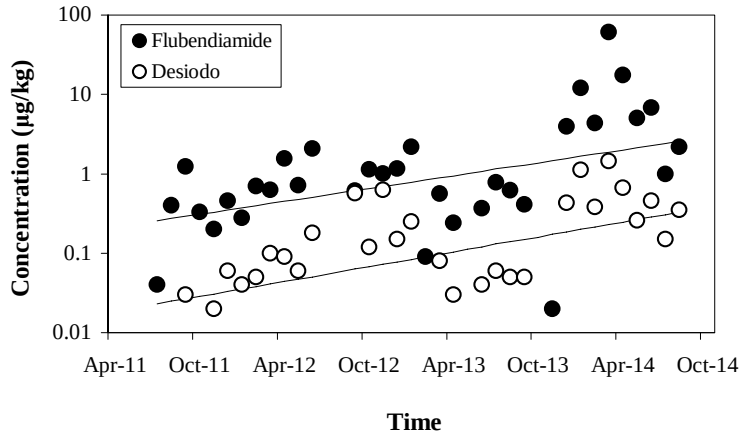
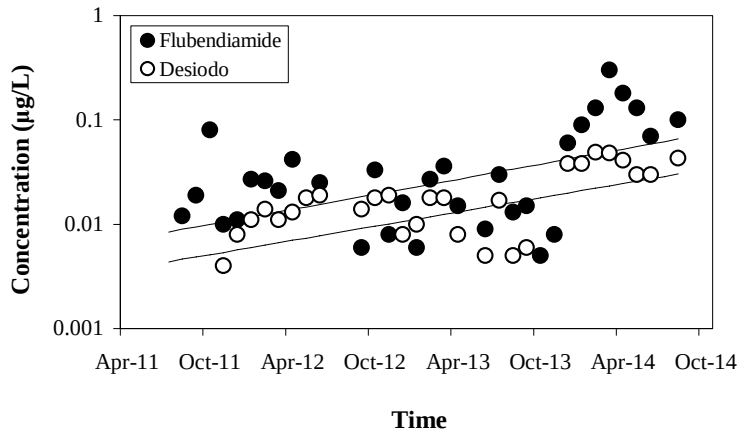
Concentration Data Over Time	Accumulation (change from beginning to end of trend line)
Water Column  	Flubendiamide: Increased 2.60× (0.071 to 0.19 µg/L) Upward exponential trend is not statistically significant (P = 0.2840) Des-iodo: Increased 1.68× (0.018 to 0.031 µg/L) Upward exponential trend is not statistically significant (P = 0.4675)
Sediment  	Flubendiamide: Increased 10.0× (0.26 to 2.57 µg/kg) Upward exponential trend is statistically significant (P = 0.0088) Des-iodo: Increased 10.55× (0.023 to 0.33 µg/kg) Upward exponential trend is statistically significant (P = 0.0002)
Pore Water  	Flubendiamide: Increased 7.84× (0.0084 to 0.66 µg/L) Upward exponential trend is statistically significant (P = 0.0005) Des-iodo: Increased 6.99× (0.0044 to 0.030 µg/L) Upward exponential trend is statistically significant (P < 0.0001)

Figure 3. Accumulation of flubendiamide and des-iodo in the water column (a), sediment (b), and pore water (c) of North Carolina pond.

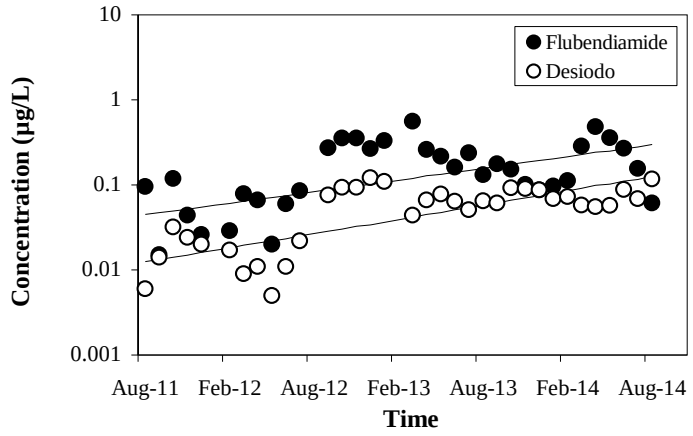
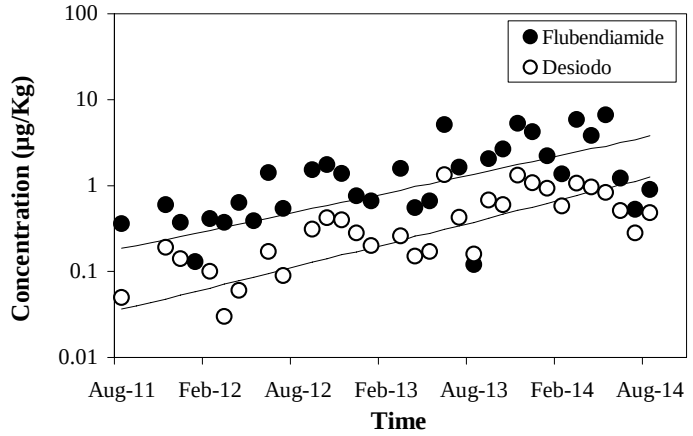
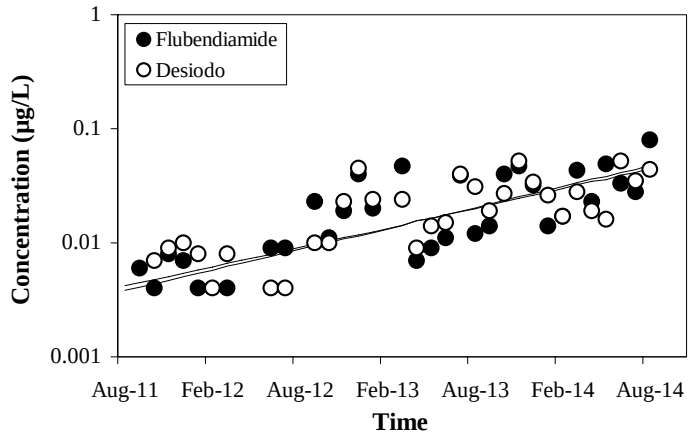
Concentration Data Over Time	Accumulation (change from beginning to end of trend line)
Water Column 	Flubendiamide: Increased 6.6× (0.045 to 0.30 µg/L) Upward exponential trend is statistically significant (P = 0.0002) Des-iodo: Increased 10.1× (0.013 to 0.13 µg/L) Upward exponential trend is statistically significant (P < 0.0001)
Sediment 	Flubendiamide: Increased 20.4× (0.19 to 3.80 µg/kg) Upward exponential trend is statistically significant (P < 0.0001) Des-iodo: Increased 34.6× (0.037 to 1.27 µg/kg) Upward exponential trend is statistically significant (P < 0.0001)
Pore Water 	Flubendiamide: Increased 12.5× (0.0039 to 0.048 µg/L) Upward exponential trend is statistically significant (P < 0.0001) Des-iodo: Increased 10.7× (0.0042 to 0.045 µg/L) Upward exponential trend is statistically significant (P < 0.0001)

Figure 4. Accumulation of flubendiamide and des-iodo in the water column (a), sediment (b), and pore water (c) of Georgia pond #1.

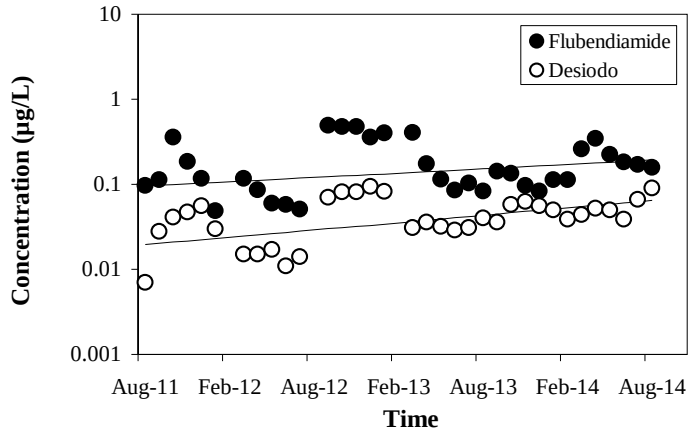
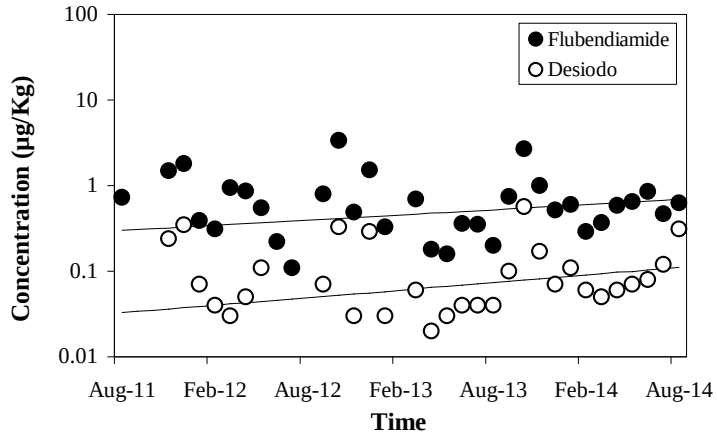
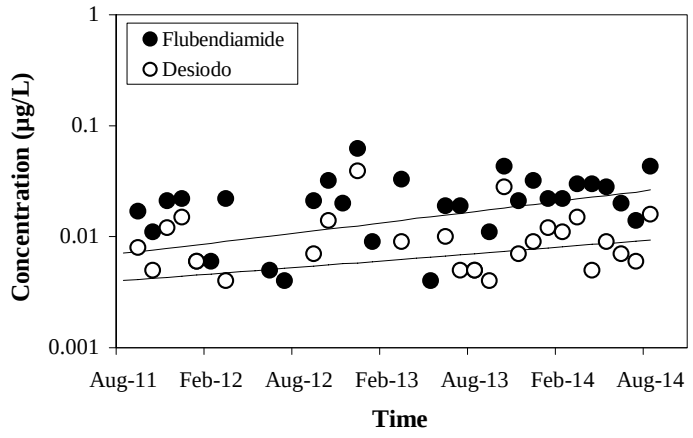
Concentration Data Over Time	Accumulation (change from beginning to end of trend line)
Water Column  	Flubendiamide: Increased 2.02× (0.096 to 0.19 µg/L) Upward exponential trend is not statistically significant (P = 0.1588) Des-iodo: Increased 3.30× (0.020 to 0.065 µg/L) Upward exponential trend is statistically significant (P = 0.0008)
Sediment  	Flubendiamide: Increased 2.30× (0.30 to 0.69 µg/kg) Upward exponential trend is not statistically significant (P = 0.1803 Des-iodo: Increased 3.38× (0.033 to 0.11 µg/kg) Upward exponential trend is statistically significant (P = 0.0377)
Pore Water  	Flubendiamide: Increased 3.71× (0.0071 to 0.026 µg/L) Upward exponential trend is statistically significant (P = 0.0044) Des-iodo: Increased 2.31× (0.0041 to 0.0094 µg/L) Upward exponential trend is not statistically significant (P = 0.0547)

Figure 5. Accumulation of flubendiamide and des-iodo in the water column (a), sediment (b), and pore water (c) of Georgia pond #2.

Comparison of Observed Concentrations in the Monitoring Study to Exposure Model Predictions
During the site selection phase of the monitoring study, the registrant made an attempt to select combinations of crops to be planted and pond watershed characteristics that were similar to EFED standard scenarios. However, EFED exposure scenarios are designed to represent high-end exposures and have many parameters embedded within the standard scenarios that would likely need adjustment to make a valid comparison between exposure model predictions to observed concentrations in a strict sense (field slopes, etc). Additionally, the SWCC cannot be parameterized for crop rotations, cannot account for VFSs (or the grassed waterways in the watershed of the GA ponds), assumes similar application timing and rates of pesticides applied each year, and assumes wind direction always deposits drift into the pond(s). Therefore the comparisons presented should be considered very "rough".

Figure 6 provides the comparison between exposure model predictions and observed concentrations for the NC pond. The SWCC modeling used the NC tobacco scenario[3] with the same input values as appear in Table 1 of the aquatic exposure report (MRID 49415301) with the exceptions that the benthic metabolism half-life value of 855 days was used (rather than the registrant modified value of 7300 days), the soil half-life of 0 (stable) was used (rather than the 10,000 day value in the aquatic exposure report), the efficiency (0.95) and drift (0.05) fractions were changed to 0.99 and 0.0082[4] because Table 1 indicates that these were ground applications under the application method section of this table, and standard pond dimensions were used. (EFED did not use the registrant modified weather files, files because they only provided to the agency in a pdf format as part of the report.)

The monitoring report does not contain sufficient information to identify a unique set of SWCC parameters for comparison with the NC pond data. For example, the report does not indicate whether the wind direction on the application date would have blown drift toward the pond. Therefore, three SWCC scenarios were run with different combinations of application rates and spray drift assumptions to bound reasonable SWCC parameterizations for the NC pond. The highest rates applied to the NC pond watershed (0.09 lb/A) with the EFED's current spray drift fraction (0.0082) is shown solid lines in Figures 6a to f). The lowest rates applied to the NC pond watershed (0.06 lb/A) with the EFED's current spray drift fraction (0.0082) is shown as dashed lines in Figures 6a to f. The third SWCC scenario used the lowest rates applied to the NC pond watershed (0.06 lb/A) with no drift (to simulate the lowest reasonable exposure scenario) and is show as dotted lines in Figures 6a to f. (Note: Figures 6a through f are presented with the y-axis as a log scale.)

The observed water column flubendiamide concentrations display a lot of scatter in Figure 6a, but contain concentrations that plot both above and below the SWCC predictions. Similarly, the observed water column des-iodo concentrations plot both above and below the SWCC predictions, but the concentrations that plot above the SWCC predictions occur toward the

[3] The crop in the NC pond watershed rotated from tobacco to soybean for two years and back to tobacco. EFED does not have mixed crop scenarios, but does have soybean scenarios from states other than NC. However, EFED simply used the scenario modeled by the registrant (MRID 49415301) without further exploration of alternative scenarios.
[4] Calculated with AgDrift based on a high boom ground application with a droplet size of ASAE fine to medium coarse (DV50 of 341um).

beginning of the monitoring. Additionally, the observed water column des-iodo concentrations display a lot less scatter (Figure 6b) than the flubendiamide concentrations (Figure 6a) and follow the trend much better in the latter half of the monitoring. The respective sediment concentrations (Figure 6c and d) and pore water concentrations (Figure 6e and f) all plot somewhat low compared to the SWCC predictions, consistent with the hypothesis that these samples are diluted with the underlying uncontaminated sediment and pore water lying below the higher surficial sediment and pore water concentrations (see previous discussion). Overall, the Agency believes the monitoring data tracks reasonably well with the modeled data and therefore, supports the previous predictions of aquatic exposure modeling and the prior flubendiamide risk assessments despite the fact that EFED's modeling cannot account any effect of the VFSs.

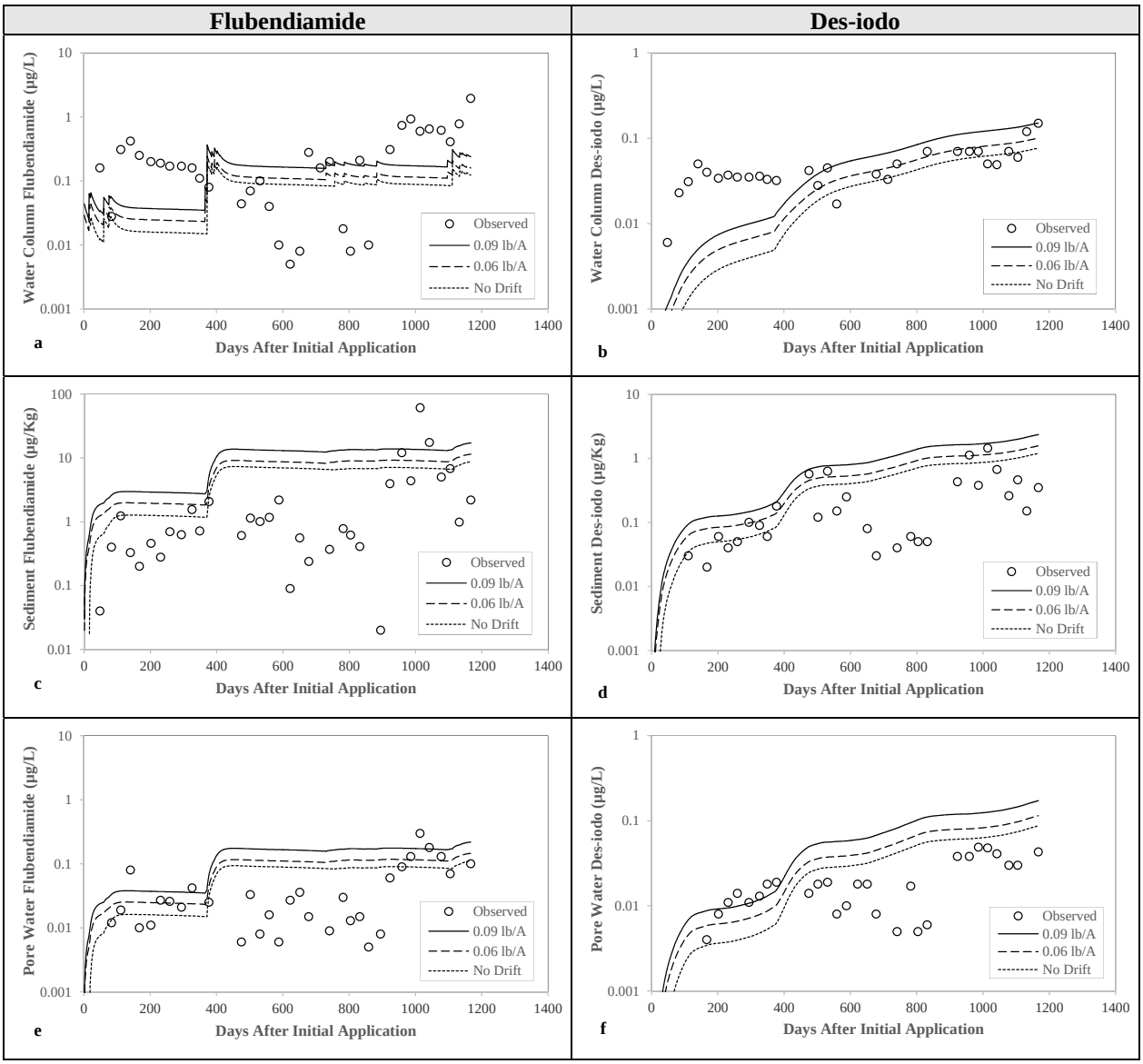


Figure 6. Comparison of Surface Water Concentration Calculator (SWCC) daily predictions from the North Carolina tobacco scenario to monitoring data from the North Carolina pond for water column flubendiamide (a) and des-iodo (b), sediment flubendiamide (c) and des-iodo (d), and pore water flubendiamide (e) and des-iodo (f) based on the range of application rates (0.06 to 0.09 lbs/A) used in the pond watershed during monitoring.

EFED assumes that any reduction in pond chemical concentrations in water column, sediment, and pore water concentrations from VFSs would be greatest when the chemical is first used and would diminish with time as the VFS became saturated with flubendiamide and des-iodo. Once saturated, the VFS might become a net source of the contaminants to the pond rather than a net sink. (EFED believes that VFSs would be more efficacious for pesticides that would rapidly breakdown into non-toxic degradates within the VFS.) From this rough comparison, the impact of the VFS does not appear to be large in the NC pond data.

Similar to the NC analysis, Figure 7 compares exposure model predictions and observed concentrations for the GA ponds. The SWCC modeling used the MS cotton[5] (solid lines in Figures 7a to f) and NC cotton[6] (dashed lines in Figures 6a to f) scenarios with the same input values as described for the NC scenario (only one application rate 0.09 lb/A was used since this did not vary in the GA pond watershed). A no drift scenario does not appear in the in Figure 7 because drift only accounts for ~2% of the flubendiamide reaching the pond in the MS and NC cotton scenarios and would have been indistinguishable from the predictions including drift. (Note: Figures 7a through f are presented with the y-axis as a log scale.)

Almost all of the GA ponds concentration data plots below the SWCC predictions. The interpretation of the GA ponds data is confounded by the presence of grassed waterways in the watershed. The combination of grassed waterways and VFSs (only VFSs are required by flubendiamide labels) would be expected to diminish transport of both flubendiamide and des-iodo to the ponds. The GA ponds data does appear to show the same pattern of sediment and pore water dilution in that the water column observations are much closer to the SWCC predictions (Figures 7a and b) than the sediment and pore water observations are (Figures 7c through d).

[5] The MS cotton scenario was modeled by the registrant in MRID 49415301.
[6] The NC cotton scenario was added by EFED because it is located in the same general region and to provide comparison with the MS cotton scenario.

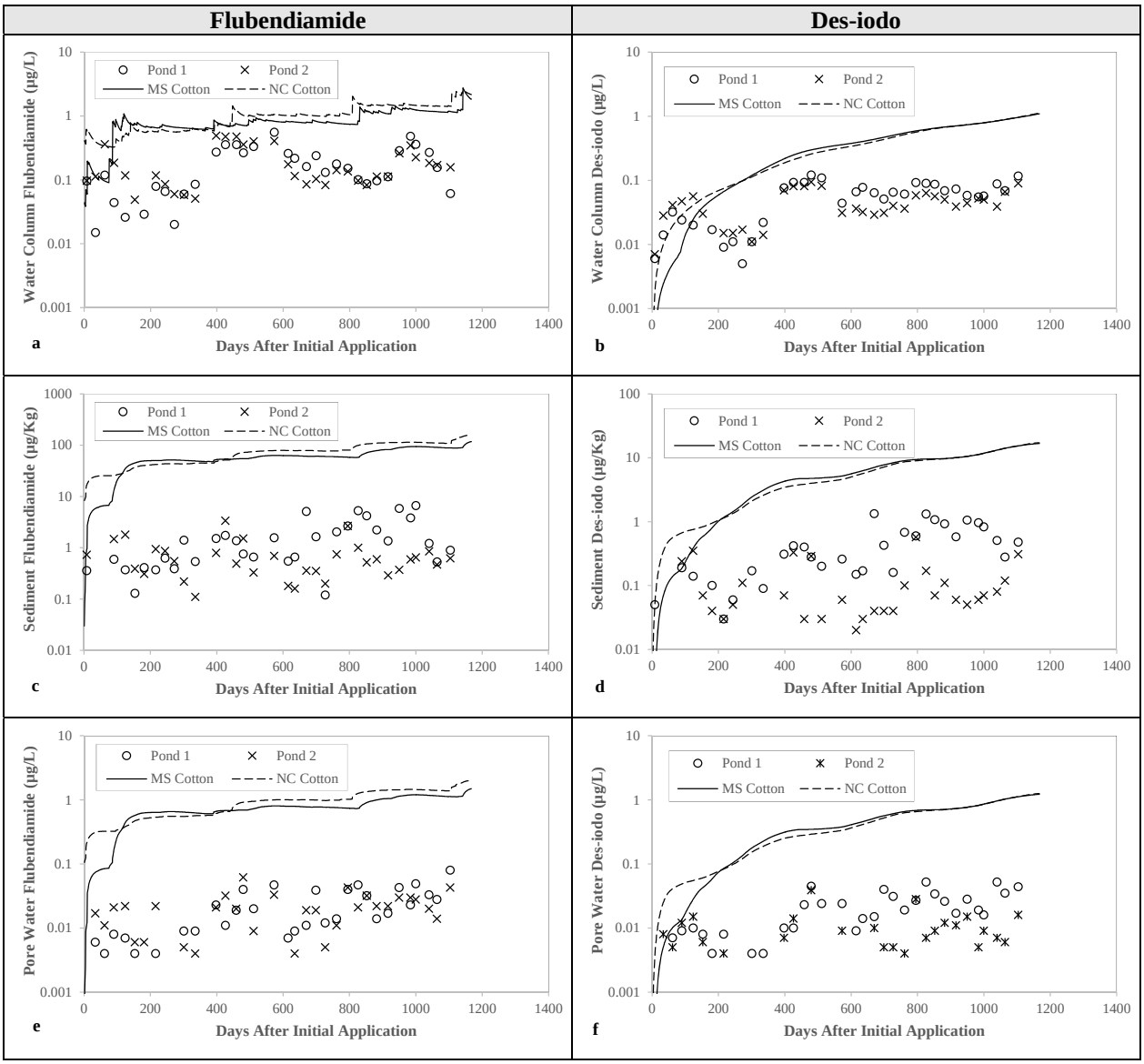


Figure 7. Comparison of Surface Water Concentration Calculator (SWCC) daily predictions from the Mississippi cotton and North Carolina cotton scenarios to monitoring data from the Georgia pond for water column flubendiamide (a) and des-iodo (b), sediment flubendiamide (c) and des-iodo (d), and pore water flubendiamide (e) and des-iodo (f).

Ecological Risk

Ecological risk is determined by comparing exposure estimates to Agency levels of concern (LOCs). Aquatic exposure is predicted over 30 years in Figure 8 for the NC tobacco scenario. These model results are based on the same parameters as the predictions that fit the NC pond data well, but use the maximum label rates instead (4 applications of 0.09 lb/A for an annual maximum of 0.375 lb/A assuming it is continuously planted to tobacco). Chronic aquatic invertebrate endpoints are also included in Figure 8. Because these chronic endpoints have an LOC of 1, an exposure exceeding an endpoint also exceeds the Agency LOC (*i.e.*, the LOC and the endpoint are the same number). Drawing a vertical line down from where the exposure crosses the appropriate endpoint indicates the time required for flubendiamide or des-iodo accumulation to exceed Agency LOCs. The water column des-iodo NOEC is exceeded after 8

years in Figure 8a and the pore water des-iodo NOEC is exceeded after 23 years in Figure 8b, while the pore water flubendiamide NOEC is exceeded after 7 years (also in Figure 8b). [Note: flubendiamide has already been on the market for 5 years (2009 to 2014). Also, at the lower application rates used in the monitoring study, it would take ~4 times as long to exceed all of these LOCs.] The NC tobacco scenario is not the worst case use (other scenarios exceed LOCs in shorter time periods).

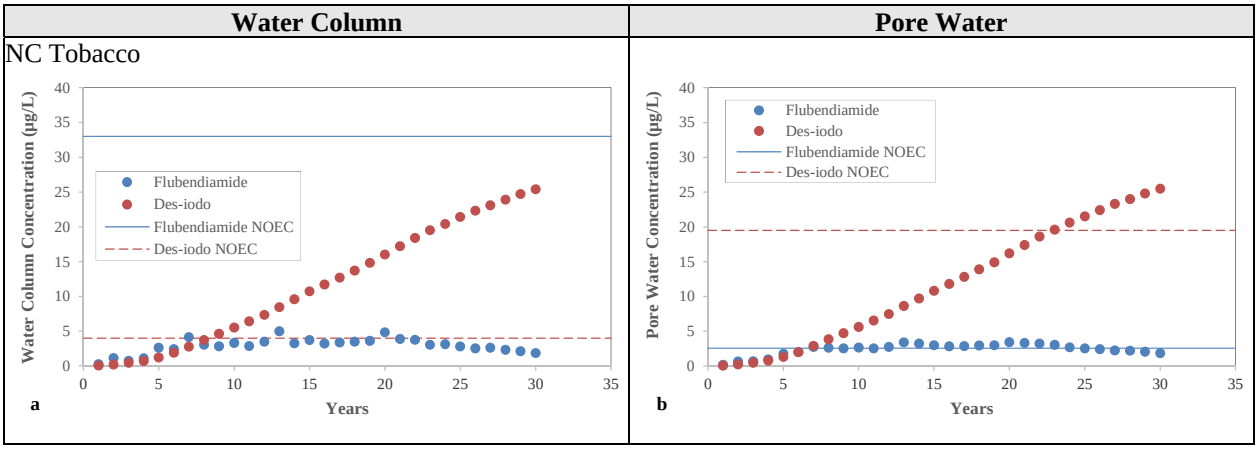


Figure 8. Accumulations of flubendiamide and its des-iodo degradate exceeding chronic risk endpoints in the standard pond water column (a) and pore water (b) based on ground applications to North Carolina tobacco at the maximum allowed application rate.

Additional monitoring at stream sites near these ponds found both flubendiamide and des-iodo in water column, sediment and pore water samples at all eight stream sites monitored (Appendix A). This stream data indicates low-level contamination in streams is currently pervasive in regions where flubendiamide is used.

The next section addresses each of the three submitted studies individually. For each study, a brief summary is provided with a list of issues raised in the study along with EFED comments on those issues.

Monitoring for Flubendiamide and its Metabolite Des-iodo Flubendiamide in Sediment and Surface Water (MRID 49415303)

Summary:
The objective of this study was to assess the potential for flubendiamide and its des-iodo metabolite to accumulate in aquatic environments (water and sediment) following drift and runoff of flubendiamide into surface water with multiple years of applications.

EFED Issue:
Much of the report only discusses measurements above the limit of quantitation (LOQ) rather than the method detection limits (MDL). For example, "(d)es-iodo flubendiamide was not detected above the LOQ in pore water in the farm pond in North Carolina" (p. 24). Yet, the flubendiamide data from the NC farm pond show a statistically significant ($P < 0.0001$) exponentially increasing trend according to the Agency's modeling from values below the LOQ. The Agency has discussed this issue with the registrant and has indicated that the registrant

should use all values down to the MDL. If the values between the MDL and LOQ are as randomly distributed as the registrant claims, including these values should make it more difficult to detect trends in accumulation over time. Use of these data should not spontaneously create trends where none actually occur.

Limits of quantitation are typically set between 3 and 10 times the MDL. The registrant has chosen 10 times the MDL for an accumulation study that modeling suggests will not accumulate to much more than the LOQ by the end of the monitoring study. Had the registrant applied the pesticide at the maximum application rate (and brought the grassed waterways to the attention of the Agency so that a different site could be monitored), using only the values above the LOQ may have been an option.

Registrant Comment:
"Overall, the results show negligible concentrations of des-iodo flubendiamide in water, pore-water or sediment, and no indication of formation of des-iodo flubendiamide in the water or sediment (*i.e.*, a decline in flubendiamide in sediment or water did not result in increases in des-iodo flubendiamide in sediment or water). Year-to-year variations in concentrations were observed, with highest residues occurring a few months after application, and then declining. There is no indication of accumulation of flubendiamide or des-iodo flubendiamide in pore-water, water or sediment in the pond, intermittent streams or permanent streams." (p. 27)

"These results indicate that low levels of flubendiamide residues can occur due to runoff from fields with recent applications of flubendiamide products. These residues are not significantly accumulating after three years of applications. This is expected due to the turnover of water and sediment in the moving water bodies, and water from the ponds. The sediment in the ponds, which might be expected to have accumulating residues, only showed year-to-year variations, and no indication of significant accumulation." (p. 30)

EFED Comments:
The report purports to look for accumulation over time, but there is no trend analysis presented. The Agency found that fitting trend lines to the data indicated that all 18 of the time series data sets from the ponds [3 ponds × 3 media [water column, sediments, and pore water] × 2 chemicals = 18 time series data sets] increased over time with 13 of the 18 identified as statistically significant. Considering just the sediment data discussed in the second quote above, five of the six sediment concentration trends were statistically significant. The Agency strongly disagrees with the registrant's assessment of no significant accumulation.

Flubendiamide Aquatic Risk – Summary of Surface Water Monitoring and Toxicity Testing (MRID 49415302)

Summary:
The registrant summarized the toxicity studies submitted to date for flubendiamide and des-iodo as well as a midge (*Chironomus riparius*) 28-d spiked sediment flubendiamide study that is yet to be submitted to the Agency.

Registrant Comment:
The appropriate chronic risk assessment endpoints to use for a flubendiamide and des-iodo flubendiamide sediment risk assessment are:

- Flubendiamide overlying water – NOEC 33 µg/L
- Flubendiamide pore water – NOEC 2.56 µg/L
- Des-iodo flubendiamide overlying water – NOEC 4 µg/L
- Des-iodo flubendiamide pore water – NOEC 19.5 µg/L

EFED Response:
EFED has evaluated all of these studies and provided a Data Evaluation Record (DER) for each with the exception of the aforementioned midge study that has yet to be submitted to the Agency. Some of these registrant-calculated endpoints differ slightly from the Agency determined endpoints. If the registrant believes the Agency-calculated endpoints are in error, the appropriate course of action would be to rebut the individual DERs. This report (MRID 49415302) does not contain sufficient explanation and analysis for the Agency to reconsider the endpoints. However for purposes of evaluating the studies submitted with the monitoring study (MRIDs 49415301 to 49415303), the Agency will use the registrant-calculated endpoints to avoid diverting focus from the issues the Agency has with the submitted monitoring and aquatic exposure reports.

Aquatic Exposure Assessment for Flubendiamide and its Metabolite Des-iodo Flubendiamide based on a 3-Year Monitoring Study (MRID 49415301)

Summary:
The overall objective of this report was to compare the results from a 3-year monitoring study at two locations with the potential aquatic estimated environmental concentrations (EECs) produced by the SWCC model. Both standard and modified scenarios were used as a means to better simulate field observations and to achieve insights into the factors governing the fate of flubendiamide and des-iodo at the field sites.

Registrant Comment:
"For GA, the SWCC overestimated peak flubendiamide concentrations in water and pore water by a factor of 3 and 17, respectively. Peak des-iodo concentrations were over-predicted by a factor of 11 and 26 in water and pore water, respectively." (p. 7)

EFED Response:
The Agency agrees the SWCC concentration predictions based on the MS cotton and NC cotton scenarios are higher than the concentrations observed in the GA pond. However, the Agency ascribes these discrepancies to problems with the registrant's data. The Agency believes the presence of the grassed waterways in the watershed of the GA ponds render these data unusable for comparison with the SWCC predictions. The pore water data discrepancy, which is larger than the water column data, is impacted by both the presence of the grassed waterways and potentially, the sample dilution issue. Additionally, there are other parameters such as field slope that would need adjustment before a direct comparisons could be made.

Registrant Comment:
"For NC, the SWCC under-predicted flubendiamide in water and pore water by a factor of 5 and 3 respectively. However, the NC site received an off-season, bare ground application in November of 2013 which led to greater runoff than would be expected in a typical growing season[7]. However, for des-iodo, the SWCC over-predicted water and pore water concentrations by a factor of 2 and 7, respectively." (p. 7)

EFED Response:
The Agency believes the SWCC predictions fit the water column data quite well (Figure 6a and b) and believes the differences in pore water concentrations (Figures 6e and f) are better ascribed to the previously discussed sample dilution issue.

Registrant Comment:
"The model also predicted exponential accumulation of both flubendiamide and des-iodo in the water and pore water, which was not observed in the field study." (p. 7)

EFED Response:
The Agency believes exponential accumulation was observed in the field study.

EFED Issue:
The registrant developed a series of increasingly complex model adjustments in order to get the SWCC predictions to align with the water column and pore water observations. The justification for making these adjustments was based almost entirely on the GA pond data and pore water data from both the GA and NC ponds, which the Agency believes to be inaccurate due to the presence of the grassed waterways (GA data) and the sample dilution issue (pore water data).

Conclusions

The monitoring study shows accumulation in all of the ponds monitored for both flubendiamide and des-iodo in water column, sediments, and pore water with 13 of the 18 pond accumulation trends identified as statistically significant. The VFS study (MRIDs 48175602, 48175604, and 48175606) and monitoring studies (MRIDs 49415301 to 49415303) did not provide evidence that VFSs provided significant reductions in flubendiamide and des-iodo transport to aquatic environments. The NC pond data provide a good match to the SWCC modeling (Figures 6a and b). This same model parameterization (after adjusting to maximum label application rates) produces exposure estimates that exceed Agency chronic LOCs (Figures 8a and b) for aquatic invertebrates in as little as 7 years. The NC tobacco scenario is not the worst case use (other scenarios exceed LOCs in shorter time periods). Flubendiamide and des-iodo are expected to accumulate in the environment and pose chronic risk concerns for aquatic invertebrates. Therefore, EFED concludes the original (D329613+) and subsequent ecological risk assessments performed by the Agency adequately reflect the risks posed by flubendiamide applications and

[7] According to the monitoring report, "The concentrations of flubendiamide and des-iodo flubendiamide were higher in 2013 and first part of 2014 which was mainly caused by the off-season application of Belt™ on bareground after soybean harvesting in 2013. Although application of Belt™ on bareground in November was not a good agricultural practice, the application was made to compensate for the grower not making a summertime application as expected."

rejects the registrant's argument that the label-required 15 ft VFSs would prevent accumulation from exceeding Agency LOCs.

Literature Cited

Dyer, D.G., and A.T. Hall. 2014. Flubendiamide Aquatic Risk – Summary of Surface Water Monitoring and Toxicity Testing. Bayer CropScience. Report Number: US0453. 16 pp. (MRID 49415302)

Hanzas, J.P., B. Toth, and J. White. 2011. Georgia Site Selection Report for "Monitoring for Flubendiamide and its Metabolite des-iodo Flubendiamide in Sediment and Surface Water". Bayer CropScience. Study Number: MEAMP011. 37 pp. (MRID 48644901)

Negley, T.L., D.K. Moore, and A.C. Newcombe. 2011. North Carolina Site Selection Report for "Monitoring for Flubendiamide and its Metabolite des-iodo Flubendiamide in Sediment and Surface Water" Bayer CropScience. Report Number: US0220. 50 pp. (MRID 48535201)

Pérez Ovilla, O. 2014. Aquatic Exposure Assessment for Flubendiamide and its Metabolite Des-iodo Flubendiamide based on a 3-Year Monitoring Study. Bayer CropScience. Report Number: US0453. 98 pp. (MRID 49415301)

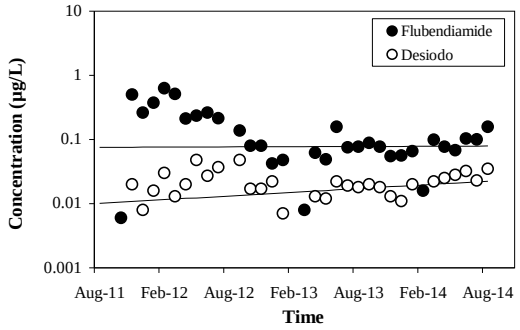
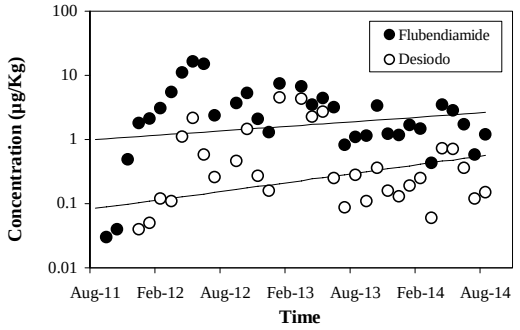
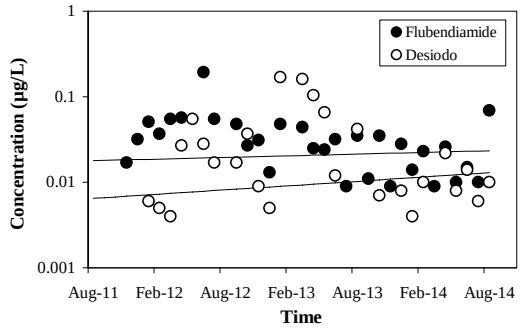
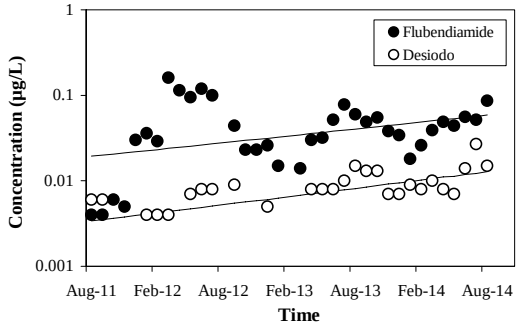
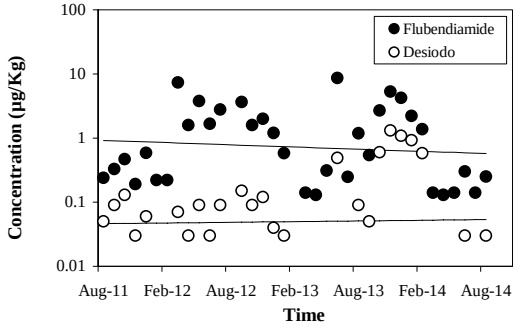
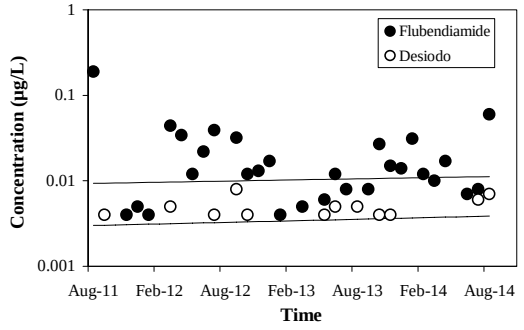
Xu, T. 2012. Monitoring for Flubendiamide and its Metabolite Des-iodo Flubendiamide in Sediment and Surface Water: Interim Report 1. Bayer CropScience. Study Number: MEAMP011. 349 pp. (MRID 48892501)

Xu, T. 2013. Monitoring for Flubendiamide and its Metabolite Des-iodo Flubendiamide in Sediment and Surface Water: Interim Report 2. Bayer CropScience. Study Number: MEAMP011. 74 pp. (MRID 49139801)

Xu, T. 2014. Monitoring for Flubendiamide and its Metabolite Des-iodo Flubendiamide in Sediment and Surface Water: Final Report. Bayer CropScience. Study Number: MEAMP011. 518 pp. (MRID 49415303)

Appendix A. Additional Monitoring Data from Flowing-Water Sites

EFED does not anticipate continuous accumulation at these flowing-water sites because any accumulation is continuously (water) or periodically (sediment) flushed downstream. Data from the Georgia and North Carolina flowing-water sites (located at different points in the larger watersheds that contain the GA and NC ponds) with trend lines (solid for flubendiamide and dashed for des-iodo) are presented in Figure A1 and A2, respectively. Because some of the data time-series from stream sites have few concentrations measured above the detection limit, the trend lines appear counter-intuitive.

Water Column	Sediment	Pore Water
Upstream Intermittent Stream Site		
		
Downstream Intermittent Stream Site		
		

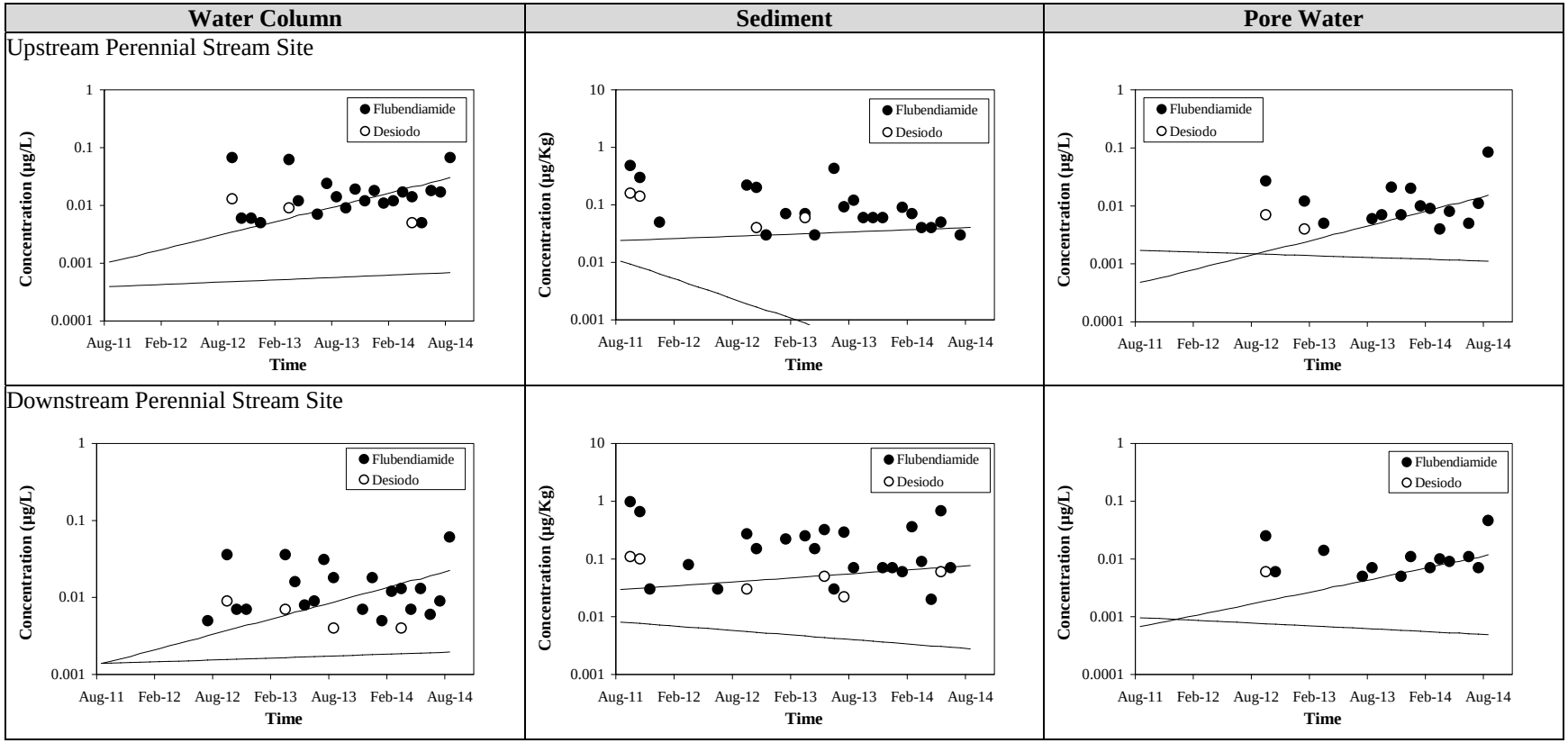
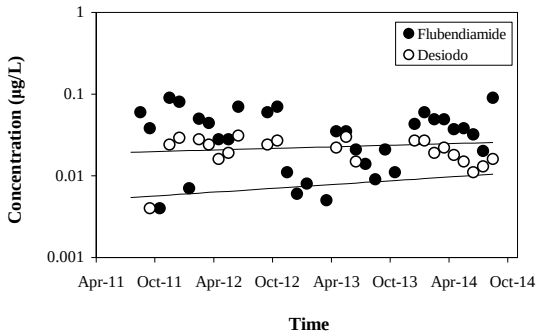
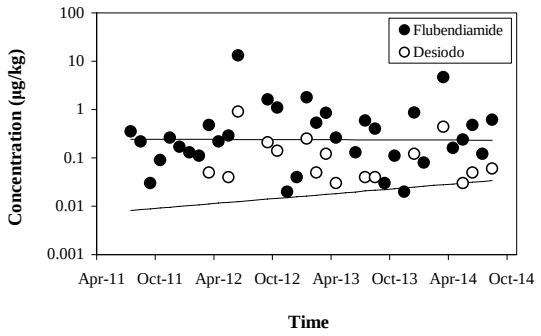
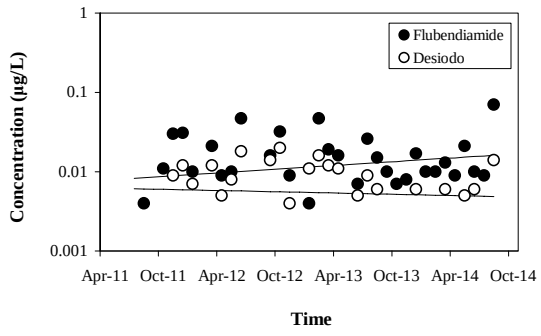
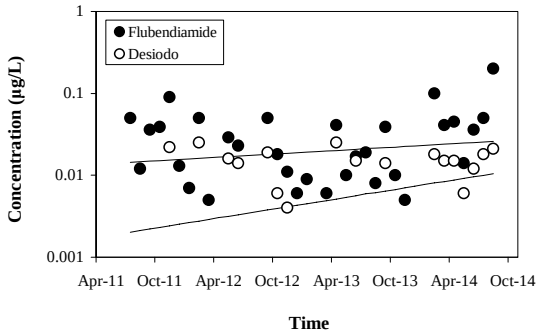
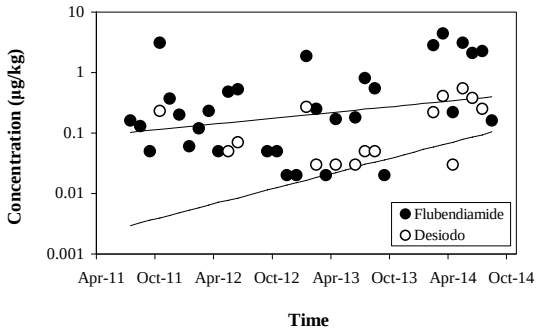
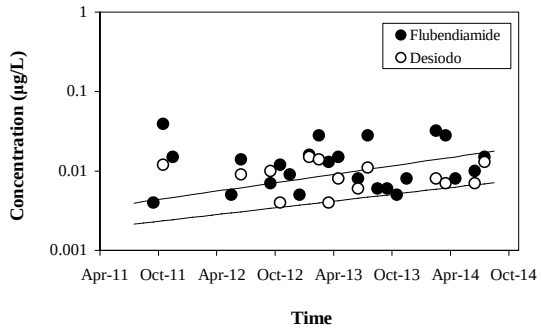


Figure A1. Georgia monitoring data from stream sites.

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

Water Column	Sediment	Pore Water
Upstream Intermittent Stream Site 		
Downstream Intermittent Stream Site 		

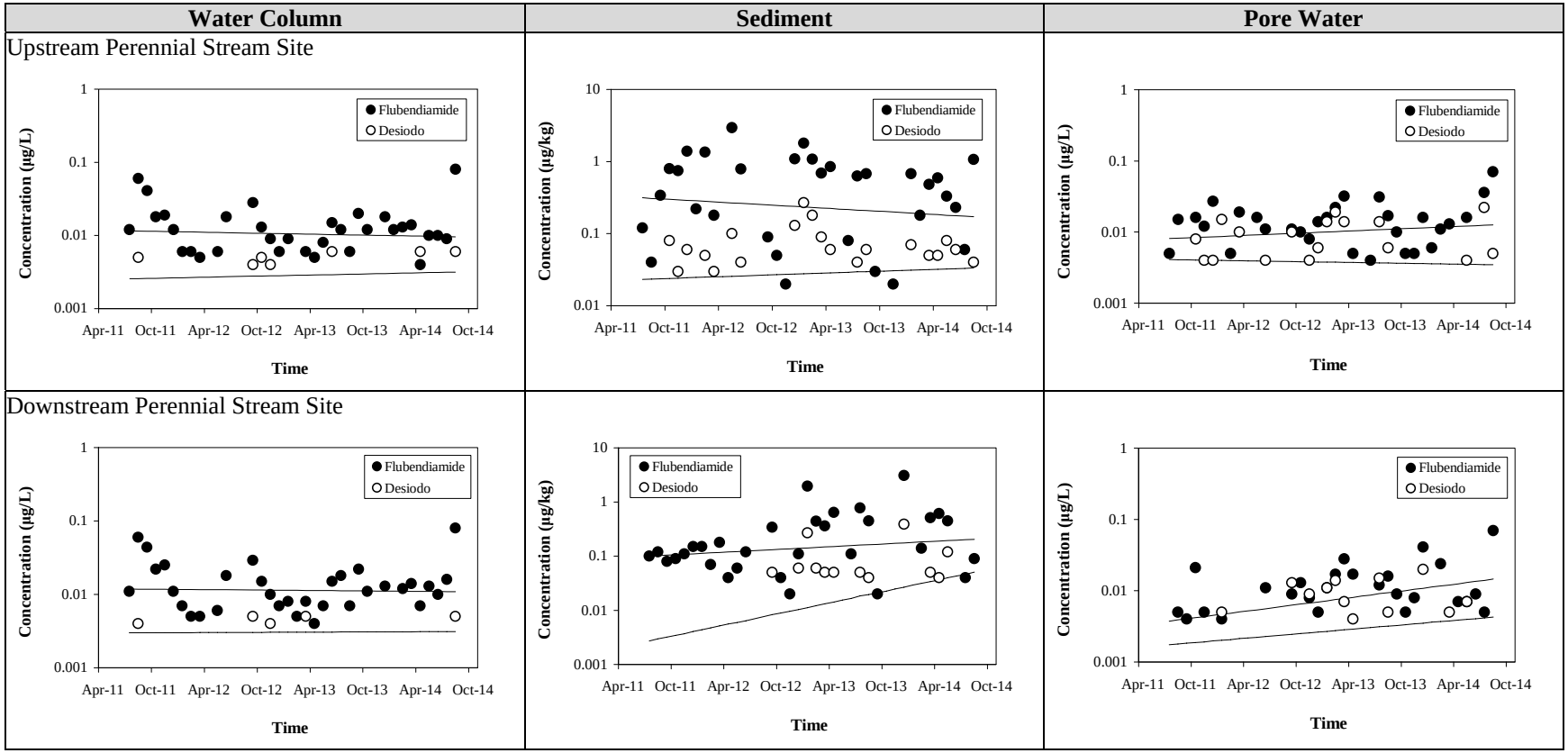


Figure A1. North Carolina monitoring data from stream sites.

Appendix B. Pore Water to Water Column Concentrations Ratios for Flowing Water Sites

The NC perennial stream exhibits pore water to water column concentration ratios that are much closer to 1 (Figure B1c and d) than the intermittent sites (Figure B1a and b) or the pond samples (see Figure 2a in the text). The NC perennial stream (the Tar River) is a large river at the sites sampled. Sediment depths are likely deeper and better mixed due to turbulent flow in the river, which may make it easier to sample sediment and pore water sample from a surficial layer with less dilution from deeper uncontaminated sediment and pore water. The intermittent stream samples had ratios that were intermediate in that they fell closer to 1 than the pond ratios, but further from 1 than the perennial stream samples.

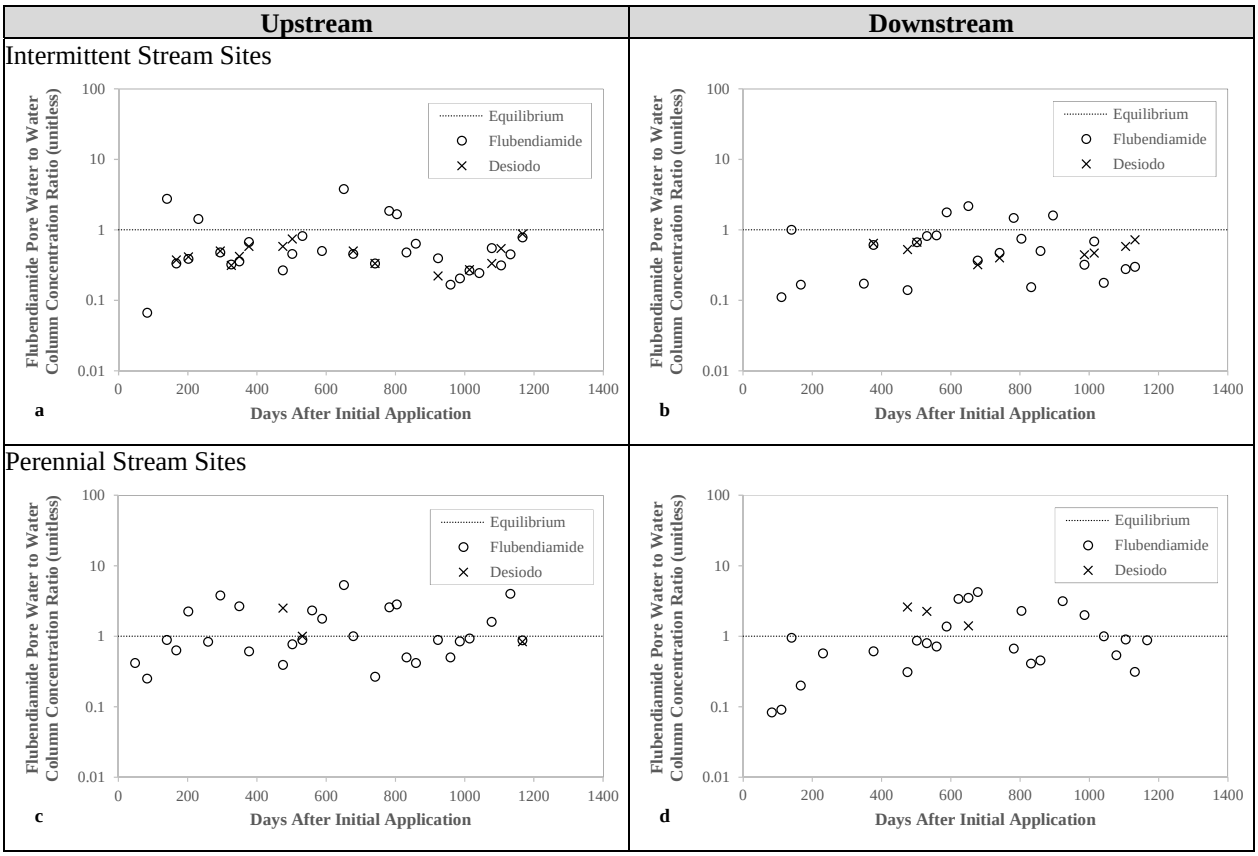


Figure B1. Comparison of pore water to water column concentration ratios for flubendiamide and des-iodo from intermittent (a and b) and perennial (c and d) near the North Carolina pond.

The GA perennial stream water column and pore water concentrations were relatively low. Therefore, early in the monitoring time frame, ratios could not be calculated because one or both concentrations fell below the detection limit. The later ratios from the GA perennial stream sites (Figure B2c and d) were distributed more like the GA (Figure B2a and b) and NC (Figure B1a and b) intermittent streams (the GA perennial stream is much smaller at the GA sample sites than the NC perennial stream is at the NC sample sites). Similar to the NC streams, the GA intermittent and perennial streams were much closer to a ratio of 1 than the GA pond ratios (Figure 2c in the text).

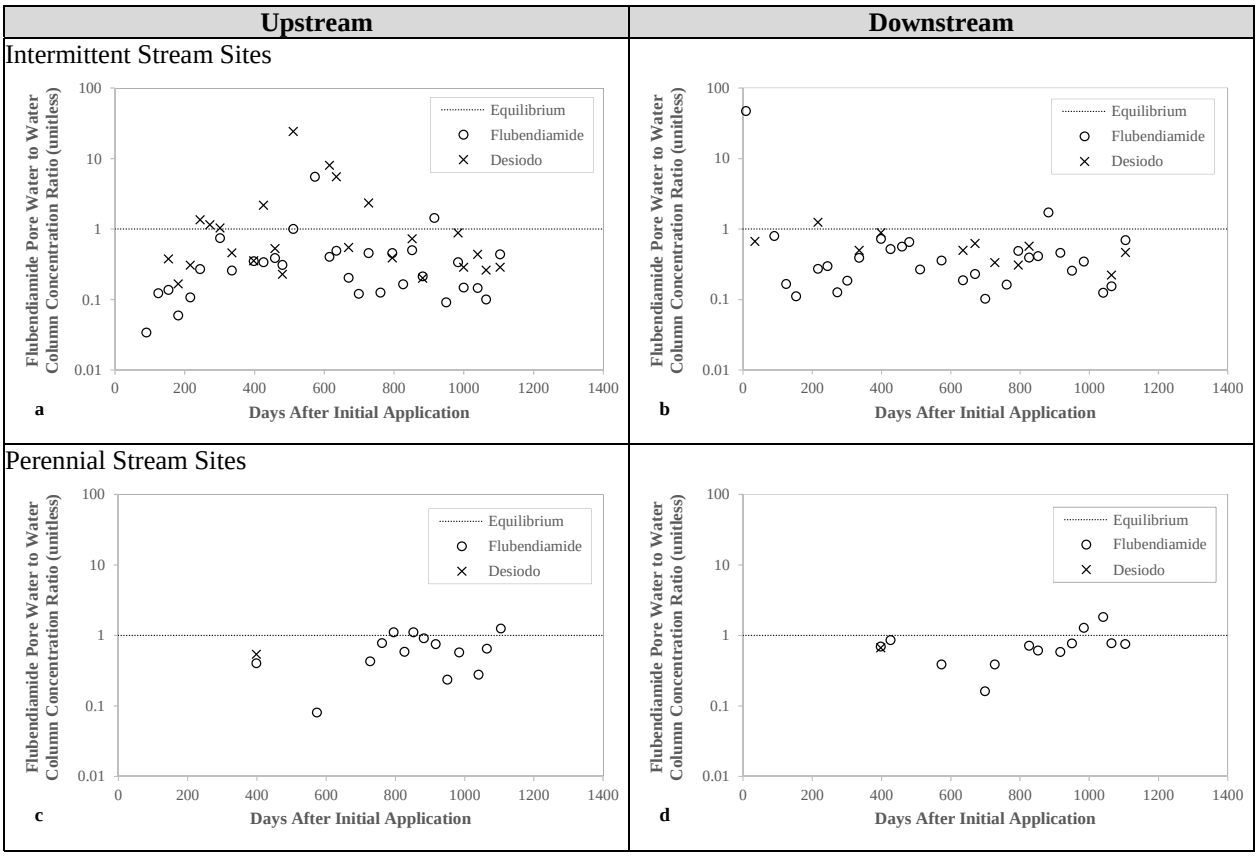


Figure B2. Comparison of pore water to water column concentration ratios for flubendiamide and des-iodo from intermittent (a and b) and perennial (c and d) near the Georgia ponds.

EXHIBIT 25

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 29, 2016

DECISION MEMORANDUM

SUBJECT: EPA Recommendation to Cancel All Currently Registered Flubendiamide Products (BELT™ SC Insecticide (EPA Reg. No. 264-1025); SYNAPSE™ WG Insecticide (EPA Reg. No. 264-1026); FLUBENDIAMIDE Technical (EPA Reg. No. 71711-26); VETICA® Insecticide (EPA Reg. No. 71711-32); and TOURISMO® Insecticide (EPA Reg. No. 71711-33))

FROM: Susan T. Lewis, Director
Registration Division (7505P)

TO: Jack E. Housenger, Director
Office of Pesticide Programs (7501P)

1. Regulatory Background

On August 1, 2008, the EPA granted a time-limited (5-year) conditional registration under section 3(c)(7) of FIFRA for flubendiamide to Bayer CropScience LP as agent for Nichino America, Inc., hereafter jointly identified as BCS/NAI. EPA issued a time-limited/conditional registration due to the Agency's initial concerns regarding flubendiamide's mobility, stability/persistence, accumulation in soils, water columns and sediments, and the extremely toxic nature of the primary degradate NNI-001-des-iodo (des-iodo) to aquatic invertebrates. Flubendiamide currently has foliar (ground & aerial) uses on over 200+ use sites with some crops having as many as 6 applications per year. Flubendiamide acts against the larvae of the target pests (Lepidoptera *spp.*) via oral ingestion of toxic residues on plants.

As a condition of registration, as established in the preliminary acceptance letter (PAL) for flubendiamide (copy attached), if the Agency makes a determination that further registration of the flubendiamide technical and end-use products will result in unreasonable adverse effects on the environment, within (1) week of this finding, BCS/NAI must submit a voluntary cancellation of the flubendiamide technical and all end use products. BCS/NAI's original release for shipment of the flubendiamide products constituted acceptance of the conditions of registration as outlined in the PAL. As stated in the notices of registration for each flubendiamide product, if the conditions of registration are not complied with, the registration for all flubendiamide products would be subject to cancellation in accordance with section 6(e) of FIFRA.
In addition, as part of these conditions of registration, BCS/NAI agreed to generate and submit a vegetative filter strip (VFS) study and, if the VFS proved to be ineffective in reducing the contamination, to conduct a farm pond water monitoring program. The VFS study was required to assess the efficacy of the BCS/NAI-proposed 15-foot VFS in field conditions. The VFS study was submitted to the Agency on August 3, 2010. Prior to the Agency's completion of the VFS study review, BCS/NAI submitted a waiver request for the farm pond water monitoring program study. This waiver request was denied by the Agency via a letter dated November 8, 2010 because the Agency had identified a major modeling error in BCS/NAI's VFS study and believed that even if the error was corrected, a VFS "would be insufficient to preclude ecological risk concerns". As a result, the second data-related condition of registration, the farm pond water monitoring program was triggered. The farm pond water monitoring program was comprised of 3 years of water monitoring from 2 VFS-protected farm ponds in Georgia and North Carolina (submitted December 22, 2014). The Agency review, provided to BCS/NAI on February 20, 2015, indicated that both flubendiamide

and des-iodo were accumulating in all of the farm ponds' overlying water, sediment, and pore water; therefore, the VFSs were ineffective at preventing flubendiamide and des-iodo from accumulating in aquatic systems downstream of the fields to which flubendiamide had been applied.

2. Time-Limited/Conditional Registration Expiration Date Extensions

The original time-limited/conditional registration expiration date for flubendiamide was July 31, 2013; however, BCS/NAI has requested several extensions to the time-limited/conditional registration expiration date, with the latest extension out to January 29, 2016. The latest extension allowed EPA to host a technical discussion between its scientists and BCS/NAI scientists on January 6, 2016, which allowed them to engage in dialogue related to the conditional data and the EPA's conclusions related to flubendiamide. This extension also allowed additional time for EPA to review 2 newly submitted data volumes (an aqueous photolysis study and a spiked sediment study) and to consider the most recent label proposal submitted by BCS/NAI on January 8, 2016.

3. Human Health Risk Assessment:

No human health concerns have been identified with the use of flubendiamide. The human health assessment for flubendiamide has not changed since the initial risk assessment in 2008. Flubendiamide has a low acute oral (LD_{50} >2,000 mg/kg body weight/day (mg/kg/day)); dermal (LD_{50} >2,000 mg/kg/day); and inhalation toxicity (LC_{50} >68.5 mg/m^3 air). Though it is a slight irritant to the eye, flubendiamide is not a skin irritant and it is not a skin sensitizer. The primary target organ is liver with thyroid and kidney effects being secondary. Ocular effects were observed in multiple studies and used for acute dietary risk assessment. Flubendiamide is considered "Not Likely to be Carcinogenic to Humans," and was not mutagenic. There is no residual uncertainty for pre- and post-natal toxicity, and flubendiamide is not neurotoxic. The FQPA safety factor was reduced to 1X. Aggregate exposure (refined food and updated estimated drinking water concentrations) are below the Agency's level of concern. EPA has not found flubendiamide to share a common mechanism of toxicity with any other substances, and flubendiamide does not appear to produce a toxic metabolite produced by other substances.

4. Ecological Fate and Effects Risk Assessments

Flubendiamide has been subject to three (3) ecological fate and effects risk assessments. The initial assessment, dated June 23, 2008, was followed by two (2) subsequent separate assessments (May 17, 2010 and December 16, 2010, respectively) to add new crops/uses in 2010. The most recent document: "*Flubendiamide: Ecological Risk Assessment Addendum Summarizing All Submissions and Discussions to Date*," dated January 28, 2016, is an addendum/compilation of all of the ecological fate and effects submissions and technical discussions with BCS/NAI to date.

The June 23, 2008 risk assessment addressed BCS/NAI's initial registration proposals for one (1) technical product and two (2) flubendiamide end-use product formulations. The 480 SC product was proposed for corn, cotton, tobacco, grapes, pome fruit, stone fruit, and tree nut crops. A second formulation, 24 WG, was proposed for use on cucurbit vegetables, fruiting vegetables, leafy vegetables, and brassica (cole) leafy vegetables.

The June 23, 2008 risk assessment's evaluation of the physical and chemical properties of flubendiamide indicated that flubendiamide is stable to hydrolysis, aerobic and anaerobic soil metabolism, and aerobic aquatic metabolism. Photolysis and anaerobic aquatic metabolism were reported to be the main routes of degradation for flubendiamide. Flubendiamide degrades to des-iodo under anaerobic aquatic conditions ($t_{1/2}$ = 364 days) and direct aqueous photolysis ($t_{1/2}$ = 11.6 days), but rather slowly by soil photolysis ($t_{1/2}$ = 70.5 days). Submitted fate data indicate flubendiamide slowly converts to its des-iodo degradate, which

does not further breakdown. Flubendiamide and des-iodo were reported to have the potential for groundwater contamination in vulnerable soils with low organic carbon content after a very heavy rainfall and/or in the presence of shallow groundwater.

The June 23, 2008 risk assessment also noted that the overall stability/persistence profiles for flubendiamide and the des-iodo degradate were suggestive of accumulation in soils, water column, and sediments with each successive application. Analysis of available ecological effects data resulted in the conclusion that both flubendiamide and its des-iodo degradate were of toxicological concern. EFED modeling predicted that flubendiamide and des-iodo would accumulate in aquatic systems eventually exceeding Agency LOCs, and concluded that there is a potential for risk to benthic invertebrates[1] exposed to flubendiamide and its des-iodo degradate, and that the formulated products 480 SC and 24 WG do result in direct acute and chronic risk to freshwater invertebrates. The acute risk issue is relatively minor and refers to enhanced toxicity of the formulations compared to the technical grade active ingredient (applicable only to direct application to aquatic environments through spray drift), while the chronic risk to freshwater invertebrates is the major risk concern. Because of these chronic aquatic risk concerns, two (2) data-related conditions of registration were imposed and conveyed to BCS/NAI by the PAL:

- Vegetative Filter Strip Study – a run-off study to determine the magnitude of the parent, flubendiamide, retained in buffer strips of various widths; and
- Farm Pond Water Monitoring Program – if a risk assessment, based on the results from the small-scale run-off/vegetative filter strip study and additional available data, indicates that there are still risk concerns, monitoring of selected receiving waters will be required within watersheds where flubendiamide will be used.

According to the flubendiamide PAL, the "Agency believed that the efficacy of vegetative buffers for flubendiamide use is uncertain." Since 2008, BCS/NAI has argued that: (1) VFSs would prevent accumulation from exceeding Agency LOCs (flubendiamide labels require a 15-foot VFS around aquatic areas); and (2) the Agency overestimates aquatic exposure because the EFED modeling cannot account for the effect of VFSs. During the Agency's cursory review of the VFS study protocol, a major modeling error was identified. The Agency requested the study be corrected and re-submitted; however, BCS/NAI never re-submitted a corrected study. Therefore, the second data-related conditional registration requirement, the 'farm pond' water monitoring program, was triggered.

The May 17, 2010 environmental risk assessment addressed additional registration proposals for 480 SC formulation use on Christmas trees and legume vegetables including soybeans, and the 24 WG formulation for rotational plant-back interval use for legume vegetables. The conclusions of the May 17, 2010 risk assessment were not markedly different from the 2008 risk assessment's characterization of the environmental fate, stressors of concern, nor the risk conclusions: (1) concern for long-term accumulation of the parent flubendiamide and the des-iodo degradate; (2) flubendiamide and the des-iodo degradate as stressors of concern and; (3) risk concerns for benthic invertebrates from both flubendiamide and the des-iodo degradate as well as surface water concerns for the formulations to freshwater invertebrates. However, the risk assessment also addressed the potential for distance buffers between application sites and surface waters as a risk mitigation option. The May 17, 2010 risk assessment concluded that buffers, from a spray drift perspective, would have little impact on the risks of concern.

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[1] Some species of aquatic invertebrates inhabit the overlying water (water above the sediment in a water body), while others inhabit the benthic zone (in or on the sediment in a water body). Because exposure and effects endpoints can vary between overlying and benthic (or pore) water, it is sometimes necessary to specify overlying or benthic if referring to only one portion of the water body or one of these groups of aquatic invertebrates.

The December 16, 2010 risk assessment addressed proposed new uses of flubendiamide on alfalfa, globe artichoke, low growing berries (except cranberry), peanut, pistachio, small fruit vine climbing (except fuzzy kiwifruit), sorghum, sugarcane, sunflower, safflower, turnip greens, and a proposed increased application rate on brassica leafy vegetables. The proposed new uses and increased rate included the water dispersible granule formulation SYNAPSE™ WG (39% flubendiamide) and BELT™ SC (24% flubendiamide), a suspension concentrate formulation. Flubendiamide was proposed for ground application, aerial application (restricted for pistachio, and small fruit vine climbing group), and chemigation. Again, as in the previous risk assessments, flubendiamide and the des-iodo degradate were identified as the stressors of concern. Environmental fate and transport data indicated that flubendiamide is stable to hydrolysis, aerobic and anaerobic soil metabolism, and aerobic aquatic metabolism. Photolysis and anaerobic aquatic metabolism appeared to be the main routes of degradation for flubendiamide.

Flubendiamide degrades to des-iodo under anaerobic aquatic conditions ($t_{1/2}$ = 364 days), direct aqueous photolysis ($t_{1/2}$ = 11.6 days), and by soil photolysis ($t_{1/2}$ = 35.3 days). Flubendiamide was expected to be slightly to hardly mobile in the environment. The des-iodo degradate was concluded to be persistent (stable in an aerobic soil environment) and expected to be moderately mobile. As in the previous risk assessments, concern was indicated for chronic risk to benthic invertebrates from exposures in the water column and pore water from the total residues of flubendiamide and des-iodo. The December 16, 2010 risk assessment mentions that a field study of the efficacy of vegetative filter strips to reduce pesticide loading to surface waters was under review at the time of writing. However, the results of that study were not incorporated into the December 16, 2010 risk assessment.

5. Label Proposal, Additional Data and Interactions with BCS/NAI

The 3-year report on the farm pond water monitoring study of water column, sediments, and pore water in 3 ponds (2 in Georgia and 1 in North Carolina) was submitted by BCS/NAI in December of 2014. The Agency's review has identified several issues with this monitoring data. Despite these issues, EPA believes the monitoring data shows clear evidence that both flubendiamide and des-iodo accumulate in the ponds monitored. The accumulation measured in the first 3 years of the pond data largely matches the initial predictions. Because 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. Our conclusion is the original and subsequent ecological risk assessments performed by the Agency adequately reflect the risks posed by flubendiamide applications and rejects BCS/NAI's argument that the label-required 15-foot VFSs around aquatic areas would prevent accumulation from exceeding Agency LOCs. Accumulation was consistent with the Agency's 2008 model predictions for a pond without grassed waterways. Since both flubendiamide and des-iodo were found to be accumulating in surface water, sediment, and pore water in all three of the VFS-protected ponds monitored, the VFSs were deemed ineffective in preventing accumulation of flubendiamide and des-iodo in water bodies.

In late October 2015 through January 2016, numerous re-review and validation refinements of the ecological and fate data evaluation records and new model scenarios occurred in critical documents. BCS/NAI also asked the Agency to consider various label mitigation options of reducing crops and application rates and frequency, deleting aerial use and considering an increase in the buffer size so that the chemical might retain its active registration status. The Agency performed numerous series of "bracketing scenarios" of label applications and rates. Also during this time, the water values were reassessed by using a time-weighted average (TWA) approach instead of a single measured value. This recalculation of TWA values reduces the LOAEC for parent flubendiamide in overlying water by a factor greater than two and pore water by a factor slightly greater than one. The TWA values factor in the variability of measured concentrations rather than relying on a single measured value at onset of test consistent with current guidance in EFED. Recalculation of TWA values for the des-iodo degradate produced no change in the NOAEC values for overlying and pore water. These latest proposed label mitigation scenarios exceed Agency

LOCs based on TWA endpoints.

6. Comparison of EPA Use of Flubendiamide and Des-iodo Toxicity Endpoints in Previous Risk Assessments

A comparison of the use of the flubendiamide toxicity endpoints in the previous risk assessments shows that TWA concentrations were not reported in the previous risk assessments for the NOAEC in overlying and pore waters, and shows that they reported the LOAEC as a single post-application measured dose of 69 µg/L in overlying water and 3 µg/l in pore water. In addition, a comparison of the use of the des-iodo degradate toxicity endpoints in the previous risk assessments shows that TWA concentrations are the same as those in previous risk assessments for the NOAEC in overlying and pore waters, and that the previous risk assessments did not report a TWA for the LOAEC. A detailed summary of the toxicity endpoints used in previous risk assessments for flubendiamide and des-iodo is shown within Tables 3 and 4, on pages 7 to 8, of the EFED document entitled "*Flubendiamide: Ecological Risk Assessment Addendum Summarizing All Submissions and Discussions to Date*," dated January 28, 2016.

7. Final Suite of Available Effects Toxicity Endpoints

Table 1 lists the final suite of flubendiamide and des-iodo chronic toxicity endpoints for *Chironomus riparius* (an aquatic invertebrate of the benthos) in spiked water and spiked sediment tests. Consistent with other studies with this species and sediment, emergence of the organisms proved to be the most sensitive endpoint. These endpoints are all based on emergence inhibition. (For example, 80% emergence inhibition indicates that 80% of the test organisms were unable to emerge as the adult, reproductive life-stage from the sediment where the juveniles reside, while 20% were able to emerge and potentially complete their life-cycle.)

Table 1. Current Flubendiamide and Des-iodo Toxicity Endpoints for *Chironomus riparius* in Spiked Water and Spiked Sediment Tests.

Overlying Water TWA (µg/L)	Pore Water TWA (µg/L)	Endpoint Label
Flubendiamide Endpoints in Chironomus Spiked Water 28-Day (MRID 46817022)		
15.5	1.51	NOAEC Percent emergence
29.9	2.50	LOAEC 22% inhibition
62.0	6.05	100% inhibition
Flubendiamide Endpoints in Chironomus Spiked Sediment (MRID 49661801) (in review)		
5.23	1.53	NOAEC Percent emergence
12.3	4.32	LOAEC Percent emergence
Des-iodo Endpoints in Chironomus Spiked Water 28-Day (MRID 46817023)		
1.90	0.278	NOAEC Percent emergence
4.14	0.737	LOAEC 17% inhibition
8.27	1.47	33% inhibition
16.0	3.91	80% inhibition
Des-iodo Endpoints in Chironomus Spiked Sediment (MRID 48175605)		
7.18	19.5	NOAEC (Highest dose tested)
>7.18	>19.5	LOAEC

8. Discussion of Ecological Fate and Effects Data Submitted after the Last Risk Assessment Dated December 16, 2010

Several ecological fate and effects studies have been submitted since the December 16, 2010 risk assessment for flubendiamide. In 2015, while the evaluation of all lines of evidence was underway with respect to the efficacy of vegetative filter strips, model assumptions, and surface water monitoring, the RD

risk managers requested that exposure modelling results be compared to the full suite of effects endpoints from the two spiked water prolonged sediment toxicity tests with *Chironomus riparius* (MRIDs 46817022 (flubendiamide) and 46817023 (des-iodo degradate)). As a result, EPA scientists issued a memorandum that summarized the approach for evaluation of the two studies, and the findings of that effort. A detailed summary of the resulting toxicological endpoints for flubendiamide and des-iodo, expressed as TWA, is shown within Tables 1 and 2, on page 7, of the EFED document entitled "*Flubendiamide: Ecological Risk Assessment Addendum Summarizing All Submissions and Discussions to Date*," dated January 28, 2016.

9. Ecological Fate Data

The flubendiamide fate data interpretation has not changed since the new chemical assessment in December 16, 2008. Additional laboratory fate data was requested and submitted for the des-iodo degradate after the new chemical assessment. All of this additional des-iodo fate data indicated that the des-iodo degradate does not degrade in the environment with the exception of the des-iodo aquatic photolysis study that was recently submitted on January 5, 2016.

10. New Des-iodo Aquatic Photolysis Study (MRID 49661701)

BCS/NAI submitted a 10-day aqueous photolysis study on January 5, 2016, that estimates a 79-day half-life for the des-iodo degradate when expressed as an environmentally relevant half-life for June in Phoenix, AZ. While this study is in review, the following is a preliminary analysis:

"At the end of the 10-day aqueous photolysis study, 77% of the des-iodo remained as untransformed des-iodo. The other 23% had transformed into 14 degradates and CO_2. Because so many degradates together make up so little mass, no degradate exceeded 6% and only two degradates could be identified. None of the degradates have toxicity data, so none can be ruled out as degradates of concern other than CO_2. Assuming that all of the degradates, other than CO_2, are degradates of concern would produce a total toxic residue (TTR) half-life exceeding 1,000 years."

11. Tree Nut Use Modeling

At the most recent technical meetings between EPA scientists and BCS/NAI scientists on January 6, 2016, BCS/NAI inquired about the possibility of submitting a new label mitigation proposal where BCS/NAI would retain only one use – tree nuts on their label, and stated that it would not exceed any of the Agency's LOCs. On January 8, 2016, BCS/NAI submitted a new revised label to the Agency that: (1) eliminated aerial applications; (2) limited use to tree nuts in California only; and (3) further limited application rates for tree nut uses below that on the current label for EPA Reg. No. 264-1025 (BELT™ SC Insecticide).

Modeling of this proposed remaining use allowed the Agency to perform an assessment of not only the reduced application rates, but also allowed EPA to incorporate the 79-day aqueous photolysis half-life data for des-iodo into this assessment. Previous analyses were unable to use this half-life estimate since it was only just submitted to the Agency on January 5, 2016. Flubendiamide air blast applications to tree nuts were modeled using the California almond scenario, based on an application rate of 0.125 pound of active ingredient per acre with a 7-day application interval and up to 3 applications per year. The scenario modeled assumes that flubendiamide has not previously been used in the fields to which it is to be applied, and includes a 30-ft spray drift buffer zone around aquatic areas based on the new proposed label (previous modeling had only included a 15-ft spray drift buffer zone which was correct based on the spray drift language of the previous labels).

To provide an estimate of the ecological effects to be anticipated at different RQ levels, the NOAEC and any additional treatment levels that showed a significant effect above the NOAEC were included. Analyzed endpoints include both the Agency endpoints based on TWAs and the BCS/NAI-suggested endpoints that are not supported by the Agency guidance.

A detailed summary of the comparison of EFED's most sensitive endpoints based on TWA concentrations and BCS/NAI-suggested most sensitive endpoints for flubendiamide and its des-iodo degradate, is shown within Table 6, on page 10, of the EFED document entitled "*Flubendiamide: Ecological Risk Assessment Addendum Summarizing All Submissions and Discussions to Date*," dated January 28, 2016. All of the existing uses for the time-limited/conditional flubendiamide registrations as well as the latest proposed use scenarios exceed the Agency LOCs for aquatic system invertebrates based on the TWA effect endpoints from *C. riparius* testing compared with estimated toxicant concentrations for sediment pore- and overlying-water.

12. Integration of New Ecological Fate and Effects Information into the Amended EFED Risk Assessment

Results from the Farm Pond Water Monitoring Study: At the end of three (3) years of water monitoring, BCS/NAI submitted the final farm pond water monitoring reports. In its review, EFED identified several issues with this monitoring data. Despite these issues, EFED believed the monitoring data showed clear evidence that both flubendiamide and des-iodo accumulated in the ponds monitored. The accumulation measured in the first 3 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. Because EPA's modeling does not account for the effect of VFSs, but still largely matched the monitoring data, EPA believes the effect of VFSs is not large enough to mitigate the ecological risks posed by flubendiamide applications. EPA concluded the original and subsequent ecological risk assessments performed by the Agency adequately reflect the risks posed by flubendiamide applications and rejects BCS/NAI's argument that the label-required 15-foot VFSs would prevent accumulation from exceeding Agency LOCs.

Analysis of Results from Four Regulatory Scenarios for Multiple Crops: The Agency compared four regulatory scenarios for multiple crops based on standard EPA aquatic modeling procedures. The crops selected were those with the largest number of acres treated according to proprietary pesticide usage data available to the Agency. The regulatory scenarios assumed maximum use rates from 2009 (the year after flubendiamide was registered) to 2015, and then changed according to the regulatory scenario modeled, which included 'no change from current label,' 'change to one ground application forever,' 'change to one ground application, then cancel in 2018,' and 'cancel uses after the 2015 application.' When considering the TWA endpoints, all four (4) of the regulatory scenarios exceed Agency LOCs for all of the simulated crops. Consistently, the greatest exceedances occur for des-iodo in pore water, and many of the scenarios achieve exposure levels that resulted in 80% emergence inhibition in the des-iodo chronic laboratory toxicity study, which indicates at this exposure level that 80% of the test organisms were unable to emerge as the adult (reproductive life-stage) from the sediment (where the juveniles reside), while 20% were able to emerge and potentially complete their life-cycle.

Flubendiamide and its des-iodo degradate pose a long-term risk long after a regulatory action may take place (*i.e.*, there is a time-lag between mitigation and the maximum risk). For example, under the "cancel now" regulatory scenario, flubendiamide applications to the watershed above the modeled pond stop after 2015; however, risk from des-iodo in pore water does not level-off (stop increasing) for more than a decade after. This time-lag is due to the time required to transport the flubendiamide from the field to the pond and subsequent conversion of flubendiamide in the pond into des-iodo.

The TWA endpoint exceedances tend to occur quite early in the temporal trends. For example, all of the

des-iodo pore water TWA endpoints exceed Agency LOCs within two years. Considering that flubendiamide applications could have started in 2009 for these crops, these projected exceedances could have occurred as early as five years ago. Even if risk were judged by the less sensitive endpoints suggested by BCS/NAI, all but two of the regulatory scenarios exceed Agency LOCs. These two regulatory scenarios are the "Change to one ground application then cancel after the studies are submitted" and "Cancel now" scenarios for the leafy vegetables (based on the CA lettuce scenario, with ground applications initially in the first time period).

Analysis Results from High and Low Exposure Analysis for 13 Crop Uses: BCS/NCI requested the Agency also consider another label mitigation option where only 13 crops remained on the labels. This analysis provided additional characterization of ecological risk through consideration of a subset of crops proposed as posing limited ecological risk to aquatic invertebrates. The crop scenarios were selected based on the 13 crops (or crop groups; i.e., alfalfa, brassica leafy vegetables, cotton (AZ and CA only), cucurbit vegetables, fruiting vegetables, grape, leafy vegetables, legume vegetables, pome fruit, stone fruit, strawberry, tobacco, and tree nuts) that BCS/NAI proposed to retain on flubendiamide labels. Only two crop scenarios (high and low exposure) were investigated for this second memo to capture the range of flubendiamide risk from the BCS/NAI-proposed crops to be retained. This analysis assumed no prior use of flubendiamide and modeled different numbers of applications from the maximum allowed on the label down to one at the maximum single application rate. Both the high and low exposure/risk crop scenarios exceed Agency LOCs (based on the TWA endpoints). There is risk for all application numbers modeled for both high and low scenarios. The low exposure scenario exceeds Agency LOCs in: 3 years at six, five, or four applications per year; 4 years at three applications per year; 6 years at two applications per year; and 9 years with only one application per year. The high exposure scenario applying two applications per year (the most allowed by the BCS/NAI proposal) exceeds Agency LOCs in 2 years, while the first exceedance occurs in 3 years with only one application per year.

Although the Agency does not agree with the use of the nominal-based endpoints that were suggested by BCS/NAI, the low exposure scenario exceeds Agency LOCs in 11 years at six applications per year, 13 years at five applications per year, 16 years at four applications per year, and 21 years at three applications per year using the BCS/NAI-suggested endpoints. The low exposure scenario based on either one or two applications per year does not exceed LOCs within the 30 years simulated based on the BCS/NAI-suggested endpoints. However, both application patterns of either one or two applications per year would be expected to eventually exceed if applications continued long enough. The high exposure scenario applying two applications per year exceeds LOCs based on the BCS/NAI-suggested endpoints in eight years, while the first exceedance occurs in 11 years with only one application per year. Therefore, when considering BCS/NAI's less conservative proposed endpoints, use of flubendiamide still results in risk concerns for aquatic system invertebrates.

Tree Nut Assessment Results: The Agency received a new proposed label for flubendiamide on January 8, 2016 that limits the label only to tree nuts in California, and further limits application rates. Modeling this proposed use allowed the Agency to perform an assessment of not only the reduced application rates, but also incorporate the 79-day aqueous photolysis half-life for des-iodo into this assessment (previous analyses had not used this half-life estimate since it was submitted to the Agency on January 5, 2016). This analysis also assumed no prior use of flubendiamide and modeled different numbers of applications from the maximum allowed on the label down to one at the maximum single application rate. Based on the TWA endpoints, the currently proposed flubendiamide tree nut use results in risk that exceeds Agency LOCs for all numbers of applications modeled. The tree nut scenario proposed by the BCS/NAI exceeds Agency LOCs in 2 years at three applications per year and 3 years at two or one application(s) per year. Although the Agency does not agree with the use of the nominal-based endpoints that were suggested by BCS/NAI, the proposed tree nut scenario exceeds Agency LOCs using these endpoints in 10 years at three applications per year, 11 years at two applications per year, and 21 years at one application per year. Therefore, when

considering BCS/NAI's less conservative proposed endpoints, the continued use of flubendiamide still results in risk concerns for aquatic system invertebrates. Based on the California almond scenario presented above, as well as the other recent modeling, significant chronic risk effects to aquatic organisms due to the use of flubendiamide could potentially occur in as little as 2 years.

While BCS/NAI has raised many issues as discussed in detail within the amended ecological risk assessment, none have persuaded the Agency that the original and subsequent ecological risk assessment conclusions were inaccurate nor have they diminished confidence in those conclusions.

13. USGS Monitoring Information

Additional information from U.S. Geological Survey (USGS) stream and river monitoring data (2012 to 2014) indicate that flubendiamide and des-iodo was detected at 26 sites in 14 states. California, Georgia, North Carolina, Mississippi, and Louisiana had multiple sites with frequent detections. These detections were filtered water samples only. The Agency fully expects higher concentrations in unfiltered water or sediment samples.

14. Other Persistent Chemicals

In terms of the Agency's history in mitigating the ecological risks posed by other persistent and toxic insecticides, EPA has limited similar insecticide products to greenhouses, perimeter structural treatments, or indoor uses. Since flubendiamide only has outdoor above-ground foliar crop uses, this type of mitigation is not a regulatory option for the compound.

15. Mitigation and Labeling Requirements

A series of meetings between EPA scientists and BCS/NAI scientists has occurred since March 2015, where the Agency has continued to engage in dialogue about the referenced conditional data and the environmental risk conclusions. After review of all the BCS/NAI data submissions and previous risk assessments, EPA's conclusions on the environmental risks posed by flubendiamide and des-iodo today are consistent with those identified in 2008. EPA originally concluded that "Flubendiamide and the des-iodo degradate's overall stability/persistence suggests that they will accumulate in soils, water column, and sediments with each successive application."

EPA's analysis of BCS/NAI's farm pond water monitoring study concludes that there is: (1) accumulation of both flubendiamide and des-iodo in the water column, sediment, and pore water for all ponds monitored; and (2) definitive evidence that VFSs do not sufficiently control off-site transport of these chemicals to downstream waterbodies. In addition, stream and river monitoring conducted by BCS/NAI and the USGS over much of the United States indicates: (1) the failure of VFSs to contain these chemicals is a widespread occurrence; and (2) the potential for water quality impacts is also widespread.

16. Benefits and Alternatives

EPA evaluated the benefits and alternatives for flubendiamide in a memo dated July 24, 2015 (copy attached). The Agency reviewed benefit information submitted by BCS/NAI, which included a combination of private pesticide surveys of growers, trade journals, articles, state extension Integrated Pest Management websites, Arthropod Management Tests, and expert opinions to support claims of benefits. The benefits of flubendiamide are that it plays a role in integrated pest management and insecticide resistance management based upon the following characteristics: (1) specificity to Lepidopteran larvae; (2) non-systemic but translaminar properties; and (3) no to low impacts on beneficial arthropods. If flubendiamide is unavailable, pyrethroids would most likely be the alternative chemistry used by growers.

Other alternatives are insect growth regulators (*e.g.*, diflubenzuron, methoxyfenozide), other diamides (*e.g.*, chlorantraniliprole, cyantraniliprole), and spinosyns (*e.g.*, spinetoram). Overall, EPA concludes that there are efficacious alternatives for flubendiamide.

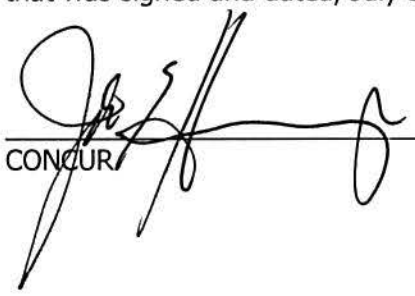
17. EPA Risk Management Decision and Regulatory Determination

The initial environmental risk concerns from 2008 to the present have continued to center around flubendiamide being a mobile, persistent, and extremely toxic insecticide and because the parent degrades only through aquatic photolysis and anaerobic aquatic metabolism to des-iodo, which does not further degrade except slowly through photolysis. EPA has identified chronic concerns for Flubendiamide to aquatic system invertebrates for both parent and its des-iodo degradate. These risks concerns are based on comparisons of overlying and sediment pore water concentrations of the two compounds to effects endpoints established using the emergent aquatic insect *C. riparius*, a commonly tested species with juvenile life stages that exist in the benthic sediment and are exposed to both sediment pore- and overlying-water. However, because des-iodo is 10X more toxic to aquatic invertebrates than the parent flubendiamide, it is des-iodo that causes the greatest risk concern. Therefore, with each successive flubendiamide application, more flubendiamide is transported to aquatic environments via runoff and spray drift where it accumulates and slowly degrades to des-iodo, which in turn accumulates, causing unreasonable adverse effects to aquatic environments.

EPA has assessed the risks and benefits associated with the continued use of flubendiamide as currently registered (and the modifications proposed by BCS/NAI), and determined that the risks of allowing the continued use of flubendiamide outweigh the benefits, and will result in unreasonable adverse effects to the environment. In conclusion, all of the existing uses for the time-limited/conditional flubendiamide registrations as well as the latest proposed use scenarios exceed the Agency's LOCs for aquatic system invertebrates based on the TWA effect endpoints from *C. riparius* testing compared with estimated toxicant concentrations for sediment pore- and overlying- water. The modelling scenarios based on the latest label submitted by BCS/NAI and the TWA endpoints exceed Agency LOCs within 2 years. Considering that flubendiamide applications most likely started in 2009 (7 years ago), these exceedances could have occurred as early as 5 years ago. Such adverse impacts would directly impact aquatic invertebrates in ponds, lakes, reservoirs, estuaries, areas of sediment accumulation in flowing waterbodies and any non-flowing waterbodies where des-iodo would accumulate-downstream of lands where flubendiamide is used as well as indirect impacts to fish and wildlife for which aquatic invertebrates serve as the basis for their food chain.

Within the parameters of the time limited/conditional registration agreement signed by both the Agency and BCS/NAI, the companies (BCS/NAI) agreed to voluntarily cancel all flubendiamide products if the Agency makes the determination that there are unreasonable adverse effects to the environment. If the companies (BCS/NAI) fail to voluntarily cancel all registrations by the close of business on Friday, February 5, 2016, I recommend the Agency move forward with cancellation under section 6(e) of FIFRA.

EPA RECOMMENDATION: I recommend that you concur with the cancellation of all flubendiamide products in accordance with the BCS/NAI and the Agency's time limited/conditional registration agreement that was signed and dated, July 31, 2008.



1-29-16

CONCUR DATE

DO NOT CONCUR DATE

EXHIBIT 26

IN THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council, Inc.,	)	
Petitioner,	)	No. 14-73353 (Consolidated with 15-71207, 15-71213, and 14-73359)
v.	)	
United States Environmental Protection Agency,	)	
Respondent,	)	
Dow AgroSciences, LLC,	)	
Respondent-Intervenor.	)	

RESPONSE TO RESPONDENTS' MOTION FOR VOLUNTARY VACATUR AND REMAND

Intervenor Dow AgroSciences, LLC (Dow) hereby responds to respondents' "Motion for Voluntary Vacatur and Remand" [Dkt. 121-1]. In support of this response, Dow states as follows:

1. Respondents have filed a "Dr. Jekyll & Mr. Hyde" motion. Part of the motion is entirely uncontroversial—the request for a remand so that the Environmental Protection Agency (EPA) may analyze new

information that may bear on the pesticide registration at issue here. But part of the motion is entirely novel and unlawful—the agency's request for this Court, without addressing the merits, summarily to vacate that registration.

2. Dow believes that the new information cited by respondents has no impact on the validity of the existing registration. But Dow has absolutely no problem with the requested remand to allow the agency to review that information, and hereby consents to such relief. Dow does not, and cannot, however, agree to the requested vacatur, which would circumvent a comprehensive regulatory scheme that specifies the agency's powers and duties (and a registrant's rights) with respect to an existing pesticide registration. Accordingly, this Court should limit its relief to a remand for the agency to exercise primary jurisdiction to review the new information and decide what additional steps, if any, are warranted. In the meantime, Dow will agree to stop sales of Enlist Duo, and to work out an appropriate agreement to that effect with the agency.

3. The premise of the motion is correct: "Agency decisions are not carved in stone," and thus "an agency must consider the wisdom of

its policy on a continuing basis,' for example, 'in response to changed circumstances.'" Mot. 6 (quoting *National Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)). That is why it is appropriate for a court to remand a case to an agency where, as here, the agency requests an opportunity to review an earlier decision in light of new information. *See, e.g.*, *California Communities Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012).

4. But an agency's desire for an opportunity to review an earlier decision in light of new information provides no basis for either the agency or a court summarily to annul that decision. To the contrary, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, and agency regulations promulgated thereunder establish an "elaborate" and "comprehensive" scheme governing pesticide registration, which "grants enforcement authority to the EPA." *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 530 (9th Cir. 2001); *Love v. Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988).

5. Under that scheme, a registrant, like Dow, has a legally cognizable property interest in a pesticide registration, which (as

respondents concede) "is a license that establishes the terms and conditions under which a pesticide may be lawfully sold, distributed, and used." Resps.' Mot. 3; *see also Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010) ("A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used.") (citing 7 U.S.C. § 136a(a), (c)-(e)); *Center for Biological Diversity v. EPA*, No. 11-cv-293, 2013 WL 1729573, at *6-7 (N.D. Cal. 2013) ("The applicants are owners of the pesticide registrations, and thus have property and financial interests in the registrations."). Needless to say, that property interest cannot be annulled without due process of law. *See, e.g., Bell v. Burson*, 402 U.S. 535, 539 (1971).

6. Congress recognized as much when it enacted FIFRA. That comprehensive regulatory scheme creates a detailed procedural mechanism for the agency to cancel or suspend an existing pesticide registration. In particular, FIFRA Section 6(b), 7 U.S.C. § 136d(b), specifies:

> If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter ... the

> Administrator may issue a notice of the Administrator's intent either —
>
> **(1)** to cancel the registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or
>
> **(2)** to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Before the Administrator may cancel a registration, however, she must provide notice to the registrant and the public. *See id.* In addition, at least 60 days prior to that notice, she must provide notice of the proposed cancellation to the Secretary of Agriculture along with an analysis of the impact of the proposed cancellation on the agricultural economy. *See id.* She must also provide the registrant and other interested parties with a public administrative hearing. *See id.* Moreover, "[i]n taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation … and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact." *Id.* Once all of the

agency's obligations under FIFRA's cancellation provisions have been met—and *only* once all of those obligations have been met—the Secretary may issue a final order of cancellation, which in turn is subject to judicial review to protect the registrant's property interest in the registration. *See id.* § 136n(b).

7. The regulatory scheme also provides for suspension as an alternative to cancellation of a registration. Thus, "[i]f the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately." 7 U.S.C. § 136d(c)(1). But there too, Congress carefully protected the rights of affected registrants by including key procedural protections in the suspension process: except in the event of an emergency, "no order of suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide ....." *Id.* The Administrator also must notify the registrant prior to any suspension, and such notice "shall include findings pertaining to the question of

'imminent hazard.'" *Id.* The registrant, in turn, "shall then have an opportunity ... for an expedited hearing before the Administrator on the question of whether an imminent hazard exists." *Id.* Once all of the agency's obligations under FIFRA's suspension provisions have been met—and *only* once all of those obligations have been met—the Secretary may issue a final order of suspension, which again is subject to judicial review to protect the registrant's property interest in the registration. *See id.* § 136d(c)(4).

8. By asking this Court summarily to vacate the existing Enlist Duo registration, EPA is trying to short-circuit this regulatory scheme and abdicate the responsibilities Congress assigned to the agency. There is no basis in law or logic for this Court to vacate the registration: all that has happened is that EPA has informed this Court that it "is in receipt of new information regarding *potential* synergistic effects between" Enlist Duo's active ingredients. Mot. 2 (emphasis added). While that new information may warrant "a voluntary remand in order to reconsider the Enlist Duo registration in light of the new information," it provides no basis for a "vacatur of the registration." *Id.*

9. EPA argues that it "cannot be sure, without a full analysis of the new information, that the current registration does not cause unreasonable effects to the environment, which is a requirement of the registration standard under FIFRA." *Id.* But that is, at most, a reason for the agency to follow the established regulatory process for reviewing that information and taking whatever steps may be appropriate under the comprehensive regulatory regime. It is not a reason for EPA to bypass that regime altogether by asking this Court summarily to vacate the existing registration.

10. The cases cited by EPA in support of its request for vacatur are entirely inapposite. For example, EPA declares as a general matter that "[i]n environmental cases, to decide whether remand with or without vacatur is the appropriate remedy, a factor this Court considers is the extent to which vacatur would cause or prevent possible environmental harm." Mot. 8 (citing *Pollinator Stewardship Council v. EPA*, __ F.3d __, 2015 WL 7003600, at *12 (9th Cir. Nov. 12, 2015)). But in that case, this Court had reviewed the disputed agency action on the merits and concluded that it was contrary to law, *see Pollinator Stewardship Council*, 2015 WL 7003600, at *7-11, and thus was

authorized to vacate the agency action, *see id.* at *12. Here, in sharp contrast, this Court has never reviewed the disputed agency action on the merits and determined that it is unlawful. In light of Dow's legally protected interest in the matter, there is no basis for this Court summarily to vacate the agency's unreviewed registration decision just because the agency has so requested.

11. Indeed, this case is closely analogous to *Reckitt Benckiser*. There, as a result of a registrant's alleged failure to comply with certain risk mitigation measures imposed by EPA, the agency threatened to institute enforcement proceedings for alleged misbranding. The registrant, citing the procedural safeguards of FIFRA Section 6 cancellation proceedings, sought declaratory and injunctive relief to bar EPA from thereby circumventing the statutory cancellation regime. The court agreed, noting that Section 6 "establishes a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration." *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011) (emphasis in original); *see also id.* ("'A pesticide product remains registered until EPA or the registrant cancels it pursuant to Section 6.'") (quoting *Reckitt Benckiser*, 613 F.3d at 1133)). As the court

explained, "[t]he process imposes certain obligations on EPA before it may issue a notice of intent to cancel or a notice of intent to hold a hearing on cancellation, and it entitles the registrant to notice, a hearing and other procedural protections before EPA can make a final decision on cancellation." *Id.* at 43. To allow EPA to seek to nullify a registration outside that process—either through a misbranding enforcement action or a request for "voluntary vacatur"—would allow the agency to "'bypass[] cancellation proceedings' and 'effect[ively] cancel[] the registrations without following the regulatory procedures provided in Section 6.'" *Id.* at 43 (quoting *Reckitt Benckiser*, 613 F.3d at 1133)); *see also id.* ("To interpret FIFRA to give EPA that authority not only renders Section 6 superfluous; it also allows EPA to avoid the rigorous cancellation process Congress provided for in the statute.").

12. In short, EPA is improperly trying to abdicate the responsibility that Congress vested in the agency for cancelling or suspending pesticide registrations, and to nullify the corresponding procedural protections for Dow. Accordingly, this Court should limit the relief here to a remand for the agency to review the new information and decide what additional steps, if any, are warranted. In the

meantime, Dow will agree to stop sales of Enlist Duo, and to work out an appropriate agreement to that effect with the agency.

CONCLUSION

For the foregoing reasons, this Court should grant the motion to remand, but deny the motion to vacate.

December 7, 2015

Respectfully submitted,

/s/ *Christopher Landau*

Christopher Landau, P.C.
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, DC 20005
(202) 879-5000
clandau@kirkland.com

Michael P. Foradas
KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, IL 60654
(312) 862-2000
mforadas@kirkland.com

Stanley H. Abramson
Donald C. McLean
ARENT FOX LLP
1717 K Street, N.W.
Washington, DC 20006
(202) 857-6000
stanley.abramson@arentfox.com
donald.mclean@arentfox.com

David B. Weinberg
WILEY REIN LLP
1776 K Street, N.W.
Washington, DC 20006
(202) 719-7000
dweinberg@wileyrein.com

Counsel for Intervenor

CERTIFICATE OF SERVICE

I, Christopher Landau, P.C., hereby certify that I served the foregoing document by ECF on this 7th day of December 2015, which will result in service on all counsel of record.

/s/ *Christopher Landau*
Christopher Landau, P.C.

EXHIBIT 27

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, Petitioner, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, Respondent, DOW AGROSCIENCES LLC, Respondent-Intervenor.	Nos. 14-73353, 15-71213 ORDER

CENTER FOR FOOD SAFETY; et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY and GINA MCCARTHY, in her official capacity as Administrator, Respondents, DOW AGROSCIENCES LLC, Respondent-Intervenor.	Nos. 14-73359, 15-71207

AT/MOATT

Before: GOODWIN, TALLMAN, and NGUYEN, Circuit Judges.

The motion of Dow Agrosciences LLC to strike the Natural Resources Defense Council's December 17, 2015 reply is denied.

The Environmental Protection Agency's unopposed motion for remand is granted.

The motion for voluntary vacatur of the registration of Enlist Duo is denied without prejudice to the rights of either party to litigate that question before the agency.

REMANDED.

EXHIBIT 28

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Reckitt Benckiser LLC, et al.	)	FIFRA Docket No. 661
	)	
EPA Reg. Nos. 3282-3, 3282-4, 3282-9, 3282-15, 3282-65, 3282-66, 3282-74, 3282-81, 3282-85, 3282-86, 3282-87, and 3282-88	)	

RESPONDENT'S CONDITIONAL OPPOSITION TO CROPLIFE AMERICA'S MOTION TO FILE AN AMICUS CURIAE BRIEF REGARDING EXISTING STOCKS OF CANCELLED PRODUCTS

On April 26, 2013, CropLife America ("CropLife"), as amicus curiae, filed a brief in support of the April 12, 2013, Reckitt Benckiser LLC ("Reckitt") Motion for an Expedited Determination That EPA's Existing Stocks Decision Is Within The Scope of The Hearing ("Reckitt's Motion"). The Assistant Administrator for Chemical Safety and Pollution Prevention ("Respondent") consented to the filing of CropLife's amicus brief conditioned upon Respondent being allowed the opportunity to reply. It is unclear whether the rules governing this proceeding, 40 C.F.R part 164, allow parties to respond to amicus briefs as a matter of right. Accordingly, Respondent files herewith its reply to CropLife's amicus brief, or, in the alternative, Respondent's opposition to CropLife's motion for leave to file an amicus brief.

I. CropLife's Substantive Contentions Are Mistaken And Provide No Support For Reckitt's Motion

CropLife does not address the cases cited in the Notice of Intent To Cancel giving rise to this proceeding that hold that the disposition of existing stocks of cancelled products are not required to be issues for a cancellation proceeding (78 Fed. Reg. 8123, 8126), but instead presents two legislative history arguments in support of its contention "that Congress in 1972 intended to include existing stocks issues within the scope of section 6(b) cancellation hearings." CropLife Brief at 8. Neither has merit.

First, CropLife identifies a letter from an EPA Assistant Administrator to a member of the Senate Committee on Agriculture and Forestry, attached to a report of that Committee regarding proposed amendments to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), and extracts from it the following nugget:

> I believe our present authority under [a House bill that did not include the existing stocks language ultimately included in FIFRA section 6(a)(1)] is sufficiently flexible to permit an orderly phase-out where farmers have relied on a pesticide for use during an upcoming growing season. It is open to registrants and user groups to raise at the hearing any question bearing on the benefits of using a product. Any showing of need for a pesticide during an upcoming season would be relevant and the statute would permit us to issue an order that would result in a label use for a given season or period of time or indeed a certain geographical location. It would be our policy to invoke this flexibility on a showing by affected groups that the particular chemical were needed for the growing season.

S. Rep. No. 92-838 at 13-14 (June 7, 1972).

CropLife represents this as evidence of a Congressional intent that the disposition of existing stocks should be decided in section 6(b) cancellation proceedings, but the text says nothing of the sort. The purpose of a FIFRA section 6(b) cancellation proceeding is to determine whether "a pesticide or its labeling or other material required to be submitted does not comply

with the provisions of this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, [such that] the Administrator [should] cancel its registration or change its classification..." *Id.* The pesticide product is cancelled without a hearing if no person files a timely request for hearing and states particular objections. FIFRA section 6(b); 40 C.F.R. § 164.22. Therefore, persons opposing cancellation necessarily must present evidence of the product's benefits in their efforts to demonstrate that the product satisfies the risk-benefit balancing required by FIFRA. So it is wholly unremarkable to observe that "[i]t is open to registrants and user groups to raise at the hearing any question bearing on the benefits of using a product" (S. Rep. at 13-14) as they must do so in order to oppose cancellation. But it is only the benefits *of continued registration* that are relevant to the question of whether the pesticide registration may continue or must be cancelled; the benefits and risks associated with whatever post-cancellation use that might subsequently be allowed are not germane to the purpose of the proceeding. Nevertheless, testimony at the hearing introduced for the purpose of showing the need for continued registration (the decision before the Administrative Law Judge) may also be relevant to the separate and independent decision of the Assistant Administrator for Chemical Safety and Pollution Prevention concerning whether, and under what conditions, to allow the sale, distribution or use of existing stocks of cancelled product. Hence "[a]ny showing of need for a pesticide during an upcoming season would be relevant and the statute would permit us to issue an order [concerning disposition of existing stocks of cancelled product]." *Id.* Finally, the circumstances-based decision rubric of the Agency's existing stocks policy (Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29362 (June 26, 1991)) stands as evidence of the continuing validity of the 1972 assertion that "[i]t would be our policy to invoke this flexibility [regarding disposition of existing

stocks] on a showing by affected groups that the particular chemical were needed for the growing season." S. Rep. at 14.[1]

CropLife's second contention is that it would be "ironic" for Congress to have established a broader scope for cancellation hearings pursuant to FIFRA section 6(e) and suspension hearings pursuant to FIFRA section 3(c)(2)(B) than it did for section 6(b) cancellation hearings. Respondent finds that Congressional choice eminently reasonable. Unlike the d-CON rodenticides at issue in this proceeding, products cancelled pursuant to FIFRA section 6(e) or suspended pursuant to FIFRA section 3(c)(2)(B) are generally not expected to pose unreasonable risks to health or the environment.[2] A section 6(e) cancellation or section

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[1] For example, regarding cancellations where the Agency has identified particular risk concerns, the Existing Stocks Policy calls for consideration of: (a) the quantity of existing stocks at each level of the market, (b) the risks resulting from the use of such stocks, (c) the benefits resulting from the use of such stocks, (d) the dollar amount users and others have already spent on existing stocks (which would be lost if distribution, sale, or use were not permitted), (e) the risks and costs of disposal or alternative disposition of the pesticide, and (f) the practicality of implementing restrictions on distribution, sale, or use of existing stocks. 56 Fed. Reg. at 29364.

[2] Section 6(e) applies only to conditional registrations (often referred to as "me-too" or "follow-on" registrations) issued pursuant to section 3(c)(7), where a person is granted a registration for a product "substantially similar" to another product already on the market, conditioned upon the new registrant satisfying certain data requirements in the future. If that new registrant subsequently fails to satisfy those outstanding data requirements, the conditional registration is subject to cancellation under Section 6(e), where "[t]he only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act." Thus a section 6(e) cancellation is about the *registrant's* failure to meet its obligations, and not about a problem with *the pesticide product itself*. A pesticide cancelled pursuant to section 6(e) is not being cancelled on account of risks, and, despite cancellation, remains "a pesticide and proposed use [that] are identical or substantially similar to [a] currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment..." Section 3(c)(7)(A).

Similarly, suspensions pursuant to section 3(c)(2)(B) are on account to the *registrant's* failure to comply with new data requirements imposed after registration, rather than any known problem with *the pesticide product itself*. Section 3(c)(2)(B)(iv) likewise provides that "[t]he only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act." Thus Congress expressly provided that the disposition of existing stocks would be within the scopes of the two adverse registration actions that are not directly related to the risks associated with the product itself.

In contrast, the provisions governing risk-based cancellations and suspensions (sections 6(b) and 6(c)) say nothing about disposition of existing stocks. The Agency's authority over existing stocks of products cancelled or suspended pursuant to sections 6(b) and 6(c) comes instead from section 6(a)(1): "The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under this section, or section 3 or 4, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this Act."

3(c)(2)(B) suspension does not result in an adjudicated determination that a product poses unreasonable risks to health or the environment. Instead, section 6(e) cancellations and section 3(c)(2)(B) suspensions result from a registrant's failure to generate data or acquire rights to use the data of others, for products that in most cases are very much like other products that will remain registered. In contrast, products cancelled pursuant to section 6(b) have been determined to pose unreasonable risks to man or the environment that require that they be removed from commerce. Inasmuch as a pesticide product cancelled pursuant to section 6(e) or suspended pursuant to section 3(c)(2)(B) would not be presumed to pose any unreasonable risk, it seems reasonable that Congress would provide different treatment for existing stocks of such products and for existing stocks of products cancelled owing to unreasonable risks pursuant to section 6(b).

In summation, CropLife's substantive contentions are mistaken and provide no support for Reckitt's Motion. Respondent has shown that the plain language of the legislative history CropLife cites does not support its contention that Congress intended that the question of existing stocks should be at issue in cancellation proceedings. The cited text is instead fully harmonious with Respondent's position that FIFRA does not create any right to hearing on the disposition of existing stocks of product cancelled pursuant to section 6(b). Respondent has shown that Congress's express inclusion of existing stocks in the scope of section 6(e) cancellation proceedings and section 3(c)(2)(B) suspension proceedings does not imply that that existing stocks must therefore be within the scope of section 6(b) cancellation proceedings. The fundamental difference between the risks associated with products cancelled on account of unreasonable risk (section 6(b) cancellations) and products cancelled or suspended on account of registrants failing to meet data requirements (section 6(e) cancellations and section 3(c)(2)(B)

suspensions) fully warrants a statutory scheme where (1) existing stocks of products cancelled owing to unreasonable risk will not be allowed to be distributed or sold, except pursuant to the Administrator's discretionary authority pursuant to section 6(b)(1), and (2) the disposition of existing stocks of products cancelled or suspended for procedural reasons unrelated to risk will be determined by an Administrative Law Judge, or the Environmental Appeals Board on appeal. Accordingly, CropLife's substantive contentions should be disregarded and Reckitt's Motion should be denied.

II. In The Alternative, Respondent Opposes CropLife's Motion For Leave To File An Amicus Brief

Respondent consented to the filing of CropLife's amicus brief conditioned upon Respondent being allowed the opportunity to reply, however, such an agreement does not bind the Administrative Law Judge. The procedural rules governing this proceeding, 40 C.F.R. part 164, do not expressly provide parties a right to respond to briefs of adverse amici, however, § 164.31 does require that "an amicus curiae shall file its brief within the time allowed the party whose position the brief will support." It is reasonable to presume that part of the rationale for that provision was to allow a party to respond to both opposing briefs simultaneously, and to infer from it a general right to respond to amicus briefs. Although it is not directly applicable to this proceeding, the fairness of allowing parties to respond to amicus briefs is acknowledged in 40 C.F.R. § 22.11(b): "Any party to the proceeding may file a response to a non-party brief within 15 days after service of the non-party brief." It would not be fair if an amicus were allowed to make arguments on behalf of one party, and the opposing party were not permitted the opportunity to respond, as this would give amicii a power beyond those enjoyed by full

parties to the proceeding.[3] Accordingly, in the event that the Administrative Law Judge determines that part 164 does not allow the response presented above, Respondent opposes CropLife's motion for leave to file an amicus brief.

Respectfully submitted,

5/6/2013
Date

Robert G. Perlis
Scott B. Garrison
David N. Berol
U.S. Environmental Protection Agency
Office of General Counsel (2333A)
1200 Pennsylvania Ave., N.W.
Washington, DC 20460
perlis.robert@epa.gov; 202-564-5636
garrison.scott@epa.gov ; 202-564-4047
berol.david@epa.gov; 202-564-6873

[3] Respondent's position here differs from its position in *Respondent's Response To Motion For Leave To File A Reply Concerning Reckitt's Motion For An Expedited Determination That EPA's Existing Stocks Decision Is Within The Scope Of The Hearing* in two major respects. First, Respondent here seeks to establish the rights of full parties to respond to amicus briefs. Second, Respondent opposed Reckitt's request for leave to file a reply because Reckitt was a moving party that simply failed to write the brief it wished it had written the first time, whereas here, Respondent was not the movant and has not had a first opportunity to address Amicus' arguments.

CERTIFICATE OF SERVICE

I hereby certify that the original and one copy of *Respondent's Conditional Opposition To Croplife America's Motion To File An Amicus Curiae Brief Regarding Existing Stocks Of Cancelled Products* were filed with the Headquarters Hearing Clerk, and a copy hand delivered to the office of:

The Honorable Susan L. Biro
U.S. Environmental Protection Agency
Office of Administrative Law Judges
1300 Pennsylvania Ave., N.W.
Washington, DC 20460

I further certify that true and correct copies were sent by first class mail and e-mail to:

Lawrence E. Culleen
Jeremy C. Karpatkin
Ronald A. Schechter
Arnold & Porter LLP
555 Twelfth Street, N.W.
Washington, D.C. 20004
Lawrence.Culleen@aporter.com
Jeremy.Karpatkin@aporter.com
Ronald.Schechter@aporter.com

Mark K. Franks
Greater Cincinnati Northern Kentucky
Apartment Association
7265 Kenwood Road, Suite 100
Cincinnati, OH 45236
Mark @gcnkaa.org

Gale Lively
Louisville Apartment Association
7400 South Park Place, Suite 1
Louisville, KY 40222
Info@laaky.com

Bob Taylor
Do It Best Corp.
P.O. Box 868
Fort Wayne, IN 46801-0868
Mail@doitbest.com

John D. Connor, Jr.
McKenna Long & Aldridge LLP
1900 K Street, N.W.
Washington, DC 20006
jconnerjr@mckennalong.com

Gregory C. Loarie
Irene V. Gutierrez
Earthjustice
50 California St., Suite 500
San Francisco, CA 94111
gloarie@earthjustice.org
igutuerrez@earthjustice.org

Dimple Chaudhary
Aaron Colangelo
Nicholas Morales
Natural Resources Defense Council
1152 15th St. NW, Suite 300
Washington DC 20005
dchaudhary@nrdc.org
acolangelo@nrdc.org
nmorales@nrdc.org

5/6/2013
Date

Scott B. Garrison
U.S. Environmental Protection Agency
Office of General Counsel (2333A)
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 31st day of March, 2016, a true and correct copy of the foregoing Request For Hearing And Statement Of Objections By Bayer CropScience LP And Nichino America, Inc. was filed electronically using the EPA OALJ e-filing system; and served in the following manner to the below addressees:

Original and 2 copies by hand delivery:

Sybil Anderson, Headquarters Hearing Clerk
Office of Administrative Law Judges
U.S. Environmental Protection Agency
Ronald Reagan Building, Room M1200
1300 Pennsylvania Avenue, N.W.
Washington, DC 20004
202-564-6261
Anderson.sybil@epa.gov

By Email:

Michael B. Wright, Staff Attorney
Office of Administrative Law Judges
USEPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 1900R
Washington, DC 20460
202-564-3247
Wright.michaelb@Epa.gov

Ryan Yaeger, Staff Attorney
Office of Administrative Law Judges
USEPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 1900R
Washington, DC 20460
202-564-4898
Yaeger.ryan@Epa.gov

Ariadne Goerke
Pesticides and Toxic Substances Law Office
Office of General Counsel (Mail Code 2333A)
U.S. Environmental Protection Agency
WJC North 7318B
1200 Pennsylvania, Avenue, N.W.
Washington, DC 20460
202-564-5471
goerke.ariadne@epa.gov

Robert G. Perlis
Office of General Counsel (Mail Code 2333A)
U.S. Environmental Protection Agency
1200 Pennsylvania, Avenue, N.W.
Washington, DC 20460
202-564-5636
Perlis.Robert@epa.gov

Scott Garrison
Pesticides and Toxic Substances Law Office
Office of General Counsel (Mail Code 2333A)
U.S. Environmental Protection Agency
1200 Pennsylvania, Avenue, N.W.
Washington, DC 20460
202-564-4047
garrison.scott@epa.gov

David A. Barker