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))

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TO: Jack E. Housenger, Director
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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.

[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.

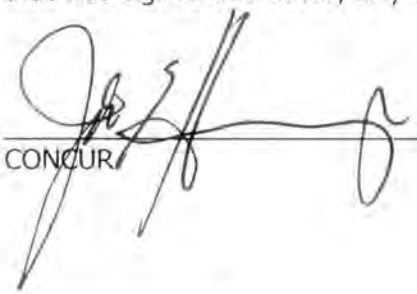
17. EPA Risk Management Decision and Regulatory Determination

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