



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.*"

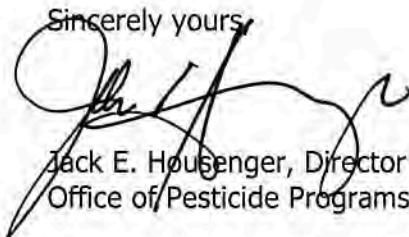
The benefits of flubendiamide are that it plays a role in integrated pest management and insecticide resistance management based upon the following characteristics: (1) specificity to Lepidopteran larvae; (2) non-systemic but translaminar properties; and (3) no to low impacts on beneficial arthropods. 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](mailto:Rodia.Carmen@epa.gov) or Mr. Richard J. Gebken by phone at (703) 305-6701 or via e-mail at [Gebken.Richard@epa.gov](mailto: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](mailto: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.