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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Thursday, July 31, 2008

CERTIFIED MAIL: (Article Number 7008 0150 0002 6191 4899)

Ms. Danielle A. Larochelle,
Registration Product Manager,
Authorized Agent for Nichino America, Inc.
c/o Bayer CropScience LP
2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

Subject: Application for a New Section 3 Registration of Flubendiamide with Associated Tolerance NNI-0001 Technical (EPA File Symbol 71711-EA); NNI-0001 24 WG (EPA File Symbol 264-RNEA); NNI-0001 480 SC (EPA File Symbol 264-RNEL); and Tolerance Petition No. 6F7065

Dear Ms. Larochelle:

The products referred to above will be acceptable for registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, provided that Bayer CropScience LP (Bayer), as authorized agent for Nichino America, Inc. (Nichino), agree/concur with the following conditions of registration and provided that the Director of the Office of Pesticide Programs concurs with the registration:

1. The subject products will be conditionally registered for a period of five (5) years from the date of the "Notice of Registration." In addition, this regulatory action will establish permanent tolerances in primary crops for residues of flubendiamide.

2. Bayer, as authorized agent for Nichino, will generate/submit acceptable data listed in the following tables, in accordance with 40 CFR §158, as follows:

Guideline Number	Title of Study	Date Due
Non-Guideline	**Small-Scale Run-Off/Vegetative Buffer Strip Study** - A run-off study is requested to determine the magnitude of the parent, flubendiamide, retained in buffer strips of various widths.	July 31, 2010
NOTE: Bayer will submit a final protocol for the small-scale run-off/vegetative buffer strip study on or before January 31, 2009. Bayer will submit one (1) progress report by December 31, 2009 and a final report on or before July 31, 2010.		
Non-Guideline	**Monitoring Program** –If risk assessment, based on the results from the small-scale run-off/vegetative buffer strip study and additional available data indicates that there are still risk concerns, there will be a need to conduct monitoring of receiving waters within watersheds where flubendiamide will be used.	July 31, 2012
NOTE: Bayer will submit to EPA a final protocol for the monitoring program on or before March 1, 2010. Bayer will revise the protocol for the monitoring study, as necessary, within one (1) month following receipt of the Agency's decision that a monitoring program is necessary.		

The Agency believes that the efficacy of vegetative buffers for flubendiamide use is uncertain. Open literature and Bayer-conducted studies on compounds with similar characteristics to flubendiamide provide information that permits an estimation of the impact of such buffers on the risk picture. A confirmatory small-scale run-off/vegetative buffer strip study with flubendiamide would allow the Agency to quantitatively consider the impact of such buffer strips on risk reduction in critical use areas. It is recommended that the protocol for the referenced study, like in past cases, be a product of a dialogue between EPA and Bayer scientists. Such dialogue, the protocols arising from it and assessment of supporting literature, should be mindful of the need to address

vulnerable use patterns and sites as well as a variety of buffer conditions. The buffer conditions used for this study should support potential mitigation enforceable by label language if, in the future, they are demonstrated to achieve meaningful reductions in off-site transport and aquatic organism risk of the pesticide.

The Agency will make use of the results of the small-scale run-off/vegetative buffer strip study in refining the aquatic exposure and risk assessment.[1] If the employment of the data from the small-scale run-off/vegetative buffer strip study, together with other available date, result in the Agency's conclusion that there are no risk concerns, then no further work, including the monitoring program, need be conducted. However, if risk concerns remain, then the other areas of critical uncertainty in the modeling assumptions must be considered. In this case, there is considerable uncertainty in the application of the EXAMS pond scenario for chemicals with suspected aquatic system accumulation. Additional information on the actual potential for the pesticide to build up in receiving waters would address the uncertainty associated with current model limitations.

3. The Environmental Fate and Effects risk assessment (copy enclosed), suggests that both flubendiamide and its NNI-0001-des-iodo (des-iodo) degradate will accumulate to concentrations in aquatic environments that will pose risk to freshwater benthic invertebrates. The available mesocosm data does not provide evidence to refute these conclusions. No degradation pathway was identified for des-iodo. As such, Bayer will commit to generate and submit the following data (studies) on the des-iodo degradate to determine if Agency assumptions of chemical stability are appropriate:

Guideline Number	Title of Study	Date Due
161-1	**Hydrolysis** – A hydrolysis study is requested to establish the significance of chemical hydrolysis as a route of degradation for des-iodo and to identify, if possible, the hydrolytic products formed to provide initial information on whether they may exhibit structures that may potentially adversely affect non-target organisms.	October 30, 2010
162-4	**Aerobic Aquatic Metabolism** – An aerobic aquatic metabolism study is requested to assist in determining the effects of des-iodo on aerobic conditions in water and sediments during the period of dispersal of 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; therefore, potentially reducing modeling uncertainty.	October 30, 2010

4. For the submitted GLN 860.1850 Confined Rotational Crop studies (MRIDs 46817133 and 46817134), Bayer will submit extraction and analysis dates of samples in order to confirm that samples were extracted and analyzed within the stated intervals (or within 6 months of harvest). Otherwise, additional storage stability data may be required by EPA.

5. Nichino America Inc. (Nichino) (or some other person who consents to Nichino's reliance on the data) understands and agrees that the time-limited registration of the flubendiamide technical product shall be cancelled if the Agency determines that the continued use of flubendiamide will result in unreasonable adverse effects on the environment.

6. The EPA and Nichino (or some other person who consents to Nichino's reliance on the data) agree on the following data review guidelines and timelines related to the conditions of registration under section 3(c)(5) of FIFRA for the flubendiamide technical product, as well as Nichino's (or some other person who consents to Nichino's reliance on the data) generation of, and the EPA's subsequent review of such additional data during the term of the time-limited registration, as follows:

   (a) Nichino (or some other person who consents to Nichino's reliance on the data) shall submit all data identified in paragraphs 2-4, on or before July 31, 2012, according to the schedules set forth in those paragraphs.

[1] The goal of the vegetative buffer strip study is to determine how much of a buffer is necessary to prevent both flubendiamide applied to a field and des-iodo formed in the field from accumulating to levels in aquatic environments that pose risk to freshwater benthic invertebrates. Therefore, showing "that the level of the des-iodo degradate leaving the field (prior to reaching the buffer) is insignificant," would be insufficient justification to remove "the 15 foot buffer requirement.

(b) The EPA shall complete its review of the entire required data set and will consider any additional data and supporting information voluntarily submitted by Nichino (or some other person who consents to Nichino's reliance on the data) by January 31, 2013. EPA scientists and Bayer scientists, as agents for Nichino, shall engage in dialogue about the data and the Agency's conclusions.

(c) By September 1, 2013, the EPA shall either: (1) Approve the registration of the flubendiamide technical product unconditionally, notwithstanding any restrictions that are deemed necessary; or (2) The EPA and Nichino will mutually agree on a path forward, revising or providing additional data under a conditional registration; or (3) The Agency will accept the voluntary cancellation of the time-limited registration of the flubendiamide technical product.

(d) If, after EPA's review of the data as set forth in 6(b) above, the Agency makes a determination that further registration of the flubendiamide technical product will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, Nichino will submit a request for voluntary cancellation of the flubendiamide technical product registration. That request shall include a statement that Nichino recognizes and agrees that the cancellation request is irrevocable.

(e) No cancellation shall occur if EPA determines, after review of the data, that the flubendiamide technical product registration could meet the standards for registration set forth in section 3(c)(5) of FIFRA, and Nichino agrees in writing to comply with any conditions (including, but not limited to, revised label language, use deletions or conditions of registration) that EPA finds necessary in order to make the registration determination.

7. Bayer understands and agrees that the time-limited registration of the flubendiamide end-use products shall be cancelled if the Agency determines that the continued use of flubendiamide will result in unreasonable adverse effects on the environment. In addition, this regulatory action will establish permanent tolerances in primary crops for residues of flubendiamide.

8. The EPA and Bayer (or some other person who consents to Bayer's reliance on the data) agree on the following data review guidelines and timelines related to the conditions of registration under section 3(c)(5) of FIFRA for the flubendiamide end-use products, as well as Bayer's (or some other person who consents to Bayer's reliance on the data) generation of, and the EPA's subsequent review of such additional data during the term of the time-limited registration, as follows:

(a) Bayer (or some other person who consents to Bayer's reliance on the data) shall submit all data identified in paragraphs 2-4, on or before July 31, 2012, according to the schedules set forth in those paragraphs.

(b) The EPA shall complete its review of the entire required data set and will consider any additional data and supporting information voluntarily submitted by Bayer (or some other person who consents to Bayer's reliance on the data) by January 31, 2013. EPA scientists and Bayer scientists shall engage in dialogue about the data and the Agency's conclusions.

(c) By September 1, 2013, the EPA shall either: (1) Approve the registration of the flubendiamide end-use products unconditionally, notwithstanding any restrictions that are deemed necessary; or (2) The EPA and Bayer will mutually agree on a path forward, revising or providing additional data under a conditional registration; or (3) The Agency will accept the voluntary cancellation of the time-limited registration of the flubendiamide end-use products.

(d) If, after EPA's review of the data as set forth in 8(b) above, the Agency makes a determination that further registration of the flubendiamide end-use products will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, Bayer will submit a request for voluntary cancellation of the flubendiamide end-use product registrations. That request shall include a statement that Bayer recognizes and agrees that the cancellation request is irrevocable.

(e) No cancellation shall occur if EPA determines, after review of the data, that the flubendiamide end-use product registrations could meet the standards for registration set forth in section 3(c)(5) of FIFRA, and Bayer agrees in writing to comply with any conditions (including, but not limited to, revised label language, use deletions or conditions of registration) that EPA finds necessary in order to make the registration determination.

The "Notice of Registration" will be issued under separate cover when you have agreed in writing to the conditions stated within this letter. **Further, this letter DOES NOT constitute registration, and the products MAY NOT be lawfully marketed until they are registered.**

Nichino and Bayer should recognize that if EPA issues any technical and/or end-use product registration pursuant to the requirements of section 3(c)(7)(C) of FIFRA, such registration will contain any conditions that are a necessary component of EPA's findings that the statutory requirements for issuing a registration are met. Any such registration will provide that Nichino's or Bayer's release for shipment of any product pursuant to any such registration signals Nichino's or Bayer's acceptance of all of those conditions. If either Nichino or Bayer does not agree with any of the conditions of registration, they should consider any such registration to be null and void. If either Nichino or Bayer notifies EPA that it is unwilling to accept any of those conditions, EPA will commence the appropriate denial process under section 3(c)(6) of FIFRA.

If you have any questions regarding anything in this letter, please contact Mr. Carmen J. Rodia, Jr. directly at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov*.

Sincerely yours,

Lois A. Rossi, Director
Registration Division (7505P)

Bayer CropScience LP hereby concurs with the time-limited conditional registration of the new insecticide flubendiamide under section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as outlined in this preliminary acceptance letter, dated July 31, 2008.

Margaret Cheung 7/31/08
CONCUR DATE

DO NOT CONCUR DATE

Enclosures:
Copy of Human Health Effects Risk Assessment for Flubendiamide, dated April 3, 2008
Copy of Environmental Fate and Effects Risk Assessment for Flubendiamide, dated June 23, 2008
Copy of Public Interest Finding for Flubendiamide, dated April 15, 2008
Copy of Acute Toxicity Review for NNI-0001 Technical, dated October 12, 2007
Copy of Acute Toxicity Review for NNI-0001 24 WG, dated July 15, 2007
Copy of Acute Toxicity Review for NNI-0001 480 SC, dated October 12, 2007
Copy of Product Chemistry Review for NNI-0001 Technical, dated October 24, 2007
Copy of Product Chemistry Review #1 for NNI-0001 24 WG, dated October 18, 2007
Copy of Product Chemistry Review #2 for NNI-0001 24 WG, dated January 25, 2008
Copy of Product Chemistry Review for NNI-0001 480 SC, dated October 19, 2007

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000264-01026 D366877
000264-01025 D366878
PP# 6F7065 D366884