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
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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