**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

**BEFORE THE ADMINISTRATOR**

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| In the Matter of: | ) | |
| | ) | |
| Bayer CropScience LP and | ) | FIFRA-HQ-2016-0001 |
| Nichino America, Inc., | ) | |
| | ) | |
| Petitioners. | ) | |

**REGISTRANTS' RESPONSE TO AMICUS CURIAE BRIEF OF THE CENTER FOR BIOLOGICAL DIVERSITY**

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## I. INTRODUCTION.

Bayer CropScience LP and Nichino America, Inc. (the "Registrants") provide the following response to the Amicus Curiae Brief of the Center for Biological Diversity ("CBD Brief"). Although the Center for Biological Diversity ("CBD") describes its interest as an advocate in this proceeding, its brief sheds no light on the issues and will not assist the ALJ in resolving the questions in dispute. Those include: whether this action is properly before this Tribunal as a risk-based cancellation decision brought in the guise of a failure to comply with an unlawful "voluntary" cancellation condition, and if so, whether the Registrants can be said to have failed to meet that cancellation condition given EPA's failure to make a sound adverse effects determination, and if so, what the disposition of existing stocks should be.

CBD's brief comments on potential harm to benthic aquatic invertebrates, but offers no facts or expertise to support EPA's flawed position or to refute the facts and evidence presented by the Registrants in the Motion for Accelerated Decision and accompanying Declarations, and that will be further presented by the Registrants' witnesses and exhibits in the pre-hearing submissions today, and at the hearing if one occurs. CBD's recitation of the history of the flubendiamide registrations is nothing more than an incomplete summary and misleading characterization of the factual record. CBD's legal arguments regarding conditional registrations and statutory cancellation requirements have for the most part been addressed in Registrants' Request for Hearing and Statement of Objections, Registrants' Motion for Accelerated Decision, and Registrants' Reply. The only new arguments CBD raises on conditional registration issues are based on a fundamental misrepresentation of the nature, purpose, and legal requirements for conditional registrations.

## II. CBD MISUNDERSTANDS CONDITIONAL REGISTRATIONS.

At various points in its brief, CBD describes conditional registration as a "second chance" for "deficient" registration applications and for pesticide products that fail to satisfy the "criteria for registration." CBD Brief at 8, 11, 15. This reflects a fundamental misunderstanding on the part of CBD.

The registration criteria established under FIFRA for both conditional and unconditional registration are identical: in both cases, EPA must conclude that use of the pesticide during the period of registration will not cause any "unreasonable adverse effects on the environment." FIFRA §§ 3(c)(5)(C)-(D) & 3(c)(7)(C), 7 U.S.C. §§ 136a(c)(5)(C)-(D) & 136a(c)(7)(C). Registrants' Motion for Accelerated Decision ("Registrants' Mot.") at 13-26; EPA's Opposition to Motion for Accelerated Decision ("EPA's Opp.") at 6-7. Moreover, for conditional registrations, EPA must make the *additional* affirmative finding that "use of the pesticide is in the public interest." FIFRA § 3(c)(7)(C); Registrants' Mot. at 15, 20; EPA's Opp. at 10; PBNX 21 at 5 (Public Interest Finding for Flubendiamide (Apr. 15, 2008)). Thus, contrary to CBD's assertion, conditional registration is not a "second chance" for pesticide products that fail to satisfy the criteria for registration.

Similarly, conditional registration is not a "second chance" for "deficient" registration applications, as CBD contends. Congress created conditional registration to provide EPA with a needed tool that allows the Agency to register a new product based on a positive "unreasonable adverse effects" determination and public interest finding while, at the same time, providing a mechanism for EPA to require the registrant to generate additional test data to support the product's registration. *See* Amicus Curiae Brief of CropLife America ("CLA Brief") at 20-21.

As the statutory structure and legislative history reflect, "a conditional registration can never be granted unless the product has passed every test that was required by EPA except a test

requirement imposed too recently to have been met." *Id.* at 21 (citing 123 Cong. Rec. S13,090-92 (1978) (Debate re Senate Passage of S. 1678 as Amended, July 29, 1977)). The conditional registration process provides a means for EPA to require additional data (such as the monitoring required for flubendiamide) to further its understanding of potential risks, confirm findings reached, or explore potential new areas of concern and to require other conditions as appropriate to ensure the registration continues to meet the Registration Standard. A desire for more information on an existing product does not mean that the product does not meet the Registration Standard or that EPA's registration determination was wrong or deficient. As Congress noted, "[w]hat provides an appropriate basis on which to reach scientific conclusions about toxicity today, the scientist may wish to augment tomorrow." *Id.*

## III. CBD MISUNDERSTANDS THE CENTRAL LEGAL ARGUMENTS IN THIS CASE.

CBD mischaracterizes the Registrants as arguing that "any cancellation of their conditional registrations should proceed under . . . FIFRA section 6(b)." CBD Brief at 16-17. The Registrants freely acknowledge that EPA can proceed under FIFRA § 6(e) to cancel "a registration issued under section 3(c)(7) [a conditional registration]" in the specific circumstances specified in § 6(e) – namely, that the registrant "has failed to initiate and pursue appropriate action toward fulfilling any condition imposed," or "at the end of the period provided for satisfaction of any condition imposed, that condition has not been meet." FIFRA § 6(e)(1). By contrast, § 6(b) governs cancellation of any type of registration if EPA determines that the product "generally causes unreasonable adverse effects on the environment" and thus fails to meet the FIFRA Registration Standard. FIFRA § 6(b).

It is CBD that misreads the statute by claiming that *all* cancellations of conditional registrations "must proceed pursuant to the procedural provisions provided in section 6(e)."

CBD Brief at 17. This is not correct. Section 6(e), by its express terms, only applies to cancellation for failure to satisfy conditions of registration and does not address cancellation for other grounds, including failure to meet the Registration Standard. Section 6(b), which does cover cancellation based on a determination that the registration fails to meet the Registration Standard, is not limited to unconditional registrations. Indeed, if CBD were correct, EPA could never cancel a conditional registration on its own initiative for reasons unrelated to an existing condition of registration.

As made clear by the Registrants in their Statement of Objections, Motion for Accelerated Decision, and Reply, EPA cannot devise an unlawful forced "voluntary" cancellation condition, refuse to grant registrations that it has found to be in the public interest and to meet the Registration Standard unless the unlawful condition is accepted, and then use the condition to claim the right to pursue under § 6(e) a cancellation that is based on an "unreasonable adverse effects" determination[1] and thus governed by § 6(b) instead of § 6(e), all the while claiming that the scope of the § 6(e) process shields its determination from any substantive challenge or review. EPA cannot create out of thin air a new type of "condition" that would allow the Agency to evade a statutory requirement and provide the Agency unchecked authority to summarily conclude that a product no longer satisfies the FIFRA Registration Standard. This forced "voluntary" cancellation condition, and EPA's attempt to use § 6(e) to enforce the "condition," exceeds EPA's authority under FIFRA and is therefore unlawful.

[1] S*ee* PBNX 30 at 10 ("EPA has . . . determined that the risks of allowing the continued use of flubendiamide outweigh the benefits, and will result in unreasonable adverse effects to the environment.").

## IV. CBD'S FACTUAL ARGUMENTS ARE UNSUPPORTED OR INACCURATE.

### A. CBD Provides No Support for the Contention That Flubendiamide Sales Will Continue to Increase Rapidly.

CBD relies on a graph of estimated flubendiamide use to argue that flubendiamide use "doubl[ed] between 2010 and 2011, and then again between 2011 and 2012" and will "continue to increase," resulting in "unreasonable adverse effects." CBD Brief at 7. The increase in use in the first several years that flubendiamide was available is unremarkable for a newly introduced product. CBD provides no basis for its claim that these increases will continue – in fact, the estimated use data it relies on show a slight decline in use the final year. *Id.* At any rate, flubendiamide is not a high volume use product; it is used where it is needed, and where used its qualitative benefits are significant.[2]

### B. CBD Provides No Evidence of Harm to Mussels or Any Other Protected Species.

CBD's Brief suggests continued use of flubendiamide will cause harm to freshwater mussels, including certain protected species. However, CBD provides no evidence or facts showing harm or any specific potential risk to mussels. EPA in its risk assessments has repeatedly concluded there are no risks of concern to estuarine and marine mollusks, and acute toxicity testing on oysters showed no risks of concern.[3] CBD relies on EPA's determination that use of flubendiamide may cause potential harm to benthic aquatic invertebrates. CBD Brief at 5. However, CBD provides no evidence to refute the facts and evidence presented by the Registrants in the Motion for Accelerated Decision and accompanying Declarations, and that will be further presented by the Registrants' witnesses and exhibits in the pre-hearing submissions today, establishing that EPA's risk determination is scientifically unsound and that

[2] Verified Written Statement of Lee Hall at 4:21-5:3.
[3] *See, e.g.*, Verified Written Statement of Dwayne R.J. Moore at 8:15-17 ("Moore Statement"); PBNX 27 at 2; PBNX 28 at 3-8 (PDF pp. 22-27); PBNX 29 at 38-41.

real-world data from seven years of use and monitoring show no concentrations exceeding any endpoint identified by EPA.[4]

### C. CBD Does Not Understand the Facts With Respect to the Synapse WG Cancellation.

CBD contends that Bayer's request to voluntarily cancel its registration for Synapse WG (EPA Reg. No. 264-1026) somehow demonstrates Bayer's compliance with the "voluntary" cancellation condition and a concession that it is lawful. CBD Brief at 15-16. This is illogical. As the Federal Register Notice cited by CBD reflects, Bayer requested voluntary cancellation of the Synapse WG registration on December 12, 2014, more than a year before EPA's January 29, 2016 letter requesting cancellation based on the unlawful "voluntary" cancellation condition.[5] Bayer cancelled the registration for Synapse WG, as well as a registration for Synapse 480, because both registrations were not commercially active, a fact reflected in the Federal Register Notice cited by CBD and in Bayer's response to the cancellation demand letter.[6] CBD's inability to grasp the most basic facts related to its positions is noteworthy.

[4] *See* Moore Statement;Verified Statement of Bernard Engel; Verified Statement of Charlotte Sanson at 15:2-20:13.
[5] Flubendiamide; Notice of Receipt of Request To Voluntarily Cancel a Pesticide Product Registration, 81 Fed. Reg. 21,344, 21,344 (April 11, 2016).
[6] *Id.* ("Bayer confirmed that neither formulation is commercially active."); PBNX 18 at 1 (informing EPA that "Bayer stopped using the Synapse WG Insecticide . . . registration in 2012 and submitted a voluntary cancellation request for that registration by letter dated December 12, 2014" and that Bayer "does not plan to resubmit a cancellation request for that registration.").

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Respectfully Submitted,

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## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 22nd day of April, 2016, a true and correct copy of the foregoing Registrants' Response to Amicus Curiae Brief of the Center for Biological Diversity using the EPA OALJ e-filing system; and served in the following manner to the below addressees:

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