UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

RESPONDENT'S POST-HEARING BRIEF

I. QUESTIONS PRESENTED

1. Whether the Registrants failed to comply with a condition of their pesticide registrations by failing to submit a request for voluntary cancellation upon receiving notice of EPA's unreasonable adverse effects determination?
2. Whether the Administrator's Determination regarding the disposition of existing stocks of flubendiamide is consistent with FIFRA?

II. STATEMENT OF THE CASE

On August 1, 2008, EPA issued notices of registration for pesticides containing flubendiamide, an active ingredient not previously registered. Each notice of registration declared the product was "conditionally registered in accordance with FIFRA section (3)(c)(7)." RE 3 at 200014-200017. Each also specified that "[y]our release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA." RE 3 at 200015, 200017. On March 4, 2009, two more products containing flubendiamide were subsequently registered subject to the same conditions.

Owing to the failure of Bayer CropScience LP and Nichino America, Inc. ("Petitioners" or "Registrants") to comply with a condition of these flubendiamide registrations, on February 29, 2016, EPA issued a Notice of Intent to Cancel (NOIC) the registrations pursuant to FIFRA section 6(e). Flubendiamide; Notice of Intent To Cancel Pesticide Registrations, 81 Fed. Reg. 11558 (March 4, 2016). In response, the Registrants filed a Request for Hearing and Statement of Objections on March 31, 2016.

FIFRA section 6(e) provides that "[t]he only matters for resolution at [a hearing pursuant to section 6(e)] shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter." FIFRA section 6(e)(2). Earlier in this proceeding, the Tribunal ruled that FIFRA section 6(e) properly governs this proceeding, and limits its scope to the matters specified in section 6(e). *Order On Petitioners' Motion For Accelerated Decision*, *In the Matter of Bayer CropScience LP, and Nichino America, Inc.*, Docket No. FIFRA-HQ-2016-0001, *slip op.* at 28 (April 25, 2016). The Tribunal subsequently ruled that the question of whether the Petitioners' flubendiamide pesticides have an unreasonable adverse effect on the environment is not an issue for this hearing. *Order On Respondent's Motion To Limit Scope Of Testimony*, *In the Matter of Bayer CropScience LP, and Nichino America, Inc.*, Docket No. FIFRA-HQ-2016-0001, *slip op.* at 7-10 (May 3, 2016). Accordingly, the sole questions at issue are (1) whether the Registrants have complied with the conditions of registration within the time provided, and (2) whether the Administrator's determination with respect to the disposition of existing stocks is consistent with purposes of FIFRA.

In the May 10, 2016, evidentiary hearing before the Tribunal, EPA presented uncontroverted evidence that the Registrants have failed to comply with the conditions of the flubendiamide registrations within the time provided, and that EPA's existing stocks determination is consistent with purposes of FIFRA. Accordingly, the flubendiamide registrations should be cancelled, and the cancellation order should incorporate EPA's existing stocks determination.

III. FINDINGS OF FACT

1. The products were conditionally registered under FIFRA section 3(c)(7). RE 3 at 200014-200019B. *See also* RE 10 at 200101.
2. The conditions of registration incorporated by reference the conditions of registration outlined in the preliminary acceptance letter for flubendiamide (PAL), dated July 31, 2008. RE 3 at 200015, 200017, 200019, 200019B; RE 10 at 200101.
3. The PAL specified that "[t]he subject products will be conditionally registered for a period of five (5) years from the date of the Notice of Registration. RE 2 at 200010. *See also* RE 1 at 200007 and RE 10 at 200014.
4. EPA extended this time limit from July 31, 2013, to August 31, 2015, in order to allow the Registrants "sufficient time to complete the 3-year monitoring program required by the original conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008." PX 10. EPA subsequently agreed to four more extensions, to December 10, 2015, December 18, 2015, January 15, 2016 and January 29, 2016, to allow further discussions and negotiations between the parties. PX 12, PX 13, PX 15, PX 16.
5. The PAL included conditions such that if, after review of data submitted by the Registrants, EPA makes a determination that further registration of the flubendiamide technical product will result in unreasonable adverse effects on the environment, the Registrants would be required to submit requests for voluntary cancellation of the flubendiamide registrations within one week of such finding. RE 2 at 200011-200013.

6. The Registrants agreed to the PAL conditions on July 31, 2008, when Margaret Cherny, Bayer's Vice President of Regulatory Affairs, signed the final negotiated PAL. RE 2 at 200013; Tr. at 118-119 (Sanson).
7. The Registrants' understood and agreed to the conditions of their registrations that they originally accepted in August 1, 2008 in the PAL. RE 2 at 200013; RE 4 at 200036.
8. The Notices of Registration specify that "Your release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA." RE 3 at 200015, 200017, 200019, 20019B.
9. The Registrants released for shipment flubendiamide products under the authority of the conditional registrations.
10. The Registrants conducted studies required pursuant to the PAL and submitted them, and other voluntary studies, for EPA review.
11. EPA reviewed all of the studies submitted by the Registrants. RE 5 200056-200074; Tr. at 125 (Sanson).
12. EPA scientists met with Registrants' scientists to discuss the flubendiamide studies on multiple occasions. RE 6 at 200077; RE 5 at 200071, 200074. See also Tr. at 71. 91-92 (Lewis); 105-109 (Sanson); 184-185 (Johnson).
13. After review of all studies submitted by the registrants and other available material, EPA concluded that continued use of the currently registered flubendiamide products will result in unreasonable adverse effects on the environment. RE 6 at 200078; RE 5 at 200075.

14. EPA notified the registrants of its unreasonable adverse effects determination and called for the registrants to submit requests for voluntary cancellation of their flubendiamide registrations as provided in the PAL. RE 6 at 200078.

15. The Registrants have refused to submit requests for voluntary cancellation of their flubendiamide registrations as required pursuant to the PAL. RE 7 at 200079-200081.

16. The Registrants' failure to request voluntary cancellation as required by the conditional registrations could have delayed cancellation for approximately three months, and Bayer continued to produce flubendiamide products during that time. Tr. at 56 (Lewis); RE10 at 200106; PBNX 116 at PBN 1614; PBNX 117 at PBN1632.

17. EPA uses registration conditions to mitigate risks as necessary in order to prevent unreasonable adverse effects on the environment, and where no such measures are feasible, does not proceed with registration. RE 10 at 200097.

18. EPA included in the flubendiamide registrations conditions designed to quickly cancel the registration because flubendiamide and its des-iodo degradate do not readily break down into other relatively low-toxicity chemicals, especially in aquatic systems, and are toxic to freshwater benthic invertebrates. RE 1 at 20008. See also PBNX 9 at PBN0030.

19. EPA would likely not have approved flubendiamide registrations without the cancellation condition. Tr. at 108 (Sanson); 146 (Johnson).

IV. The Flubendiamide Registrations Should Be Cancelled Pursuant To FIFRA Section 6(e) Because The Registrants Failed To Comply With Conditions Requiring Them To Submit Requests For Voluntary Cancellation Upon Receiving Notice Of EPA's Unreasonable Adverse Effects Determination

A. EPA Has Established All of the Elements of A Prima Facie Case For Cancellation of The Flubendiamide Registrations

EPA has established that the flubendiamide products were conditionally registered under FIFRA section 3(c)(7), and that those registrations included a specific condition – either condition 6(d) or 8(d) of the PAL, as applicable – which required that if EPA made a certain determination and communicated that determination to the Registrants, then the Registrants must within one week submit requests for voluntary cancellation of the flubendiamide registrations.[1]

EPA has established that it informed registrants of its determination that further registration of the flubendiamide products would result in unreasonable adverse effects on the environment on January 29, 2016, and called for the Registrants to submit requests for FIFRA section 6(f) voluntarily cancellation of their flubendiamide registrations pursuant to condition 6(d) and 8(d) of the PAL. The Registrants informed the Agency on February 5, 2016 that they would not comply with the voluntary cancellation condition, and remain noncompliant to date.

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[1] The two combination flubendiamide/buprofezin products that were registered in March 1, 2009 (Vetica Insecticide, EPA Reg. No. 71711-32, and Tourismo Insecticide, EPA Reg. No. 71711-33) were also registered subject to the same terms and conditions as the earlier flubendiamide products. The March 4, 2009, notices of registration for the products contain an incorrect citation to the PAL, suggesting that there is a separate preliminary acceptance letter for the flubendiamide/buprofezin combination. During the evidentiary hearing, Judge Biro asked EPA's witness about a preliminary acceptance letter for flubendiamide and buprofezin products. Such a letter was never created and does not exist. Tr. at 85-87 (Lewis). The only preliminary acceptance letter for flubendiamide registrations was the July 31, 2008 PAL. The shared understanding of the Parties since March 9, 2009, has been that the Vetica and Tourismo registrations are subject to the conditions of the July 31, 2008 PAL, and all of the Parties' respective actions have been consistent with that shared understanding. Official notices and documents of the Agency consistently reflect that all flubendiamide registrations are subject to the PAL. RE 8 at 200082-200083; RE 6 at 200077; RE 7; PBNX 10; PBNX 12; PBNX 13; PBNX 15- PBNX 18. Nowhere in the Registrants' objections or request for a hearing is there any suggestion that the July 31, 2008 PAL does not equally apply to the Vetica and Tourismo registrations, so the Registrants have waived any right to raise that issue now.

EPA has established that the conditions precedent to the voluntary cancellation request have been satisfied: EPA completed its review of all of the studies and information submitted by the Registrants; EPA scientists and Registrants' scientists engaged in dialogue about the data and the Agency's conclusions; EPA made a determination that further registration of the flubendiamide products would result in unreasonable adverse effects on the environment; and EPA communicated that finding to the Registrants no earlier than September 1, 2013. RE 5; RE 6; RE 10.

EPA has further established with record evidence and testimony admitted at hearing that Registrants' understood and agreed to the conditions of their registrations when they originally accepted them on August 1, 2008; that the conditions of the PAL were incorporated by reference into the Notices of Registration of the flubendiamide products; that the flubendiamide registrations were conditionally registered for a period of five years; and that EPA extended this time limit on five occasions to allow further testing, discussions and negotiations between the parties. EPA established that the cancellation conditions were included in the original registrations because of EPA's concern that flubendiamide and its des-iodo degradate may accumulate in aquatic environments to concentrations that would cause unreasonable adverse effects on the environment. RE 1 at 200008. EPA established that the cancellation conditions were triggered in 2016 because EPA had determined that, because of the same aquatic concerns, continued registration would cause unreasonable adverse effects on the environment RE 5 at 20075. EPA established that EPA uses registration conditions to mitigate risks as necessary in order to prevent unreasonable adverse effects on the environment, and where no such measures are feasible, does not proceed with registration, and that EPA would not have approved flubendiamide registrations without the cancellation condition. RE at 200097.

When Registrants accepted conditional registrations pursuant to FIFRA section 3(c)(7), they knowingly accepted registrations that, as a class, are subject to cancellation in accordance with FIFRA section 6(e) in the event that the registrant should fail to comply with any condition of registration. This fact was expressly stated in the NOR: "Your release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA." RE 3 at 200015, 200017. As the facts here clearly establish that the Registrants failed to comply with a condition of their flubendiamide registrations, the Tribunal should issue an order cancelling the flubendiamide registrations pursuant to FIFRA section 6(e).

B. Registrants Have Not Carried Their Burden of Persuasion Regarding Cancellation

Under FIFRA, the burden of demonstrating that a pesticide satisfies the statutory standard for registration rests at all times on the registrant, applicant, or other proponent of initial or continued registration. *Environmental Defense Fund v. EPA*, 548 F. 2d 998, 1004, 1012-18 (D.C. Cir. 1976, *cert. den.*, 431 U.S. 925 (1977). Although the Registrants have introduced extensive testimony and exhibits on a range of peripheral issues, they have not presented any credible evidence to support a finding that the Registrants complied with all conditions of their flubendiamide registrations. As noted in the Tribunal's April 25, 2016, Order, the "Petitioners … do not dispute that 'voluntary withdrawal' was a condition of their conditional registration and that they did not comply with that condition." *Order On Petitioners' Motion For Accelerated Decision* at 28. Accordingly, pursuant to FIFRA section 6(e), the registrations should be cancelled.

The Registrants suggested at hearing that a necessary precondition had not been met because the Agency did not have sufficient scientific dialogue with the Registrants prior to triggering the cancellation condition. Tr. at 12-15 (Szmuszkovicz); 147, 151, 163 (Johnson). This argument is an untimely and groundless attempt to justify their non-compliance with the cancellation condition. This argument was not raised in the March 31, 2016, Request For Hearing And Statement Of Objections, nor was it mentioned in Registrants' February 5, 2016 refusal letter as a rationale for not complying with the cancellation condition. The PAL stated that "EPA scientists and [Registrants' scientists] shall engage in dialogue about the data and the Agency's conclusions." It is uncontroverted that scientific discussions were held. RE 6 at 200077; RE 5 at 200071, 200074. See also Tr. at 71. 91-92 (Lewis); 105-109 (Sanson); 184-185 (Johnson). It is equally clear that there is a genuine scientific dispute between EPA and the Registrants related to the risks posed by flubendiamide. RE 7 at 200080-200081; Tr. at 105-106 (Sanson), 149 (Johnson). But the conditional registration does not require that scientific disputes be resolved by consensus; the PAL clearly provides that the Agency can trigger the cancellation condition if "the Agency makes a determination that further registration of the [flubendiamide products] will result in unreasonable adverse effects on the environment." The PAL does not require a level of scientific discourse greater than what occurred here. EPA did not produce more testimony addressing this issue because Registrants did not appropriately raise it in their Request for Hearing and Statement of Objections. While the argument should be rejected because it was not raised in a timely manner, it is also clear that Registrants have not carried their burden of demonstrating that the PAL required more dialogue than occurred here.

Registrants also raise the speculation that EPA's decision to trigger cancellation was "political" in nature. Tr. at 17 (Szmuszkovicz); Tr. at 128 (Sanson); Tr. at 187-190 (Johnson).

While it is not clear what relevance this argument would have to this proceeding even if true, Registrants did not come close to carrying their burden of demonstrating at hearing that EPA's unreasonable adverse effects determination was based on anything other than the Agency's view of the relevant science.

The Registrants' contention that EPA materially changed its position in regard to the adverse effects of flubendiamide in the fall of 2015 is mistaken, as the documents supporting the 2008 and 2015-2016 actions are fully consonant. But even if the Registrants' view were correct it would be irrelevant because nothing in the PAL suggests that EPA's unreasonable adverse effects determination must be based on the Agency's 2008 understanding of the risks and benefits of flubendiamide. To the contrary, the entire point of the five-year conditional registration was to allow for the generation of studies that might change EPA's 2008 determination.

V. EPA's Determination with Regard to Existing Stocks of Flubendiamide is Consistent with FIFRA

FIFRA section 6(e) allows the Agency to permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been cancelled, to the extent that the Administrator determines that such sale or use would not be inconsistent with the Act. FIFRA Section 6(a)(1) authorizes the Administrator to "permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or cancelled …under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this Act." The Agency's existing stocks determination for cancelled flubendiamide products was announced in the NOIC and would prohibit any further sale or distribution, by Registrants or any other person, of existing stocks of their products, except to the extent that distribution is for the purposes of returning material back up the channels of trade, for purposes

of disposal, or for purposes of lawful export. Existing stocks already in the hands of end users could be used in accordance with the label until exhausted, but use of existing stocks of technical flubendiamide for the purpose of manufacturing other pesticide products would be prohibited. 43 Fed.Reg. 11558, 11560.

The Agency rationale for its existing stocks determination is articulated in the testimony of Susan Lewis, Director of the Registration Division, and addresses three major points. First, the existing stocks determination is consistent with the Agency's Statement of Policy for Existing Stocks of Pesticide Products ("Policy")(RE 9) in that it would generally prohibit sale or distribution by registrants who have failed to comply with a specific, as opposed to general, condition of registration. The Agency's existing stocks determination differs from the Policy in that it would also generally prohibit third party sale and distribution of cancelled flubendiamide products already in the chain of commerce, because some of the existing stocks currently in the chain of commerce may be there as a consequence of the Registrants' having deliberately reneged on a condition of registration expressly intended to stop the further introduction of persistent toxic chemicals from entering commerce and the environment. RE 10 at 200107; Tr. at 56 (Lewis). See also PBNX 116 at PBN 1614; PBNX 117 at PBN 1632. The Registrants' failure to request voluntary cancellation as required by the conditional registrations could have delayed cancellation for approximately three months, and Bayer continued to produce flubendiamide products during that time. Tr. at 56 (Lewis); PBNX 116 at PBN 1614; PBNX 117 at PBN 1632.

Second, EPA's decision to adopt an existing stocks determination more strict than the position generally applicable under the Policy was based in part on the importance of deterring registrants from intentionally violating important, specific conditions of registration, especially where the Registrants were clearly aware of how important that condition was to EPA's decision

to approve the registration. RE 10 at 200107-100108. The Policy does not speak to such violations, and it is reasonable for EPA to depart from the Policy to address this extraordinary circumstance. If EPA is unable to rely on registrants' compliance with the terms and conditions of registration, EPA will, at least in some circumstances, become less able to make the finding that the terms and conditions of a pesticide's registration are sufficient to conclude that the pesticide will not cause unreasonable adverse effects. RE 10 at 200108-100109. Such a scenario could impact many companies and applications not involved in this proceeding, and slow the introduction of promising new pesticide products into the market. Accordingly, the existing stocks determination in the NOIC relies solely upon the conclusion that continued sale or distribution of existing stocks of the cancelled pesticides would be inconsistent with the purposes of FIFRA because the Registrants have reneged on commitments they made to comply with a specific condition of registration that was material to EPA's approval of the registration. EPA's ability to rely upon registrants to fulfill specific conditions of registration is vitally important to the registration process. RE 10 at 200109.

Third, EPA made a determination that the quantity of existing stocks in the hands of end users is likely to be small and the cost and risks associated with returning them for disposal would be high compared with the use of the cancelled product in accordance with its labeling. NOIC, 81 Fed. Reg. at 11,560; RE 10 at 200109-200110. Although EPA does not have specific information about the precise quantities of flubendiamide products in end users hands or in the chain of commerce, experience suggests that they are small. Tr. at 54-55 (Lewis).

The Registrants' contention that the existing stocks determination is punishment for exercising their right to request a hearing is mistaken and frivolous. As explained above, the Agency's existing stocks determination is based on discouraging the intentional reneging on

important, specific conditions of registration. The Registrants' contention that their refusal to comply with the cancellation condition was in order to enable them to challenge the cancellation condition is disingenuous, as they had several other legitimate ways to challenge the conditions. *Woodstream I*, 2011 U.S. Dist. LEXIS 151994, *17–19; *Order On Petitioners' Motion For Accelerated Decision, In the Matter of Bayer CropScience LP, and Nichino America, Inc.*, Docket No. FIFRA-HQ-2016-0001, *slip op.* at 27 n.23 (April 25, 2016).

CONCLUSION

For the reasons set forth above, EPA respectfully requests that this Tribunal order the cancellation of Registrants' flubendiamide products pursuant to FIFRA section 6(e), and include in that cancellation order the existing stocks provisions specified in the NOIC.

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Respectfully Submitted,

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