# IN RE BAYER CROPSCIENCE LP

FIFRA Appeal No. 16-01

## *FINAL DECISION AND ORDER*

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Decided July 29, 2016

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Syllabus

The Environmental Protection Agency's Pesticide Program Office ("Pesticide Program" or "Program") issued a cancellation notice for flubendiamide, a pesticide conditionally registered in 2008 and 2009 for sale, distribution, and use under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. The Pesticide Program asserts that flubendiamide's registrants, Bayer CropScience LP ("Bayer") and Nichino America, Inc. ("Nichino"), refused to comply with a key condition of their registrations. That condition, which Bayer and Nichino had negotiated and agreed to in writing, requires them to initiate termination of their registrations by requesting voluntary cancellation if the Pesticide Program concludes that flubendiamide causes unreasonable adverse effects on the environment. Bayer and Nichino object, arguing that, (1) the termination condition is unlawful; (2) in any event, they did not violate that condition because the Pesticide Program did not fulfill its obligations under the registrations; and (3) the Pesticide Program's determination prohibiting the continued sale and use of existing stocks of the canceled pesticide is flawed. They contend that before flubendiamide may be removed from the market they are entitled to a full cancellation hearing on the question of whether flubendiamide causes unreasonable adverse effects.

HELD: Bayer and Nichino's flubendiamide registrations are canceled. With one exception, the Board upholds the Pesticide Program's determination on the disposition of existing stocks of the canceled flubendiamide products.

1. The Pesticide Program appropriately commenced this proceeding under the expedited cancellation procedures in FIFRA section 6(e), 7 U.S.C. § 136d(e), for conditional registrations, rather than under the general cancellation provision in FIFRA section 6(b), 7 U.S.C. § 136d(b). In any event, Bayer and Nichino cannot now demand a section 6(b) hearing on whether flubendiamide causes unreasonable adverse effects because they willingly accepted the termination condition in 2008 and 2009, knowing that it required them to submit a request for voluntary cancellation if the Program were to issue a determination that flubendiamide causes unreasonable adverse effects.

2. The scope of a cancellation hearing under FIFRA section 6(e) is narrowly limited to the resolution of two issues: (a) whether registrants have complied with the conditions of registration (or have initiated and pursued appropriate action toward fulfilling those conditions), and (b) whether the Pesticide Program's determination with respect to the continued sale and use of existing stocks is consistent with FIFRA. Bayer and Nichino's challenge to the lawfulness of the termination condition in their registrations does not fall within the scope of a section 6(e) cancellation hearing. Bayer and Nichino could have, but declined to, exercise a number of options to challenge the lawfulness of the condition – most prominently, by accepting a denial of their registration applications so that they could challenge the termination condition in a denial hearing.

3. By failing to request voluntary cancellation of their flubendiamide registrations within one week of the Program's January 29, 2016 determination that flubendiamide causes unreasonable adverse effects, Bayer and Nichino failed to satisfy the termination condition in their flubendiamide registrations.

4. Bayer and Nichino did not timely object or argue with sufficient particularity that the Program failed to comply with a condition of the flubendiamide registrations by failing to "engage in dialogue" with Bayer scientists regarding the data and the Program's conclusions. Therefore, Bayer and Nichino are precluded from raising this objection as grounds for excusing their failure to comply with the termination condition.

5. Even assuming that Bayer and Nichino are not precluded from arguing that the Program failed to engage in dialogue, Bayer and Nichino failed to establish by a preponderance of the evidence that the Program did not engage in dialogue with Bayer's scientists about the data and the Program's conclusions.

6. The Pesticide Program's determination to prohibit Bayer and Nichino's continued sale, distribution, and use of existing stocks of flubendiamide products is consistent with FIFRA.

7. The Pesticide Program's determination to prohibit the continued sale and distribution of existing stocks of flubendiamide end-use products by distributors and retailers other than Bayer and Nichino is not supported by the record.

***Before Environmental Appeals Judges Mary Kay Lynch, Kathie A. Stein, and Mary Beth Ward.***

***Opinion of the Board by Judge Stein:***

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## I. *INTRODUCTION*

In this matter, the Environmental Protection Agency's Pesticide Program Office seeks to cancel several pesticide registrations that it conditionally granted in 2008 and 2009 under "special circumstances." On February 29, 2016, the Pesticide Program issued a cancellation notice for flubendiamide, a pesticide registered for sale, distribution, and use under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. The Pesticide Program asserts that flubendiamide's registrants, Bayer CropScience LP ("Bayer") and Nichino America, Inc. ("Nichino"), refused to comply with a key condition of their registrations.

That key condition requires them to initiate termination of their registrations by requesting voluntary cancellation if the Pesticide Program concludes that flubendiamide causes unreasonable adverse effects on the environment. The termination condition was the subject of extensive negotiation between the parties, and Bayer and Nichino agreed to the condition so as to obtain the Program's approval to sell and distribute flubendiamide products. Bayer and Nichino now oppose the cancellation notice, arguing that the termination condition is unlawful. Additionally, they argue in the alternative that they did not violate that condition because the Pesticide Program did not fulfill its obligations under the registrations. Finally, they contend that the Pesticide Program erred in prohibiting the continued sale and distribution of existing stocks of the canceled flubendiamide products.

After an evidentiary hearing, an administrative law judge denied Bayer and Nichino's challenge to the cancellation notice. Corrected Initial Decision at 37. With one exception, we affirm, although our decision is based, in part, on different grounds.

FIFRA allows the Pesticide Program to conditionally register pesticides for sale and distribution in three "special circumstances." FIFRA § 3(c)(7), 7 U.S.C. § 136a(c)(7). The circumstances pertinent here apply to new pesticides, such as flubendiamide, that lack sufficient data for a general registration, where those data are mandated by newly-imposed requirements. Unlike general registrations, conditional registrations for new pesticides are statutorily limited to the period of time "reasonably sufficient for the generation and submission of required data." *Id*. § 3(c)(7)(C), § 136a(c)(7)(C). Another significant difference between the two registration types is that the statute provides a special cancellation process for conditional registrations. If a conditional registrant violates a condition of its registration, FIFRA section 6(e) mandates that the Pesticide Program expeditiously cancel that registration in a sharply-restricted proceeding. *Id*. § 6(e)(1), § 136d(e)(1). Where a hearing is requested, a determination on the cancellation action must be made within 75 days, and the hearing is limited to two issues: whether the registrant satisfied the conditions of its registration, and whether the Pesticide Program's determination on the disposition of existing stocks of the canceled pesticide is consistent with FIFRA. *Id*. § 6(e)(2), § 136d(e)(2). In contrast, FIFRA's general cancellation proceeding in section 6(b) imposes no time restrictions on the cancellation hearing and principally focuses on the broad question of whether the pesticide causes unreasonable adverse effects on the environment. *See id*. § 6(b), § 136(b).

The central issues in this case involve the termination condition in Bayer and Nichino's registrations. After extensive negotiations prior to approval of the flubendiamide registrations, Bayer and Nichino agreed to the registration term that required them to submit an irrevocable request for voluntary cancellation if the Pesticide Program were to determine that flubendiamide causes unreasonable adverse effects on the environment. They did so in writing, endorsing the negotiated terms of the registration as follows: "Bayer CropScience LP [as authorized agent for Nichino] hereby concurs with the time-limited conditional registration of the new insecticide flubendiamide under section 3(c)(7)(C) of FIFRA." Letter from Lois A. Rossi, Director, Registration Division, Office of Prevention, Pesticides and Toxic Substances, U.S. EPA, to Danielle A. Larochelle, Registration Product Manager, Authorized Agent for Nichino America, Inc., Bayer CropScience LP, PBNX 8, at PBN0017-20 (July 31, 2008). The record shows that Bayer and Nichino accepted this termination condition because the Pesticide Program agreed not to invoke it until after the Program had reviewed all data that Bayer and Nichino submitted, and had engaged in a dialogue with Bayer scientists on its conclusions. Once Bayer and Nichino had concurred in the terms of the registrations, the Program granted them conditional registrations to sell and distribute flubendiamide products. The official Notices of Registration advised

Bayer and Nichino that failure to comply with the conditions in the registrations would make "the registration[s] subject to cancellation *in accordance with section 6(e) of FIFRA*." Notices of Registration for Flubendiamide Technical and Belt SC Insecticide, RE 3, at RE015 (Aug. 1, 2008) (emphasis added).

Seven years later, the Program triggered the termination condition by issuing a determination that flubendiamide causes unreasonable adverse effects. Bayer and Nichino, however, refused to request voluntary cancellation. Although they had accepted the termination condition as the price for obtaining market access, Bayer and Nichino now claim that the termination condition is unlawful and, thus, their refusal to comply with it cannot be grounds for cancellation of their registrations. Moreover, they argue that the Program erred by initiating this proceeding under the section 6(e) procedures for canceling conditional registrations; they contend that before flubendiamide may be removed from the market they are entitled to the full cancellation hearing provided by FIFRA section 6(b) on the question of whether flubendiamide causes unreasonable adverse effects.

The Board concludes that the Pesticide Program properly initiated this cancellation action under FIFRA section 6(e), rather than FIFRA section 6(b). The statute directs that the Program *must* initiate a cancellation proceeding under section 6(e) if the Program determines, as here, a conditional registrant has not satisfied a condition of its registration. FIFRA § 6(e)(1), 7 U.S.C. § 136d(e)(1). Further, the Board holds that Bayer and Nichino may not challenge the lawfulness of the termination condition in a properly-initiated section 6(e) cancellation proceeding. The statutory language could not be more clear: "[t]he only matters for resolution" in a section 6(e) hearing are whether the registrant has satisfied the conditions of its registration and whether the Pesticide Program has appropriately addressed existing stocks of the canceled pesticide. *Id*. § 6(e)(2), § 136d(e)(2). This strict limitation on the scope of a section 6(e) cancellation proceeding precludes a registrant from collaterally attacking, in the cancellation proceeding, the lawfulness of a registration or any of its conditions.

Section 6(e) does not insulate Pesticide Program decisions granting or denying conditional registrations – or the terms thereof – from administrative and judicial review. Rather, it only precludes the after-the-fact review of a conditional registration decision in a section 6(e) cancellation proceeding. Bayer and Nichino did not avail themselves of numerous prior opportunities to challenge the lawfulness of the termination condition. Most prominently, Bayer and Nichino could have refused to accept registrations with such a condition, thereby requiring the Pesticide Program to issue a denial of their registration applications. The Pesticide Program expressly gave Bayer and Nichino that option. A denial would

have entitled Bayer and Nichino to a full administrative hearing and independent scientific review under section 6(b).

With respect to the two issues that may be addressed in a section 6(e) cancellation proceeding, the Board first holds that Bayer and Nichino did not satisfy the termination condition in their flubendiamide registrations. Bayer and Nichino refused to request voluntary cancellation following the Pesticide Program's unreasonable adverse effects determination. During the evidentiary hearing, Bayer and Nichino raised for the first time a claim that scientists from the Pesticide Program did not engage in a dialogue with Bayer's scientists concerning newly-submitted data and the Program's conclusions and thus failed to trigger the termination condition. Because Bayer and Nichino did not timely raise this claim, they are precluded from raising it here. Even if this argument had been timely raised, the Board finds that Bayer and Nichino did not meet their burden to show that the Pesticide Program failed to engage in dialogue with their scientists concerning the data and the Program's conclusions.

Second, the Board rejects Bayer and Nichino's challenge to the Pesticide Program's decision to prohibit Bayer and Nichino from selling or distributing existing stocks of the canceled flubendiamide products. The Pesticide Program reasonably concluded that allowing Bayer and Nichino to sell and distribute existing stocks of flubendiamide is inconsistent with the purposes of FIFRA, given the refusal by Bayer and Nichino to abide by the termination condition in their registrations. However, the Board reverses the existing stocks determination to the extent that it bars the sale and distribution of existing stocks of end-use products by parties other than Bayer and Nichino.

The main thrust of Bayer and Nichino's challenge to this proceeding has been that it deprives them of a full administrative hearing under section 6(b) on whether flubendiamide causes unreasonable adverse effects prior to the removal of flubendiamide from the market. But the option of obtaining a section 6(b) hearing on this question has always been within the control of Bayer and Nichino, and remains so today. They could have obtained a section 6(b) hearing on their applications to register flubendiamide but declined that option in favor of obtaining immediate market access under the negotiated terms for their conditional registrations. After obtaining conditional registrations for flubendiamide, Bayer and Nichino had the option of applying for general registrations. If Bayer and Nichino had applied for, but been denied, general registrations based on a finding of unreasonable adverse effects, Bayer and Nichino would have been entitled under section 6(b) to a full evidentiary hearing on that denial. FIFRA § 3(c)(6), 7 U.S.C. § 136a(c)(6). The option to apply for general registration of the flubendiamide

products is still available today. If they wish, they may immediately re-apply for a FIFRA registration for flubendiamide. And Bayer and Nichino's statutory and regulatory hearing rights on an application denial by the Program remain intact. What Bayer and Nichino are not entitled to is a full administrative hearing on whether flubendiamide causes unreasonable adverse effects in this section 6(e) cancellation proceeding.

## II. *STATUTORY AND REGULATORY BACKGROUND*

FIFRA is a "comprehensive regulatory statute" governing the sale, distribution, and use of pesticides for the purpose of protecting both human health and the environment. *Ruckelshaus v. Monsanto*, 467 U.S. 986, 991-92 (1984). FIFRA's primary regulatory mechanism is a registration program that mandates safety clearance of pesticides by EPA prior to their sale and distribution. FIFRA § 3(a)-(c), 7 U.S.C. § 136a(a)-(c). As the D.C. Circuit Court of Appeals explained, "[a] FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used." *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010).

The statute provides for both general registrations and registrations under "special circumstances," otherwise known as "conditional" registrations. *See* FIFRA § 3(c)(5), 7 U.S.C § 136a(c)(5) (general registrations); *id*. § 3(c)(7), § 136a(c)(7) (conditional registrations). Mirroring these different types of registrations, FIFRA includes both a general provision addressing the cancellation of pesticide registrations and a specific provision that applies only to the cancellation of conditional registrations. *Id*. § 6(b)-(e), § 136d(b)-(e).

### A. *General Registrations under FIFRA Section 3(c)(5)*

FIFRA's general registration provision directs that the EPA Administrator "shall register" a pesticide if she determines that, among other requirements, "it will perform its intended function without unreasonable adverse effects on the environment; and * * * when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." *Id*. § 3(c)(5), § 136a(c)(5); *see also* 40 C.F.R. § 152.112(e). The phrase "unreasonable adverse effects on the environment" is defined, in relevant part, as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA § 2(bb), 7 U.S.C. § 136(bb).

B. *Conditional Registrations under FIFRA Section 3(c)(7)*

FIFRA also includes a separate mechanism in section 3(c)(7) to conditionally register pesticides under three "special circumstances." *Id*. § 3(c)(7), § 136a(c)(7). Congress added section 3(c)(7) to FIFRA to allow registration of pesticides "in certain situations, even though certain of the data that are required for complete registration or reregistration have not yet been generated." S. Rep. No. 95-1188, at 34 (1978) (Conf. Rep.). The House viewed the adoption of a conditional registration provision as "imperative to a timely and equitable registration and reregistration program." H.R. Rep. 95-343, at 9 (1977). The Senate concluded that authorizing conditional registrations was important in giving EPA "flexibility" and in eliminating a "double standard" between registrants for previously-registered pesticides and applicants for new registrations. S. Rep. No. 95-334, at 4 (1977). This double standard resulted from a timing disparity: compared to previously-registered pesticides, newer pesticides might have a better safety profile but might nevertheless be ineligible for the newly-imposed registration requirements because they lack the available safety data. *Id*.; *see also Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174, 181 (D.D.C. 2012) ("*Woodstream II*").

The three "special circumstances" warranting conditional registration are, (1) registering pesticides that are substantially identical to currently registered pesticides, (2) permitting additional uses of currently registered pesticides, and (3) registering new pesticide active ingredients not contained in a currently registered pesticide that are "lacking" required data "because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement." FIFRA § 3(c)(7)(A)-(C), 7 U.S.C. § 136a(c)(7)(A)-(C). As noted, pertinent to this matter is the last category for new active ingredients. Section 3(c)(7)(C) allows EPA to issue a conditional registration that is "in the public interest" for a period of time "reasonably sufficient for the generation and submission of required data," as long as the Administrator determines that the pesticide "will not cause any unreasonable adverse effect on the environment" during that registration period. *Id*. § 3(c)(7)(C), § 136a(c)(7)(C). Congress expressed some reservation about this type of conditional registration and indicated that conditional registrations should be the exception rather than the norm. The House Report states that "[a]lthough we think that the exercise of this conditional registration authority for new chemicals would be rare, we feel that it should be available in appropriate cases." H.R. Rep. No. 95-343, at 10. Similarly, the Senate Report instructed that "the Administrator in implementing this provision should take necessary steps to assure that conditional registrations are granted only

in circumstances in which the risk of unreasonable adverse effects would be minimal." S. Rep. No. 95-334, at 11.

A conditional registration granted under FIFRA section 3(c)(7)(C) for a new active ingredient must specify that any "required data" that are "lacking" be submitted in a timely manner, and that the data that are submitted "do not meet or exceed risk criteria" established by implementing regulations. FIFRA § 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C). Expanding on the timely submission requirement, the regulations require that section 3(c)(7)(C) registrations must provide that, (1) the applicants must submit required data in accordance with an approved schedule, and (2) "[t]he registration will expire upon a date established by the Agency, if the registrant fails to submit data as required by the Agency." 40 C.F.R. § 152.115(b)(2). The Administrator may append "other conditions" in her discretion in addition to these mandatory conditions. FIFRA § 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C); *see also* S. Rep. No. 95-334, at 21 ("The Administrator is also empowered to establish such other conditions as he determines are necessary."). The implementing regulations allow the Agency to impose conditions beyond data submission alone. 40 C.F.R. § 152.115(c) ("The Agency may establish, on a case-by-case basis, other conditions applicable to registrations to be issued under FIFRA section 3(c)(7).").

C. *Denial of Registration Applications under FIFRA Section 3(c)(6)*

If the Administrator determines that the pesticide will not meet the standard for either a general or conditional registration, the Administrator "may refuse to register the pesticide." FIFRA § 3(c)(6), 7 U.S.C. § 136a(c)(6); *see also* 40 C.F.R. § 152.118(a) (allowing denial if the "pesticide product does not meet the criteria for registration under either FIFRA sec. 3(c)(5) or (7)"). The Administrator must notify the applicant and "promptly publish in the Federal Register notice of [any] denial of registration and the reasons therefor." FIFRA § 3(c)(6), 7 U.S.C. § 136a(c)(6). If the applicant disagrees with the Administrator's denial, the applicant is entitled to the same full administrative hearing as provided under the general cancellation provision in section 6(b). *See id*. ("[T]he applicant shall have the same remedies as provided in [FIFRA] section 6."); 40 C.F.R. § 152.118(e) (upon denial, "an applicant, or any interested person with written authorization of the applicant, may request a hearing in accordance with FIFRA sec. 6(b)").

D. *Cancellation and Suspension Procedures under FIFRA Sections 6(b) and 6(c)*

Section 6(b) provides the general mechanism for canceling pesticide registrations under FIFRA. Under this provision, the Administrator "may issue" a notice of intent to cancel a pesticide's registration or hold a hearing to determine

whether it should be canceled, if "it appears to the Administrator" that the pesticide "does not comply with the provisions of [FIFRA] or * * * generally causes unreasonable adverse effects on the environment." FIFRA § 6(b), 7 U.S.C. § 136d(b). For agricultural pesticides, the Administrator is required to provide the notice of intent to cancel to the Secretary of Agriculture and the EPA Scientific Advisory Panel for review. *Id.* §§ 6(b), 25(d)(1), §§ 136d(b), 136w(d)(1). The proposed cancellation becomes effective 30 days after receipt by the registrant unless the registrant makes the necessary corrections or requests a hearing. *Id.* § 6(b), § 136d(b).

If a hearing is requested, it must be conducted in accordance with FIFRA section 6(d). *Id.* § 6(d), § 136d(d). The Hearing Officer shall receive evidence and may, upon request, refer any questions of scientific fact to a Committee of the National Academy of Sciences. *Id.* EPA has promulgated detailed hearing regulations addressing, among other things, the presentation and cross-examination of witnesses, and the participation of third parties. 40 C.F.R. pt. 164. These same hearing procedures apply to denials of registration applications. *Id.* §§ 164.3, .20. There is no set timeframe for conducting this hearing. After the hearing has concluded, the Administrator is required to "evaluate the data and reports" and within 90 days issue an order either revoking the notice of intent to cancel, canceling the registration, changing its classification, denying the registration, or requiring modification to the labeling of the pesticide. FIFRA § 6(d), 7 U.S.C. § 136d(d).

When a hearing is requested on a notice of intent to cancel, the notice does not become final and effective until the hearing is completed and the Administrator issues her final decision. *Id.* § 6(b), § 136d(b). If the Administrator wishes to remove the pesticide from the market more quickly, she may issue a notice of intent to suspend the registration or an emergency suspension order in conjunction with the notice of intent to cancel. *See id.* § 6(c), § 136d(c). A notice of intent to suspend, like a notice of intent to cancel, does not become effective until any requested hearing on the notice is completed. The issue in a suspension hearing is whether the pesticide poses "an imminent hazard during the time required for cancellation * * * proceedings." *Id.* § 6(c)(1), § 136d(c)(1). When "an emergency exists that does not permit the Administrator to hold a hearing before suspending," the Administrator may issue an "emergency order." *Id.* § 6(c)(3), § 136d(c)(3). Such an order remains in effect "pending expeditious completion" of the suspension hearing. *Id.* Thus, in the absence of emergency circumstances, a pesticide subject to cancellation or suspension under sections 6(b) or 6(c) may remain on the market pending completion of the hearing.

E. *Cancellation Procedures under FIFRA Section 6(e)*

Congress also created a separate, narrower cancellation procedure applicable only to conditional registrations. FIFRA section 6(e) requires that the Administrator "shall issue" a notice of intent to cancel a section 3(c)(7) conditional registration if she "at any time during the period provided for satisfaction of any condition imposed, determines 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 met." *Id*. § 6(e)(1), § 136d(e)(1). The implementing regulations provide that the Program must issue a notice of intent to cancel under FIFRA section 6(e) if "any condition of the registration of the product is not satisfied." 40 C.F.R. § 152.115(d). The notice of intent to cancel the registration may allow for the "continued sale and use of existing stocks * * * to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of [FIFRA] and will not have unreasonable adverse effects on the environment." FIFRA § 6(e)(1), 7 U.S.C. § 136d(e)(1).

A notice of intent to cancel becomes final and effective thirty days from receipt by the registrant unless a request for hearing is made. *Id*. § 6(e)(2), § 136d(e)(2). That hearing, like a hearing under section 6(b), is governed by the procedural requirements in section 6(d). *Id*. But, unlike a section 6(b) cancellation hearing, Congress expressly limited the scope of any section 6(e) cancellation hearing, specifying that the "only matters for resolution at that hearing" are: (1) whether the registrant has satisfied the conditions of registration; and (2) whether the EPA's determination with respect to existing stocks is consistent with FIFRA.[1] *Id*. The Administrator's determination[2] after the hearing must be

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[1] The exact statutory language reads: "The only matters for resolution at that hearing 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 [FIFRA]." FIFRA § 6(e)(2), 7 U.S.C. § 136d(e)(2).

[2] The Administrator has delegated her determination authority to the Board. *See* U.S. EPA Delegation of Authority 1-38A, *Administrative Proceedings* (Apr. 14, 2015) (citing 40 C.F.R. pt. 164); U.S. EPA Delegation of Authority 5-7 § 3(c), *Cancellation and Suspension* (May 11, 1994).

made "within seventy-five days after receipt" of a FIFRA section 6(e) hearing request. *Id*.

The House Report confirms that cancellation proceedings under section 6(e) are markedly different from proceedings under section 6(b). Referring specifically to conditional registrations for new active ingredients, the Report states:

> We strongly believe that the Agency should be required to cancel the registration if the conditions are not met within the appropriate time interval, and that any hearing on such a cancellation should be confined to whether or not the conditions were met and how existing stocks should be handled.

H.R. Rep. No. 95-343 at 10-11. Concluding, the House Report emphasizes that "[p]ublic resources should *not* be devoted to long, drawn-out cancellation procedures for these types of registrations." *Id*. at 11.

F. *Voluntary Cancellations under FIFRA Section 6(f)*

In addition to the procedures outlined above for EPA-initiated cancellation proceedings, FIFRA allows a registrant to request a "voluntary cancellation" of its own registration. FIFRA § 6(f)(1)(A), 7 U.S.C. § 136d(f)(1)(A). Once the Administrator receives a request for voluntary cancellation under section 6(f), she must publish notice of receipt of the request in the Federal Register and provide for a 30 day public comment period. *Id*. § 6(f)(1)(B), § 136d(f)(1)(B). After the close of this public comment period, the Administrator may approve or deny the request. *Id*. § 6(f)(1)(D), § 136d(f)(1)(D).

## III. *FACTUAL HISTORY*

A. *Background on Flubendiamide*

Flubendiamide is an insecticide designed for use against larval lepidopterous pests (caterpillars).[3] Request for Hearing and Statement of

[3] Lepidopterous pests include armyworms, bollworms, corn borers, cutworms, diamondback moths, fruitworms and loopers. U.S. EPA, *Pesticide Fact Sheet: Flubendiamide Conditional Registration*, PBNX 9, at PBN0022 (Aug. 1, 2008) ("Pesticide Fact Sheet"). Flubendiamide interferes with the calcium release channel of these insects, causing muscle paralysis and, eventually, death. Bayer CropScience LP, *Benefits Document Supporting the Continued Registration of Flubendiamide*, PBNX 22, at PBN0131 (May 20, 2015).

Objections by Bayer CropScience LP and Nichino America, Inc. at 5 (Mar. 31, 2016) ("Req. for Hearing"); Pesticide Fact Sheet, PBNX 9, at PBN0022.[4] Bayer and Nichino's registrations allow the use of flubendiamide on corn, cotton, tobacco, tree fruits, vegetables, tree nuts, and vine crops. Pesticide Fact Sheet, PBNX 9, at PBN0022. Flubendiamide is manufactured in Japan by Nihon Nohyaku Ltd., and is sold and distributed in the United States by Bayer and Nichino. ALJ Hearing Transcript at 181-82 ("ALJ Tr.") (testimony of J. Johnson).

B. *Terms of the Conditional Registrations*

On August 1, 2008, the Pesticide Program[5] conditionally registered several pesticide products containing flubendiamide.[6] The Program limited these

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[4] Bayer and Nichino and the Pesticide Program each submitted exhibits with consecutive page numbering. Exhibits submitted by Bayer and Nichino are cited as PBNX __ with page numbers preceded by "PBN." Exhibits submitted by the Pesticide Program are cited as RE ___ with page numbers preceded by "RE." The Pesticide Program's exhibits are numbered consecutively beginning with the number 200,000**.** However, for ease in citation, we use only the last three digits. For the sake of efficiency, where identical documents were submitted by both parties, we cite only to the PBNX version.

[5] Organizationally within EPA, the Administrator's authority for regulation of pesticides has been delegated to the Assistant Administrator for the Office of Chemical Substances and Pollution Prevention ("OCSPP"), formerly known as the Office of Pesticides, Pollution, and Toxic Substances ("OPPTS"). *See* U.S. EPA Delegation of Authority 5-1-A, *New Chemical Registration* (May 11, 1994). The day-to-day operation of EPA's pesticide program, however, is administered by the Office of Pesticide Programs, a sub-office in OCSPP. Within the Office of Pesticide Programs, much of the critical work on flubendiamide connected with this case was performed by the Registration Division and the Environmental Fate and Effects Division ("EFED"). For the reader's convenience, we refer generically to EPA's pesticide program as "the Pesticide Program" or the "Program." Where necessary for clarity we occasionally reference a specific office or division by its official name.

[6] The Program issued Notices of Registration for FLUBENDIAMIDE Technical (NNI-0001 Technical), SYNAPSE Insecticide (NNI-001 24 WG) and BELT SC Insecticide (NNI-0001 480 SC) on August 1, 2008. Notices of Registration for Flubendiamide Technical and Belt SC Insecticide, RE 3, at RE014-17 (Aug. 1, 2008) ("Notices of Registration"). Bayer subsequently requested voluntary cancellation of SYNAPSE Insecticide. *See* Letter from Dana Sargent, Vice President of North American Regulatory Affairs, Bayer CropScience LP, to Jack E. Housenger, Office of Pesticide Programs, U.S. EPA, PBNX 18, at PBN0098 (Feb. 5, 2016) [hereinafter *Cancellation Refusal*]. On March 4, 2009, the Program issued additional notices of

registrations to the category of "conditional," based on a concern that flubendiamide and its primary degradate NNI-001-des-iodo ("des-iodo") would persist in the environment and may, according to estimates from the Program's predictive exposure modeling, accumulate to levels that are toxic to freshwater benthic invertebrates such as such as sponges, mussels, oysters, worms, and snails.[7] Memorandum from Lois Rossi, Director, Registration Division, Office of Prevention, Pesticides and Toxic Substances, U.S. EPA, to Debra Edwards, Director, Office of Pesticide Programs, U.S. EPA, RE 1, at RE007 (August 1, 2008) [hereinafter *Registration Decision Memo*]; *see also* EPA EFED, *Addendum to Clarify Invertebrate Terminology in Ecological Risk Assessment Addendum*, PBNX 32, at PBN0908 (Jan. 29, 2016). In making its decision, the Program also weighed the apparent risks of flubendiamide against its potential benefits. In particular, the Program noted that because flubendiamide poses no significant risk to human health and no potential risk to most terrestrial and aquatic species, flubendiamide could potentially serve as an alternative to existing insecticides that pose greater risks. *Id*. at RE007-08; Pesticide Fact Sheet, PBNX 9, at PBN0022-31. The Program included risk mitigation measures in the registrations, principally requiring growers to place vegetative buffer strips around treated fields. Pesticide Fact Sheet, PBNX 9, at PBN0030. Bayer and Nichino argued that these strips would limit flubendiamide and des-iodo from reaching nearby water bodies and the Program indicated that the strips "may be effective." *Registration Decision Memo*, RE 1, at RE007; *see also* EPA EFED, *Flubendiamide Ecological Risk Assessment Addendum*, PBNX 31, at PBN 0856 (Jan. 28, 2016) [hereinafter *Assessment Addendum*].

The terms of the conditional registrations are set forth in a Preliminary Acceptance Letter dated July 31, 2008, and in the Notices of Registration. Letter from Lois A. Rossi, Director, Registration Division, Office of Prevention,

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registration for VETICA Insecticide (NNI-0871 SC) and TOURISMO insecticide (NNI-0772 SC). Notices of Registration, RE 3, at RE018-019B.

[7] "Flubendiamide and des-iodo have the potential to contaminate surface water through run-off due to their persistence in soil and also have the potential for groundwater contamination in vulnerable soils with low organic carbon content, after heavy rainfall and/or in areas with high water tables (because there is less depth to travel before reaching groundwater). * * * Flubendiamide and des-iodo's overall stability/persistence suggest that they will accumulate in soils, water column and sediments with each successive application. * * * There is a potential risk to freshwater benthic invertebrates exposed to flubendiamide and its degradate des-iodo." *Registration Decision Memo*, RE 1, at RE006.

Pesticides and Toxic Substances, U.S. EPA, to Danielle A. Larochelle, Registration Product Manager, Authorized Agent for Nichino America, Inc., Bayer CropScience LP, PBNX 8, at PBN0017-20 (July 31, 2008) ("Preliminary Acceptance Letter" or "PAL"); Notices of Registration, RE 3, at RE014-19B. The registrations required Bayer and Nichino to collect and submit various forms of data bearing on the levels of flubendiamide and des-iodo that could be expected in the aquatic environment, including data from hydrolysis and aerobic aquatic metabolism studies and data from a small-scale run-off study undertaken to evaluate the effectiveness of vegetative buffer strips at preventing the spread of flubendiamide and des-iodo. PAL, PBNX 8, at PBN0018 & n.1. The registrations also provided that if, after reviewing the results of the small-scale run-off study, the Pesticide Program were to continue to have concerns about risk, Bayer and Nichino would perform a farm pond monitoring program ("Farm Pond Monitoring Study") in areas where flubendiamide was being used. *Id*. at PBN0017; Memorandum from Susan T. Lewis, Director, Registration Division, U.S. EPA, to Jack E. Housenger, Director, Office of Pesticide Programs, U.S. EPA, PBNX 30, at PBN0845 (Jan. 29, 2016) [hereinafter *Cancellation Decision Memo*]. The Program's registration decision memorandum had noted that "[t]here is considerable uncertainty in application of the EXAMS [Exposure Analysis Modeling System][8] pond scenario for chemicals with suspected aquatic system accumulation." *Registration Decision Memo*, RE 1, at RE007. The registrations stated that the Farm Pond Monitoring Study would provide information "on the actual potential for the pesticide to build up in receiving waters [and] would address the uncertainty associated with current model limitations." PAL, PBNX 8, at PBN0018. Initially, all of the data were due by July 31, 2012.[9] *Id*. at PBN0018-19.

The Pesticide Program was required to review all of the data – including both the data from the required studies as well as of any additional data and information voluntarily submitted by Bayer and Nichino – within six months of the due date. *Id*. As part of its review of the data, the Program's scientists were

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[8] EXAMS "is an interactive software application for formulating aquatic ecosystem models and rapidly evaluating the fate, transport, and exposure concentrations of synthetic organic chemicals including pesticides." U.S. EPA, *Exposure Assessment Models*, https://www.epa.gov/exposure-assessment-models/exams-version-index (last visited July 29, 2016).

[9] The Program later extended the deadline to allow completion of the Farm Pond Monitoring Study. *See* Part III.C.1.(i), below.

required to "engage in dialogue about the data and the Agency's conclusions" with scientists from Bayer. *Id*.

The registrations included a novel arrangement for either amending, extending, or terminating the registrations once all of the scientific data had been submitted and reviewed and the scientists from Bayer and the Program had engaged in dialogue about the data and the Program's conclusions. The Program had three options, one of which had to be selected by September 1, 2013. It could either, (1) approve the general registration of the flubendiamide products, including any restrictions the Program deems necessary, (2) reach agreement with Bayer and Nichino regarding terms for further conditional registration of the flubendiamide products, or (3) accept Bayer and Nichino's voluntary cancellation of the flubendiamide products. PAL, PBNX 8, at PBN0019. Regarding the third option, which we refer to as "the termination condition," the registrations provide that "[i]f, after EPA's review of the data * * *, the Agency makes a determination that further registration of the flubendiamide [products] will result in unreasonable adverse effects on the environment, within one (1) week of this finding, * * * [Bayer and Nichino] will submit [an irrevocable] request for voluntary cancellation" of their registrations. *Id*. at PBN0019 (combining separate paragraphs 6(d) and 8(d) addressing Nichino and Bayer, respectively).

The termination condition appears to be unique to these registrations, as Bayer and Pesticide Program witnesses all testified that they were not aware of any other conditional registrations that included such a condition. *See, e.g.,* Verified Written Statement of Charlotte Sanson, PBNX 116, at PBN1611 ("Sanson Statement"). This provision, as well as the data review and dialogue conditions, resulted from extensive negotiations between the parties over whether the registration should contain an automatic expiration provision. Ultimately, the Program and Bayer and Nichino compromised by agreeing to the above-described procedures that preserved the Program's authority to quickly remove flubendiamide from the market if it determined that flubendiamide causes unreasonable adverse effects, but ensured that the Program would review and discuss with Bayer and Nichino any data they submitted on flubendiamide before making such a determination. *See* Part V.B.1.b.(i), below.

C. *Post-Registration Events*

The post-registration period saw numerous interactions between the Pesticide Program and Bayer and Nichino, as the registrants submitted data in an attempt to resolve the Program's uncertainties regarding flubendiamide risk. These interactions are relevant to Bayer and Nichino's claim that the Program failed to engage in the required scientific "dialogue" on the data they submitted.

1. *Data Submission*

Bayer and Nichino completed all of the scientific studies required by the terms of the conditional registrations. They submitted the results of the hydrolysis and aerobic aquatic metabolism studies within the initial five-year registration period and the results of the small-scale vegetative buffer study on August 3, 2010. Letter from Richard Gebken, Product Manager, Pesticide Registration Division, U.S. EPA, to George Sabbagh, Registration Product Manager, Registered Agent for Nichino America, Inc., PBNX 10, at PBN0086 (July 18, 2013) [hereinafter *First Extension*]; *see also Cancellation Decision Memo*, PBNX 30, at PBN0834. Citing a "major modeling error," however, the Pesticide Program rejected the vegetative buffer study, which triggered the requirement that Bayer and Nichino monitor water quality in farm ponds located near fields treated with flubendiamide products. *Cancellation Decision Memo*, PBNX 30, at PBN0845; *see also* PAL, PBNX 8, at PBN0017-18. Following discussions with the Pesticide Program, Bayer agreed to conduct this three-year Farm Pond Monitoring Study. *Assessment Addendum*, PBNX 31, at PBN0857. In order to allow time for the Study to be completed and reviewed, the Pesticide Program extended the flubendiamide conditional registrations for another two years, through August 31, 2015. *First Extension*, PBNX 10, at PBN0086. Bayer and Nichino submitted the Farm Pond Monitoring Study by its due date, December 31, 2014. U.S. EPA EFED, *Review of Three Reports Related to a 3-Year Flubendiamide Water Monitoring Project*, PBNX 35, at PBN0977 (Feb. 20, 2015) [hereinafter *Farm Pond Monitoring Study Review*].

In addition to the studies required under the conditional registrations, Bayer and Nichino conducted a photolysis study[10] ("Photolysis Study") that the Pesticide Program recommended in 2008 as part of its ecological risk assessment prepared for the initial registrations as well as for two amended flubendiamide registrations granted in 2010.[11] Bayer submitted the results of the Photolysis Study on January 5, 2016. *Assessment Addendum*, PBNX 31, at PBN0863.

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[10] Photolysis studies examine the "photochemical transformation" that can occur when a pesticide in water is exposed to sunlight. U.S. EPA, *Fate, Transport and Transformation Test Guidelines, OPPTS 835.2210 Direct Photolysis Rate in Water by Sunlight* 1 (1998) https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0011.

[11] In 2010, the Pesticide Program approved two amendments to the conditional registrations that allowed for expanded use of the flubendiamide products on additional crops. *See Cancellation Decision Memo*, PBNX 30, at PN0844. In connection with the

Bayer and Nichino also submitted a study in 2010 that was neither required by the registrations nor recommended by the Program. The study, titled a Freshwater Sediment *Chironomus riparius* Emergence Test, involved spiking sediment at the bottom of a laboratory-simulated water body with des-iodo to evaluate its chronic toxicity to benthic invertebrates ("Sediment-Spiked Toxicity Study").[12] Des-iodo Spiked Sediment Study Data Evaluation Record, PBNX 34, at PBN0948 (July 19, 2011) [hereinafter *Sediment-Spiked Toxicity Study Review*]. The 2010 study was similar to earlier ones that Bayer and Nichino had conducted for flubendiamide and des-iodo in conjunction with its application for registration of the flubendiamide products, although the earlier studies evaluated chronic toxicity by spiking the overlying water – not the sediment – with the test product ("Water-Spiked Toxicity Study").[13] EPA EFED, *Risk Assessment for the Section 3 New Chemical Registration of Flubendiamide*, PBNX 27, at PBN0467 (June 23, 2008) [hereinafter *New Registration Risk Assessment*]. In its risk assessment for

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amendments, the Program conducted revised ecological risk assessments. Each revised risk assessment reached a conclusion similar to the 2008 ecological risk assessment: expected exposure to flubendiamide and its degradate des-iodo poses risks of concern to aquatic invertebrates. EPA EFED, *Risk Assessment for Legume Vegetable and Christmas Tree New Uses for the Insecticide Flubendiamide*, PBNX 28, at PBN0608 (May 17, 2010) [hereinafter *Christmas Tree Risk Assessment*]; EPA EFED, *Ecological Risk Assessment for the New Use of Flubendiamide on Alfalfa and Certain Other Crops*, PBNX 29, at PBN0755 (Dec. 16, 2010) [hereinafter *Alfalfa Risk Assessment*].

[12] This study was conducted pursuant to an Organization for Economic Co-operation and Development ("OECD") for Sediment-Water Chironomid Toxicity Test Using Spiked Sediment. *OECD Guidelines for the Testing of Chemicals, Test No. 218: Sediment-Water Chironomid Toxicity Test Using Spiked Sediment*, PBNX 46, at PBN1361 (Apr. 13, 2004) [hereinafter *OECD Guidelines*]. The test is conducted in 600 milliliter beakers containing a 1:4 ratio of sediment to water. *Id*. at PBN1363. The sediment is spiked with the test substance and then larvae of the test species are added to the beaker. *Id*. at PBN1365-66. The measured endpoints or effects "are the total number of adults emerged and the time to emergence." *Id*. at PBN1361. Although the OECD Guidelines were excluded by the ALJ as irrelevant to this proceeding, we have considered them as explanatory background material.

[13] For the 2008 registrations, Bayer and Nichino submitted separate versions of this chronic toxicity test for flubendiamide and des-iodo. *New Registration Risk Assessment*, PBNX 27, at PBN0500. Bayer and Nichino submitted the Sediment-Spiked Toxicity Study for des-iodo in 2010 and for flubendiamide in 2016. *Assessment Addendum*, PBNX 31, at PBN0860.

the 2008 registration decision, the Pesticide Program concluded that although spiking the sediment was the preferred approach, the existing Water-Spiked Toxicity Studies were adequate for estimating the flubendiamide and des-iodo toxicity to benthic invertebrates:

> Two 28-day chronic toxicity studies indicate that flubendiamide and its des-iodo degradate are toxic to the midge, *Chironomus riparius*, in an overlying-water spiked system. * * * Neither of the two chronic toxicity midge studies followed sediment toxicity guidelines which require the sediment to be spiked as opposed to the overlying water. Regardless of the route of administration in the studies, there were measured [sediment] pore water concentrations and these combined with available mesocosm data suggest that there is sufficient information to reach a risk conclusion for benthic invertebrates.

*Id*. at PBN0467-68. The Pesticide Program's 2010 ecological risk assessments for the two subsequent amendments to the flubendiamide conditional registrations confirmed that "no new sediment toxicity data [are] requested at this time."[14] *Christmas Tree Risk Assessment*, PBNX 28, at PBN0612; *Alfalfa Risk Assessment*, PBNX 29, at PBN0756.

2. *The Pesticide Program's Review of and Response to the Submitted Data*

a. *Data Bearing on the Persistence and Accumulation of Flubendiamide and Des-iodo in the Environment*

The Pesticide Program reviewed the Farm Pond Monitoring Study and issued a detailed memorandum presenting its analysis on February 20, 2015. The Program identified "six major issues" with the study and found that each of these issues made it more difficult to detect trends in the data. *Farm Pond Monitoring Study Review*, PBNX 35, at PBN0978-82. Nonetheless, the Pesticide Program found a statistically significant accumulation trend for flubendiamide and des-iodo, *id.* at PBN0982, and concluded that "the monitoring data [showed] clear evidence that both flubendiamide and des-iodo accumulate in the ponds monitored." *Id.* at PBN0977; *see also Assessment Addendum*, PBNX 31, at PBN0865 n.4. Additionally, the Pesticide Program compared the actual values from the Farm

[14] Although the second of these amendments was issued after the submission of the Sediment-Spiked Toxicity Study, the Pesticide Program did not consider the study at that time because the Program did not complete its review of the study until July 2011. *Sediment-Spiked Toxicity Study Review*, PBNX 34, at PBN0942.

Pond Monitoring Study with the values predicted by the model. *Farm Pond Monitoring Study Review*, PBNX 35, at PBN0986-90 & figs.6 – 7. Although the Program noted that model assumptions were high-end and did not take into account the variability in pesticide usage and crops in the study or the vegetative buffers and grass waterways at the ponds, the Program concluded that its analysis showed that "the monitoring data tracks reasonably well with the modeled data and therefore, supports the previous predictions of aquatic exposure modeling and the prior flubendiamide risk assessments." *Id*. at PBN0987. Given this coherence between the monitoring results from the Farm Pond Monitoring Study and the model predictions, the Program also concluded that "the effect of [vegetative filter strips] is not large enough to mitigate the ecological risks posed by flubendiamide applications." *Id*. at PBN0977.

Following release of the Pesticide Program's review of the Farm Pond Monitoring Study, Bayer submitted written comments on the review to the Program on June 22 and 30, 2015. *See Assessment Addendum*, PBNX 31, at PBN0858; EPA EFED, *Response to Bayer CropScience LP Aquatic Risk E-mail Submission*, PBNX 36, at PBN1001 (July 8, 2015). Bayer asserted that the study showed "limited, if any accumulation of residues" and argued that monitoring may need to be continued "two to three more years to fully confirm the accumulation profile anticipated by [the Pesticide Program] is not occurring." Bayer CropScience, *White Paper: Flubendiamide Benefits, Aquatic Risk Assessment Summary and Proposed Path Forward*, PBNX 24, at PBN0438 (June 29, 2015) ("Flubendiamide White Paper"). The Pesticide Program responded to both of these submissions in writing in July 2015. *See Assessment Addendum*, PBNX 31, at PBN0858.

The Program also prepared a brief analysis of Bayer's 2016 Photolysis Study and included that analysis in its ecological risk assessment supporting the Program's January 29, 2016 unreasonable adverse effects finding. *Id*. at PBN0863. That analysis concluded that the study's estimate that des-iodo had a half-life of 79 days was optimistic as a data point for risk assessment for several reasons, including a failure to identify the toxicity of most of the degradation products of des-iodo and the limited applicability of a study performed in pure water to agricultural drainage waters that typically contain dissolved or suspended sediment. *Id*. at PBN0863, 67-68.

b. *Data Bearing on the Toxic Endpoint Level of Des-iodo*

As mentioned above, Bayer and Nichino, on their own initiative, submitted the Sediment-Spiked Toxicity Study for des-iodo in 2010 that involved administering the test substance by spiking the sediment in the test environment. In a similar test conducted in 2004 by Bayer and Nichino, the des-iodo had been

administered by spiking the overlying water. *See* U.S. EPA, *Des-iodo Spiked Water Study Data Evaluation Record*, PBNX 33. Because the Pesticide Program's reliance, or lack thereof, on the Sediment-Spiked Toxicity Study or the Water-Spiked Toxicity Study is a matter of considerable dispute in this proceeding, we provide further background information on how the Pesticide Program uses toxicity studies in risk assessment before discussing the results of these particular studies.

Toxicity studies seek to identify toxic endpoints – "an observable or measurable biological event * * * used as an index of an effect of a chemical exposure." Office of Research & Dev., U.S. EPA, *Vocabulary Catalog List Detail - Integrated Risk Information System (IRIS) Glossary*, http://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary (last updated Aug. 31, 2011); *accord* Office of Pesticide Programs, U.S. EPA, *Guidance for Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* 3 n.3 (Jan. 29, 1999) ("Toxic endpoint is a quantitative expression of a toxic effect occurring at a given level of exposure."). In the chronic toxicity studies for des-iodo involving benthic invertebrates, the biological event examined was the effect on emergence of adult benthic invertebrates when juvenile invertebrates are exposed to the test substance. *OECD Guidelines*, PBNX 46, at PBN1361. These tests are conducted at several different dose levels for the purpose of identifying both a concentration level of the des-iodo that causes an observable adverse effect on emergence (the lowest concentration that shows an observable adverse effect is referred to as the "LOAEC") and a concentration level that results in no observable adverse effects on emergence (the "NOAEC"). *Id*. at PBN1365; *OECD Guidelines for the Testing of Chemicals, Test No. 219: Sediment-Water Chironomid Toxicity Test Using Spiked Water*, PBNX 45, at PBN1341 (Apr. 13, 2004). Commonly, the Pesticide Program uses the NOAECs from toxicity studies as toxic endpoints in ecological risk assessments. U.S. EPA, *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs* 42 (Jan. 23, 2004); *see, e.g.*, *New Registration Risk Assessment*, PBNX 27, at PBN0500. To quantitatively express ecological risks, the Pesticide Program divides estimated exposure to the pesticide by the toxic endpoint to produce a "risk quotient." U.S. EPA, Risk Assessment Forum, *Guidelines for Ecological Risk Assessment* 103 (May 1998); *New Registration Risk Assessment*, PBNX 27, at PBN0509.

In conducting its 2008 and 2010 risk assessments for flubendiamide, the Pesticide Program used the Water-Spiked Toxicity Study to determine chronic toxic endpoints for des-iodo on benthic invertebrates in both the overlying water and in water present in the pores of sediment at the bottom of water bodies

("sediment pore water"). The NOAEC in the overlying water was 1.9 micrograms/liter ("µg/L") of des-iodo in water and the NOAEC in the sediment pore water was 0.28 µg/L. *New Registration Risk Assessment*, PBNX 27, at PBN0500, 0512; *see also Alfalfa Risk Assessment*, PBNX 29, at PBN0782. These toxic endpoints for overlying water and sediment pore water were combined with projections of des-iodo exposure levels in overlying water and sediment pore water, respectively, to calculate expected risks (i.e., risk quotients) to benthic invertebrates.[15] *Christmas Tree Risk Assessment*, PBNX 28, at PBN0648-49.

In July 2011, the Pesticide Program completed a Data Evaluation Report on Bayer's Sediment-Spiked Toxicity Study. *Sediment-Spiked Toxicity Study Review,* PBNX 34, at PBN0942. The reviewer classified the study as "Supplemental" based on the conclusion that the study "does not fulfill any current U.S. EPA data requirement." *Id*. at PBN0943. The reviewer agreed with the study's authors that there were no adverse effects on the emergence of adult test organisms at any of the tested dose levels. *Id*. at PBN0960. Further, the reviewer identified NOAECs for both exposure in the overlying water (7.18 µg/L) and in the sediment pore water (19.5 µg/L). *Id*. at PBN0943. The Data Evaluation Report focused on the quality and results of this study in isolation from other des-iodo toxicity studies in the Pesticide Program's database. It does not discuss whether the results from this study, as compared to the results from the earlier Water-Spiked Toxicity Study,

[15] Excerpts from Table 28 in the May 2010 flubendiamide risk assessment illustrate how toxic endpoints and estimated exposures are used to calculate risk quotients:

**Table 28. Risk quotients for the des-iodo degradate based on benthic water column and pore water endpoint concentrations for aerial and ground applications to legumes and Christmas trees**

| | **Water Column Concentrations** | | **Pore Water Concentrations** | |
|---|---|---|---|---|
| **Spray Application** | **1 in 10-years EEC in Water Column (µg/L)** | **RQ MRID 468170-23 NOAEC = 1.9 µg/L** | **1 in 10-years EEC in Benthic Pore Water (µg/L)** | **RQ MRID 468170-23 NOAEC = 0.28 µg/L** |
| **Soybean** | | | | |
| Ground | 2.658 | **1.4** | 2.646 | **9.45** |
| Legume vegetables except soybean. Crops of Crop Groups 6 and 7 | | | | |
| Illinois Beans: Ground | 5.404 | **2.84** | 5.396 | **19.27** |

EEC – estimated environmental concentration; RQ – risk quotient; MRID – Master Record Identification. *Christmas Tree Risk Assessment*, PBNX 28, at PBN0649 tbl.28.

should be used in choosing toxic endpoints for assessing flubendiamide risk (from des-iodo) to benthic invertebrates.

The results of the Sediment-Spiked Toxicity Study are quite different than the findings from the Water-Spiked Toxicity Study. The differences are most dramatic as to effect levels in sediment pore water. The Sediment-Spiked Toxicity Study showed no treatment-related effects attributed to des-iodo and established a NOAEC of 19.5 μg/L in sediment pore water. The Water-Spiked Toxicity Study identified adverse effects on the test species at 0.7 μg/L (a LOAEC) in the sediment pore water and showed the NOAEC to be 0.28 μg/L in that compartment. *New Registration Risk Assessment*, PBNX 27, at PBN0500. The respective NOAECs are different by roughly a factor of 70. The difference in the NOAECs was less substantial for the overlying water in the two studies.[16]

In early 2015, the Pesticide Program used the 19.5 μg/L NOAEC in sediment pore water from the Sediment-Spiked Toxicity Study, as well as other Bayer and Nichino-suggested toxic endpoints, in assessing flubendiamide risk as a part of its February 2015 review of the Farm Pond Monitoring Study. *Farm Pond Monitoring Study Review*, PBNX 35, at PBN0992. The February 2015 memorandum contains no detailed evaluation of whether to rely on the NOAECs from the Water-Spiked Toxicity Study or the NOAECs from the Sediment-Spiked Toxicity Study to assess flubendiamide risk. Rather, the Program simply states that "the Agency will use the registrant-calculated endpoints to avoid diverting focus from the issues the Agency has with the submitted [Farm Pond Monitoring Study] and aquatic exposure reports." *Id*. By late 2015, the Pesticide Program had reverted to calculating toxic endpoints based on the Water-Spiked Toxicity Study similar to the approach in the 2008 and 2010 risk assessments.

3. *Negotiations Between Bayer and the Pesticide Program in 2015 and Early 2016*

The Pesticide Program's February 2015 review of the Farm Pond Monitoring Study states that the Pesticide Program's risk concerns with

[16] The NOAECs for des-iodo based on the initial nominal concentration level were 4 μg/L in both the Water-Spiked and Sediment-Spiked Toxicity Studies for the overlying water. *Assessment Addendum*, PBNX 31, at PBN0861 tbl.2 & 0862. Calculating the NOAEC based on the time weighted average of the measured exposure over the course of the Studies, which is the Program's preferred approach, yields NOAECs of 1.89 μg/L for the overlying water in the Water-Spiked Toxicity Study and 7.19 μg/L in the overlying water in the Sediment-Spiked Toxicity Study. *Id*. at PBN0862 tbl.5.

flubendiamide had not been resolved by the data submitted by Bayer under the conditional registrations.[17] *Farm Pond Monitoring Study Review*, PBNX 35, at PBN0993-94. Over the next eleven months, the Pesticide Program had a number of written and oral discussions with Bayer and Nichino over a series of interrelated issues: whether the data justified the Pesticide Program's risk concerns; whether the conditional registrations should be extended so that additional data could be generated; and whether restrictions on flubendiamide usage under the conditional registrations (fewer crops and/or lower application rates and frequency of application) would allay the Pesticide Program's risk concerns. Each of these issues is discussed in more detail below.

The Pesticide Program's continued concerns[18] about flubendiamide prompted discussions between the Program and Bayer and Nichino in mid-2015 about amending the conditional registrations to require additional studies and impose new restrictions on the pesticide's use.[19] E-mail from Carmen Rodia, Environmental Protection Specialist, Registration Division, U.S. EPA, to Bayer CropScience, PBNX 11, at PBN0087-88 (Aug. 4, 2015). In August, the Pesticide Program extended the flubendiamide conditional registrations from August 31, 2015, to December 10, 2015, to "provide time for [Bayer] and the [Pesticide Program] to discuss whether potential additional data requirements and label amendments are necessary to address areas of uncertainty within EPA's Environmental Fate and Effects Division's (EFED) ecological risk assessment." Letter from Richard Gebken, Product Manager, Registration Division, U.S. EPA, to Nancy Delaney, Regulatory Manager, Authorized Agent for Nichino America, Inc., Bayer CropScience LP, PBNX 12, at PBN0090 (Aug. 26, 2015). Negotiations

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[17] In a July 2015 filing with the Pesticide Program, Bayer noted that "[s]ome uncertainties lead to the difference in opinion between [Bayer] and [the Pesticide Program's Environmental Fate and Effects Division]." Bayer CropScience LP, *Flubendiamide White Paper*, PBNX 24, at PBN0431.

[18] These concerns were apparently so serious that Nichino delayed a production run of flubendiamide from August 2015 to the end of September 2015. ALJ Tr. at 174-75 (testimony of J. Johnson).

[19] The Program proposed that Bayer and Nichino undertake seven additional studies involving both toxicity testing and exposure monitoring. The Program also proposed that Bayer and Nichino agree to a ban on aerial application, a limitation on the frequency of application to no more than once per year, and a bar on Bayer and Nichino seeking any additional outdoor crop uses during the extension period.

on these modifications to the conditional registrations proved unsuccessful, and none of the proposals was ultimately adopted.

In December 2015 and January 2016, the Pesticide Program held a series of meetings with Bayer and Nichino to discuss the risk posed by flubendiamide. The two most critical meetings occurred on December 15, 2015, and January 6, 2016. Participants at the December 15th meeting included the Assistant Administrator of EPA's Office of Chemical Substances and Pollution Prevention, and the Chief Executive Officers of Bayer and Nichino. According to Bayer, the Assistant Administrator informed Bayer and Nichino that the flubendiamide conditional registrations would expire in three days unless the Pesticide Program extended the registrations, and that he "would consider whether to take action and would inform the registrants of [his] decision by the end of the day on December 18, 2015." Sanson Statement, PBNX 116, at PBN1606. After further discussion, the Assistant Administrator agreed to another extension (until January 15, 2016) and "suggested that the registrants submit the best, final mitigation proposal they could develop, as promptly as possible." *Id.* Bayer submitted a proposal later that same day that limited flubendiamide use to thirteen crops or crop groups.[20] *Id.*

According to Bayer and Nichino, they became aware on the following day, December 16, 2015, that the Pesticide Program had decided to revert to using the 0.28 μg/L NOAEC from the Water-Spiked Toxicity Study as a toxic endpoint to assess flubendiamide risk rather than the higher toxic endpoints that Bayer and Nichino advocated using – that is, those derived from the Sediment-Spiked Toxicity Study used in the risk analysis for the February 2015 memorandum on the monitoring study. E-mail from Dana Sargent to Jim Jones, PBNX 14, at PBN0092 (Dec. 16, 2015) ("Sargent E-mail"), *see also* Sanson Statement, PBNX 116, at PBN1609. On December 16, 2015, Dana Sargent, Vice President of North America Regulatory Affairs at Bayer, contacted the Assistant Administrator to "confirm" he was aware of this "new development." Sargent E-mail, PBNX 14, at PBN0092. Ms. Sargent claimed that the toxic endpoint from the Sediment-Spiked Toxicity Study "was the foundation for all the risk analyses Bayer prepared and EPA reviewed and discussed with Bayer." *Id.* She asserted that the Pesticide Program's failure to disclose its intent to revert to the earlier toxic endpoint

[20] Crop groups are groups of related crops. For example, the leafy vegetables crop group contains 27 leafy vegetables ranging from arugula to swiss chard. *See* 40 C.F.R. § 180.40 - .41(c)(5).

"undercuts the integrity of our prolonged scientific discussions and renders them useless." *Id*.

According to Bayer and Nichino, the January 6, 2016 meeting was scheduled so that the Pesticide Program's Environmental Fate and Effects Division could "present its evaluations" of flubendiamide risk. Sanson Statement, PBNX 116, at PBN1609. Prior to the meeting, the Pesticide Program provided Bayer and Nichino with several risk analyses including an additional risk analysis of Bayer and Nichino's proposed mitigation amendment that would limit flubendiamide use to thirteen crops or crop groups. *Assessment Addendum*, PBNX 31, at PBN0858-59; Sanson Statement, PBNX 116, at PBN1609. At this meeting, the Pesticide Program used the morning to address scientific issues including its risk estimates based on its preferred toxic endpoints, and the afternoon to discuss regulatory matters. ALJ Tr. at 91 (testimony of S. Lewis). The day before the meeting, Bayer submitted two new studies to the Pesticide Program, including a Photolysis Study investigating the rate at which des-iodo degrades when exposed to sunlight. Sanson Statement, PBNX 116, at PBN1609. Two days after the meeting, Bayer submitted a new proposed mitigation amendment to the flubendiamide registrations, which would have limited flubendiamide use to a single crop group, tree nuts. *Assessment Addendum*, PBNX 31, at PBN0863.

D. *Cancellation Proceedings*

1. *The Pesticide Program's Determination that Flubendiamide Causes Unreasonable Adverse Effects*

On January 29, 2016, the Pesticide Program informed Bayer and Nichino that it had determined that flubendiamide causes unreasonable adverse effects on the environment and notified Bayer and Nichino of their obligation under the conditional registrations to submit an irrevocable request for voluntary cancellation within one week. Specifically, the letter said:

> [Bayer and Nichino] understood and agreed by signing the [Preliminary Acceptance Letter] that if, after review of the referenced conditional data, EPA makes a determination of unreasonable adverse effects on the environment, that [Bayer and Nichino] 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.

Letter from Jack E. Housenger, Director, Office of Pesticide Programs, U.S. EPA, to Nancy Delaney, Regulatory Manager, Bayer CropScience LP, PBNX 17, at PBN0097 (Jan. 29, 2016). Bayer and Nichino responded by letter on February 5, 2016, declining to submit a voluntary cancellation request. *Cancellation Refusal* PBNX 18, at PBN0098. Bayer and Nichino claimed the termination condition was unlawful and also disputed the substance of the Program's unreasonable adverse effects finding.

2. *Notice of Intent to Cancel*

The Pesticide Program issued a Notice of Intent to Cancel the flubendiamide registrations under FIFRA section 6(e) on February 29, 2016, on the grounds that Bayer and Nichino violated the terms of registration by failing to submit an irrevocable voluntary cancellation request for their flubendiamide products. *Flubendiamide; Notice of Intent to Cancel Pesticide Registrations*, 81 Fed. Reg. 11,558, 11,559-60 (Mar. 4, 2016) (also introduced in the record as PBNX 20 and RE 8). The Pesticide Program declined to authorize the continued sale and distribution of existing stocks of flubendiamide, noting that it would be "inappropriate to reward registrants * * * [who] simply refuse to comply with a condition they earlier chose to accept in order to obtain the registration initially" by allowing them to continue to sell and distribute existing stocks of the canceled product. *Id*. at 11,560. For similar reasons, the Program prohibited the use of the existing stocks of Nichino's manufacturing (technical) products because the technical products are used solely for manufacturing other pesticide products. *Id*. However, the Program did authorize the continued use of existing flubendiamide stocks by growers, reasoning that "the costs and risks associated with collecting [existing stocks in the hands of growers] for disposal would be high compared to those associated with the use of the cancelled product in accordance with its labeling." *Id*.

The Pesticide Program closed the Notice by alerting registrants and other adversely affected parties that they have a right to request a hearing on a section 6(e) cancellation notice, but the Program noted that the statute limited the hearing to two issues: "whether the registrants satisfied the condition of registration requiring them to submit timely requests for voluntary cancellation when notified by EPA of its determination that the registrations caused unreasonable adverse effects on the environment, and whether the proposed existing stocks provision is consistent with FIFRA." *Id*. at 11,561.

3. *Request for Hearing*

Bayer and Nichino timely objected to the Notice of Intent to Cancel and filed a hearing request and a statement of objections. Req. for Hearing. Bayer and Nichino listed five objections, the first three of which are closely related. These three objections argue that the Notice should be dismissed because it was based solely on their alleged noncompliance with the termination condition, which Bayer and Nichino assert is unlawful. *Id*. at 41, 48-49. They contend that the only way to cancel a registration after a finding of unreasonable adverse effects is for the Program to initiate a general cancellation proceeding under FIFRA section 6(b) and not the more limited cancellation proceeding under section 6(e). *Id*. at 40-42, 46. Bayer and Nichino argue that the Pesticide Program should not be allowed to avoid substantive review of its unreasonable adverse effects finding "by presenting powerless entities the Hobson's choice of either accepting conditions designed to bypass the cancellation process or receiving no registration at all." *Id*. at 45. Finally, they assert – and the Program does not disagree – that they have complied with all other conditions of registration, including submitting all of the required data on time. *Id*. at 48-49.

In their fourth objection, Bayer and Nichino argue at length that the Pesticide Program's unreasonable adverse effects determination is substantively incorrect, challenging the Program's selection of a toxic endpoint, use of modeling to estimate flubendiamide and des-iodo residues in the environment, and weighing of the risks and benefits of flubendiamide. *Id*. at 49-58. As to the toxic endpoint, Bayer and Nichino argue that the use of the NOAEC from the Water-Spiked Toxicity Study "is contrary to the weight of the evidence and is inconsistent with EPA and OECD guidance and well-accepted toxicological practice." *Id*. at 55. Bayer and Nichino challenge the Pesticide Program's reliance on its exposure modeling approach, claiming that the monitoring data demonstrate that the Pesticide Program's model "not only significantly overstates the actual results but also that the mean value of the observed data [from the Farm Pond Monitoring Study] is a better predictor than the modeled values." *Id*. at 56. Additionally, Bayer and Nichino argue that the Pesticide Program undervalued the benefits of flubendiamide, citing flubendiamide's "excellent [human] safety profile," low risk to beneficial insects including pollinators, value to Integrative Pest Management programs, and low cost. *Id*. at 57, 64-65.

Lastly, Bayer and Nichino's fifth objection challenges the Pesticide Program's decision to bar the sale and distribution of existing stocks. Bayer and Nichino argue that the Program's decision is an attempt to punish them for exercising their lawful right to request a hearing and that the Program erred by

failing to consider the risks and benefits associated with the sale and distribution of flubendiamide existing stocks. *Id*. at 60-61.

4. *The ALJ's Accelerated Decision and Order on the Scope of the Hearing*

After filing their hearing request, Bayer and Nichino moved for an accelerated decision to dismiss the Notice of Intent to Cancel, largely for the reasons stated in its Request for a Hearing – that the voluntary cancellation condition in the flubendiamide registrations was an unlawful attempt to bypass section 6(b) cancellation procedures. Motion for an Accelerated Decision by Bayer CropScience LP and Nichino America, Inc. at 3 ("Mot. for Acc. Dec.").

At about the same time, the Pesticide Program moved to limit the scope of testimony at the hearing. Respondent's Motion to Limit Scope of Testimony ("Mot. to Limit"). The Pesticide Program contends that because there was no question that Bayer and Nichino had not submitted a voluntary cancellation request following the Program's unreasonable adverse effects finding, the only factual issue for the hearing was whether the Program's existing stocks determination is consistent with FIFRA. *Id*. at 1. Further, the Pesticide Program emphasizes that it based its determination to disallow the sale and distribution of existing stocks solely on the ground that "it is consistent with FIFRA that registrants should not benefit from unlawfully refusing to comply with conditions of their registrations." *Id*. at 4. Thus, the Program requested that the ALJ bar any testimony from Bayer and Nichino in support of their argument that consideration of the risks and benefits of flubendiamide usage support allowing sale and distribution of existing stocks. *Id*. at 5.

The ALJ denied Bayer and Nichino's motion for an accelerated decision and granted the Pesticide Program's motion to limit testimony at the hearing. In denying Bayer Nichino's motion, the ALJ ruled that, in the circumstances of this case, the termination condition is lawful. In reaching this conclusion, the ALJ relied on two decisions in a federal district court case that upheld the lawfulness of a conditional registration that included a fixed expiration date if the registrant did not comply with certain mitigation steps. Order on Petitioners' Motion for Accelerated Decision at 24-27 ("Order Denying Acc. Dec."); *see also Woodstream Corp. v. Jackson*, No. 11-867, 2011 U.S. Dist. LEXIS 151994 (D.D.C. June 3, 2011) ("*Woodstream I*"); *Woodstream II*, 845 F. Supp. 2d 174. Additionally, the ALJ found that the record shows that Bayer understood the significance of the termination condition, but nonetheless "made a business decision, likely for excellent economic reasons," * * * [to] accept[] the conditions and put their products on the market under conditional registrations." Order Denying Acc. Dec. at 27.

The ALJ granted the Pesticide Program's motion to limit testimony given the narrow basis on which the Program made its existing stocks determination. Order on Respondent's Motion to Limit Scope of Testimony ("Order Limiting Scope"). The statute, the ALJ noted, gives the Pesticide Program discretion to permit the sale and use of existing stocks if the Program determines both that sale or use of existing stocks is not inconsistent with the purposes of FIFRA and that sale and use of existing stocks will not cause unreasonable adverse effects to the environment. But nothing in the statute, the ALJ concluded, requires the Pesticide Program to evaluate these criteria short of the Pesticide Program affirmatively deciding to exercise its discretion to consider allowing sale or use of existing stocks. *Id*. at 9. Thus, because the Pesticide Program did *not* consider whether flubendiamide causes unreasonable adverse effects in making its existing stocks determination, the ALJ held that testimony on flubendiamide's potential to cause unreasonable adverse effects was irrelevant to the cancellation proceeding. *Id*. at 9-10.

5. *The ALJ's Initial Decision*

In her Initial Decision following the evidentiary hearing, the ALJ addressed whether Bayer and Nichino had satisfied the termination condition in their registrations and whether the Pesticide Program's existing stocks determination was consistent with FIFRA. She concluded that Bayer and Nichino had failed to satisfy the termination condition and held that they had waived the argument that their failure to request voluntary cancellation was excused because the Pesticide Program had not engaged in the required scientific dialogue on the submitted data and its conclusions. Corrected Initial Decision at 28 ("Init. Dec."). Further, the ALJ ruled that, even if Bayer and Nichino had presented such an argument, the evidence showed that "Petitioners' and EPA's scientists *did* engage in a good faith dialogue." *Id*. at 30. Finally, the ALJ upheld the Pesticide Program's determination on existing stocks, finding that the Program reasonably concluded that it "*is consistent* with the purpose of FIFRA section 3" to deny sale and distribution of existing stocks to Bayer and Nichino because they "are intentionally out of compliance" with their registrations. *Id*. at 36.

6. *Appeal to the Board*

Bayer and Nichino timely appealed from the ALJ's Corrected Initial Decision, the April 25, 2016 order denying their Motion for Accelerated Decision, and the May 3, 2016 order granting the Pesticide Program's Motion to Limit. Appeal Brief of Bayer CropScience LP and Nichino America, Inc. at 1 (June 13, 2016) ("App. Br."). At the same time, they moved for the hearing to be reopened to admit evidence excluded by the ALJ on flubendiamide's risks and benefits.

Motion to Reopen Hearing at 1 ("Mot. to Reopen"). At Bayer and Nichino's request, the Board held oral argument. After the argument, the Board requested additional briefing from the parties on seven specific questions, including the issue of whether the narrow scope of a section 6(e) proceeding barred the Board from considering Bayer and Nichino's challenge to the lawfulness of the termination condition. *See* Order on Post-Argument Briefing at 1-3; *see also* Post-Argument Brief of Bayer CropScience LP and Nichino America, Inc. ("BN Post-Arg. Br."); Post-Argument Brief of the US Environmental Protection Agency [Pesticide Program] ("Program Post-Arg. Br.").

## IV. *STANDARD OF REVIEW*

The Board reviews an ALJ's findings of fact and conclusions of law in the Initial Decision on a *de novo* basis. *See* Administrative Procedure Act ("APA"), 5 U.S.C. § 557(b) ("On appeal from or review of the initial decision, the agency has all of the powers which it would have in making the initial decision * * *."); *see also In re Martex Farms, S.E.*, 13 E.A.D. 464, 473 (EAB 2008); *In re Microban Prods. Co.*, 11 E.A.D. 425, 439 (EAB 2004). [21]

A final order from a cancellation hearing must be "based only on substantial evidence of record of such hearing." FIFRA § 6(d), 7 U.S.C. § 136d(d). Based on the Supreme Court's decision in *Steadman v. SEC*, 450 U.S. 91, 95 (1981), and prior decisions by EPA in cancellation proceedings, *see, e.g., In re Stevens Indus., Inc.*, 1 E.A.D. 9, 23-24 (Adm'r 1972), we interpret this as imposing a preponderance of the evidence standard.[22] In a FIFRA section 6 cancellation

[21] Although the cited Board cases arise in the context of FIFRA enforcement proceedings, the standard of review remains the same for review of an Initial Decision from a hearing under FIFRA section 6(e). The regulations governing the hearing make clear that it is "conducted pursuant to the provisions of [subchapter II of the APA]." 40 C.F.R. § 164.2(i). Thus, the Board sees no reason to deviate from longstanding precedent regarding the standard of review from an ALJ's determinations.

[22] The term "substantial evidence" is not defined in FIFRA, and is used in both FIFRA sections 6(d) and 16(b). 7 U.S.C. §§ 136d(d), 136n(b). The term commonly refers to the judicial standard of review of administrative decisions as it is used in the APA. *See* 5 U.S.C. § 556. The Supreme Court, when faced with a similar issue of applying the term "substantial evidence" in separate sections of the APA addressing evidentiary hearings and judicial review, interpreted the substantial evidence standard as imposing a preponderance of the evidence standard of proof on evidentiary hearings because the APA requires agencies to "weigh the evidence and decide [the issue], based on the weight of the evidence." *Steadman*, 450 U.S. at 99. FIFRA section 6(d) similarly requires us to weigh

hearing, the burden of going forward, also known as the burden of production, falls on the proponent of cancellation. 40 C.F.R. § 164.80(a).[23] The ultimate burden of persuasion, however, falls to the proponent of registration. *Id*. § 164.80(b). Therefore, in this FIFRA section 6(e) hearing, Bayer and Nichino as proponents of registration must meet their burden by either rebutting the Pesticide Program's prima facie case for cancellation, or demonstrating by a preponderance of the evidence that they initiated and pursued appropriate action to comply with the condition(s) of registration and that the Administrator's determination on existing stocks is not consistent with FIFRA. Bayer and Nichino admit that they bear this burden by a preponderance of the evidence. EAB Oral Argument Transcript at 94 ("EAB Tr."); BN Post-Arg. Br. at 7.

## V. *ANALYSIS*

The Pesticide Program issued a Notice of Intent to Cancel the flubendiamide registrations under FIFRA section 6(e), which applies specifically to the cancellation of conditional registrations. 7 U.S.C. § 136d(e)(2). Bayer and Nichino object, arguing that a section 6(e) cancellation proceeding is not appropriate in the present circumstances. Before examining whether the information in the Notice and the evidence presented at the hearing meet the requirements for cancellation under section 6(e), we first consider Bayer and Nichino's challenges to this overall proceeding.

### A. *Bayer and Nichino's Challenges to the Overall Proceeding*

Bayer and Nichino assert that the "central issue" in this cancellation proceeding is whether EPA's Pesticide Program may lawfully include in a conditional registration a provision that "bypass[es] statutory due process requirements" included in the FIFRA section 6(b) general cancellation provision.

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the evidence presented at the hearing – to "evaluate the data and reports before the Administrator" – and decide whether cancellation should be ordered "based only on substantial evidence of record of such hearing." 7 U.S.C. § 136d(d). Thus, it is appropriate to similarly interpret the substantial evidence standard in section 6(d) as imposing a preponderance of the evidence standard.

[23] *See, e.g., Stevens Indus.*, 1 E.A.D. at 23 n.30 ("[T]he burden of going forward [] is generally a rule to establish the order for the presentation of evidence. * * * Where a party which has the burden of going forward fails to satisfy that burden, the facts will be decided against him, even though the other party may have been responsible for the burden of persuasion."); *FMC Corp. v. EPA*, 279 F.R.D. 14, 15 (D.D.C. 2011).

BN Post-Arg. Br. at 1. A critical hurdle to reaching this question is the statutorily-limited scope of section 6(e) proceedings. Bayer and Nichino have offered several reasons as to why we can consider the lawfulness of the termination condition despite this statutory restriction. Bayer and Nichino's arguments raise two questions: (1) whether the Pesticide Program has properly initiated this cancellation action under section 6(e) rather than section 6(b), and (2) if the proceeding is properly initiated under section 6(e), whether Bayer and Nichino can nonetheless challenge the lawfulness of a condition in their registrations in a section 6(e) proceeding.

1. *Did the Pesticide Program Properly Initiate This Cancellation Proceeding under FIFRA Section 6(e)?*

    a. *The Plain Language, Structure, and Legislative History of FIFRA Support the Program's Decision to Initiate a Section 6(e) Proceeding*

Section 6(e) directs the Pesticide Program to issue a notice of intent to cancel a conditional registration "issued under section 3(c)(7) of [FIFRA]" if the Program determines that "the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed," or "[any] condition has not been met." FIFRA § 6(e), 7 U.S.C. § 136d(e). Thus, there are two necessary elements for initiating a section 6(e) cancellation proceeding. First, the registration must have been issued as a conditional registration under FIFRA section 3(c)(7). *Id*. Second, the Pesticide Program must have determined that a registrant has failed to satisfy a condition of the registration. *Id*. Both elements are present in this proceeding.

As to the first element, it is undisputed that the flubendiamide registrations were issued conditionally under FIFRA section 3(c)(7). The Preliminary Acceptance Letter that set out the terms negotiated by the parties for the flubendiamide registrations concluded with a signed concurrence from Bayer acknowledging that the registrations were to be granted under section 3(c)(7):

> 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.

PAL, PBNX 8, at PBN0020. Further, each Notice of Registration declared that "[t]his product is conditionally registered in accordance with FIFRA section 3(c)(7)" and provided notice to Bayer and Nichino that if "the conditions of registration as outlined in the preliminary acceptance letter * * * are not complied

with, the registration will be subject to cancellation *in accordance with section 6(e) of FIFRA*." Notices of Registration, RE 3, at RE014-15 (emphasis added).

The Notice of Intent to Cancel the flubendiamide registrations shows that the second element for initiating a section 6(e) cancellation proceeding was also met. In that Notice, the Pesticide Program described the termination condition in the flubendiamide registrations, asserted that Bayer and Nichino had violated the terms of their registrations by failing to submit voluntary cancellation requests, and concluded that "the registrants' failure to comply with [the termination] condition by submitting requests for voluntary cancellation makes the flubendiamide products identified [above] subject to cancellation under FIFRA section 6(e)." 81 Fed. Reg. at 11,560. Accordingly, under the plain language of section 6(e), the Pesticide Program properly initiated a cancellation of the flubendiamide conditional registrations under section 6(e).

Although the Pesticide Program's decision to proceed under section 6(e) is authorized both by FIFRA and by the specific terms of the registrations, Bayer and Nichino argue that the Board lacks subject matter jurisdiction over this section 6(e) cancellation proceeding because the Program's attempt to cancel the flubendiamide registrations is "properly governed by § 6(b)&(c)." BN Post-Arg. Br. at 3. They argue that if the Pesticide Program determines that a pesticide causes unreasonable adverse effects, the Pesticide Program "*must* issue a notice of intent to cancel (NOIC) and follow the process provided by Congress in FIFRA §§ 6(b) & (d) and 25(d)." App. Br. at 6. Otherwise, Bayer and Nichino contend, the Pesticide Program would deprive the affected registrant of "statutorily-required [due] process." *Id*. at 8. Essentially, Bayer and Nichino argue that if the Pesticide Program has made an unreasonable adverse effects finding, FIFRA's general cancellation provision in section 6(b) trumps section 6(e) and bars the Program from initiating a 6(e) cancellation proceeding, even where the elements for a section 6(e) cancellation are met. As discussed below, neither the plain language of the statute, its structure, nor legislative history support such an argument.

FIFRA establishes two categories of registrations for pesticides: general registrations and conditional registrations. A general registration licenses an applicant to sell and distribute a pesticide for the indefinite future. In contrast, a conditional registration is a temporary license that allows an applicant to sell and distribute a pesticide while developing the "required data" necessary for determining whether a full general registration is appropriate. FIFRA § 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C). Because of the different nature of general registrations under FIFRA section 3(c)(5) and conditional registrations under FIFRA section 3(c)(7), the statute and its implementing regulations contain different standards for

establishing each. *Compare* 7 U.S.C. § 136a(c)(5) and 40 C.F.R. § 152.112 *with* 7 U.S.C. § 136a(c)(7) and 40 C.F.R. §§ 152.113-115. And recall, FIFRA section 6(e) establishes an expedited and narrowly-focused cancellation process that applies only to conditional registrations. FIFRA § 6(e), 7 U.S.C. § 136d(e).

Importantly, when the Pesticide Program has determined that a conditional registrant has not satisfied a condition of its registration, the statute mandates that the Pesticide Program *must* initiate a section 6(e) cancellation proceeding. Specifically, section 6(e) commands that the Pesticide Program "*shall* issue a notice of intent to cancel" under that subsection when the Program determines that a "condition [of registration] has not been met." *Id*. § 6(e)(1), § 136d(e)(1) (emphasis added). The legislative history reinforces the mandatory nature of section 6(e). The House Report emphasizes that Congress "strongly believe[s] that the Agency *should be required* to cancel a [section 3(c)(7)(C) conditional] registration if the conditions are not met within the appropriate time interval." H.R. Rep. No. 95-343, at 10-11 (1977) (emphasis added).

The language in the general cancellation provision in section 6(b) differs markedly. Section 6(b) authorizes the Pesticide Program to cancel pesticides that cause unreasonable adverse effects, yet its language is permissive. Section 6(b) states that the Pesticide Program "*may* issue a notice of * * * intent * * * to cancel" a pesticide's registration if it appears to the Pesticide Program that the pesticide "generally causes unreasonable adverse effects on the environment." FIFRA § 6(b), 7 U.S.C. § 136d(b) (emphasis added).

Thus, the plain language of the statute and the legislative history do not support Bayer and Nichino's argument that if the Pesticide Program has determined both that a pesticide causes unreasonable adverse effects and that the registrant has violated a condition of registration, the Program may not initiate a section 6(e) cancellation proceeding but must use section 6(b) to cancel the pesticide. If anything, the statute compels the opposite result.

Bayer and Nichino's argument that section 6(b) takes priority over section 6(e) is inconsistent with the structure and environmental protection goals of FIFRA.[24] By adding section 6(e) to FIFRA in 1978, Congress created two quite

[24] *See* S. Rep. 92-838, at 3 (1972) (explaining that FIFRA "provide[s] for the protection of man and his environment and the enhancement of the beauty of the world around him"); H.R. Rep. 92-511, at 4 (1971) (FIFRA recognizes "the growing awareness of possible undesirable effects of pesticides and a realization of the necessity of considering

different cancellation procedures in section 6. *See* Pub. L. No. 95-396, § 12, 92 Stat. 819, 828-29 (1978). Prior to that date, FIFRA had a single cancellation provision – section 6(b). The standard for cancellation under section 6(b) is whether the pesticide "generally causes unreasonable adverse effects on the environment," a standard that "tak[es] into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA §§ 2(bb), 6(b), 7 U.S.C. §§ 136(bb), 136d(b). Section 6(b) expressly emphasizes the broad scope of this cancellation standard, directing the Pesticide Program to consider "the impact of the action * * * on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.[25] *Id.* § 136d(b). Further, section 6(b) mandates that the Pesticide Program obtain review of its cancellation determination from the FIFRA Scientific Advisory Panel and the U.S. Department of Agriculture. Finally, the statute imposes no time limitation on the conduct of the hearing.[26]

In contrast, section 6(e) authorizes the Pesticide Program to initiate an expedited cancellation proceeding – lasting only 75 days from start to finish – for the cancellation of conditional registrations. To make such an expedited hearing possible, Congress limited section 6(e) cancellation hearings to two narrow and carefully-delineated issues: whether a condition of registration has been violated and whether the Pesticide Program's disposition of the existing stocks of the pesticide is consistent with FIFRA. The legislative history emphasizes congressional intent that "[p]ublic resources should *not* be devoted to long, drawn-

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these disadvantages along with the beneficial effects realized through protection of public health and enhancement of agricultural efficiency").

[25] The Pesticide Program's history with section 6(b) cancellation proceedings has shown that these proceedings can be quite lengthy and the actual evidentiary hearings alone usually take months to complete. *See Dichlorvos (DDVP); Order Denying NRDC's Objections and Requests for Hearing*, 73 Fed. Reg. 42,683, 42,710 (July 23, 2008) (citing examples of cancellation proceedings in which the evidentiary hearing process lasted between four and thirteen months); *Diazinon; Ciba-Geigy, et al., Petitioners*, 53 Fed. Reg. 11,119, 11,120-21 (Apr. 5, 1988) (documenting that EPA's last section 6(b) cancellation proceeding that was prosecuted to completion lasted nearly one and one-half years and included an evidentiary hearing lasting over four months).

[26] Although there is no time limitation on the hearing, once the hearing is complete the Agency must issue a final decision within 90 days. FIFRA § 6(d), 7 U.S.C. § 136d(d).

out cancellation procedures for these types of registrations." H.R. Rep. 95-343, at 11 (1977).

Given Congress' decision to add an expedited cancellation provision to FIFRA – separate and independent from section 6(b) – it is difficult to square FIFRA's environmental protection goals with Bayer and Nichino's argument that the Pesticide Program must use the more time-consuming and resource-intensive section 6(b) procedures to cancel a pesticide in circumstances where section 6(e)'s expedited procedures are applicable. That is particularly the case when one considers that, unless the Program issues an "emergency order," a registrant is allowed to sell and distribute the pesticide during the course of section 6 cancellation proceedings. *See* FIFRA § 6(b)-(c), 7 U.S.C. § 136d(b)-(c). If the Program were required to initiate cancellation proceedings under section 6(b) instead of under section 6(e), registrants would, in effect, be rewarded with additional time to sell and distribute their pesticides. Had Congress intended such a result, it could have subordinated section 6(e) to section 6(b) when it added the new conditional registration authority (including section 6(e)) to the existing statutory structure in 1978. *See* S. Rep. No. 95-1188, at 11 (1978) (Conf. Rep.). But Congress did not take such a step. Rather, in creating the possibility of allowing pesticides to be introduced to the market conditionally when they could not meet all the requirements for a general registration, Congress took steps to assure that such pesticide registrations could be promptly canceled when the terms of the conditional registrations were not met.[27]

[27] Bayer and Nichino claim that the Pesticide Program has previously taken the position that cancellation under section 6(e) is only for "the *registrant's* failure to meet its obligations, and not about a problem with the *pesticide product itself*. A pesticide cancelled pursuant to section 6(e) is not being cancelled on account of risks." PBNX 126, at 4 n.2 (emphasis in original); *see also* App. Br. at 13-14. The quoted language comes from a footnote in a litigation brief in a different case involving a different question. Moreover, the Program's previous statement appears directed at section 3(c)(7)(A) conditional registrations and not section 3(c)(7)(C) "new active ingredient" conditional registrations such as the ones involved in this case. PBNX 126, at 4 n.2. The eligibility prerequisites for, and required conditions of, a section 3(c)(7)(C) registration differ significantly from those applicable to a section 3(c)(7)(A) registration. In any event, in this proceeding flubendiamide is not being canceled under section 6(e) on the ground that it poses unreasonable risks, but instead it is being canceled because Bayer and Nichino failed to live up to the termination condition in their registrations.

Nor does the federal district court decision in *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011), upon which Bayer and Nichino heavily rely, suggest anything to the contrary. The judge in *Reckitt* held that the Pesticide Program could not use an enforcement proceeding for misbranding under FIFRA section 12 to compel, in effect, the cancellation of a pesticide. Such an approach, the judge concluded, would render the language of FIFRA section 6 "superfluous." *Id*. at 43. But the *Reckitt* judge did not address the present situation, in which the Pesticide Program initiated a cancellation proceeding under section 6(e), rather than a cancellation proceeding under section 6(b). And the Pesticide Program's use of section 6(e)'s cancellation provision to cancel a conditional registration does not, as a definitional matter, render the general cancellation provision in section 6(b) superfluous. Section 6(e) covers only conditional registrations, not general registrations, and is only triggered by a violation of a condition in the registration. On the other hand, section 6(b) applies to all registrations and permits cancellations "[i]f it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of [FIFRA] or * * * [the pesticide] generally causes unreasonable adverse effects on the environment." 7 U.S.C. § 136d(b)(2).

b. *Bayer and Nichino Knowingly Accepted the Terms of the Conditional Registration and Cannot Now Challenge Those Terms*

Bayer and Nichino's argument that the Pesticide Program should have initiated this cancellation proceeding under section 6(b) also fails in light of their knowing agreement to the termination condition in the registrations. Procedural rights, whether statutory or constitutional, may be waived so long as the waiver is knowing. *D. H. Overmyer Co. v. Frick Co.*, 405 U.S. 174, 185-86 (1972) (holding that a party waived its due process right to prejudgment notice and hearing by a confession of judgment clause in a contract). Specifically as to the waiver of statutory rights, the Supreme Court has stated that "absent some affirmative indication of Congress' intent to preclude waiver, we have presumed that statutory provisions are subject to waiver by voluntary agreement of the parties." *U.S. v. Mezzanato*, 513 U.S. 196, 201 (1995).

Here, Bayer and Nichino knowingly accepted the termination condition. Both Bayer and Nichino are sophisticated participants in the pesticide regulatory arena. Bayer, in particular, admitted to holding roughly 250 pesticide registrations under FIFRA. ALJ Tr. at 135-36 (testimony of L. Hall). Bayer and Nichino knew that they were obtaining conditional registrations for flubendiamide, and given the record of their negotiations with the Pesticide Program, they were intimately

familiar with the terms of those registrations. The termination condition, in particular, was the subject of extensive negotiations between the parties.

Initially, the Program proposed including an expiration date in the conditional registrations but Bayer and Nichino objected. E-mails between Clive Holder, Director of Regulatory Affairs, Bayer CropScience; Danielle Larochelle, Registration Product Manager, Bayer CropScience; and EPA Registration Division, RE 4, at RE025 (July 17 – 31, 2008) [hereinafter *Negotiation E-mails*]; *see also* ALJ Tr. at 39-41 (testimony of S. Lewis). Instead, Bayer and Nichino proposed a version of the multi-step process that would ultimately be adopted. *Negotiation E-mails*, RE 4, at RE029. While the Program indicated that it was amenable to many of the changes suggested by Bayer and Nichino – including eliminating the fixed expiration date – the Program nevertheless indicated that it wished to retain some mechanism for speedy termination of the conditional registrations if concerns about the risks of flubendiamide were not addressed by the required data. *See id*. at RE036; *see also* ALJ Tr. at 42 (testimony of S. Lewis). The Program thus proposed a condition that would require Bayer and Nichino to request voluntary cancellation within one week of being notified that the Program had made an unreasonable adverse effects determination. *Negotiation E-mails*, RE 4, at RE033.

Bayer and Nichino negotiated and agreed to this requirement. In an email to the Program, Bayer's then Director of Regulatory Affairs, Clive Halder, stated that they had "little problem" accepting the voluntary cancellation requirement, which he termed a "'fast death' approach." *Id*. at RE036. He also emphasized, however, that Bayer and Nichino had a "sore point" concerning the possibility that the Program might issue a determination on unreasonable adverse effects before Bayer scientists had the opportunity to engage in a "measured dialogue" with Program scientists. *Id*.

> It is a "sore point" because, first off, [the language] is so vague as to not be understandable to us. Second, [the language] appears to allow EPA to demand cancellation without any due process from us. My take is that the Agency would like to avoid having to go through Section 6 cancellation proceedings. We understand this, so have little problem with fitting in the "fast death" approach, i.e. voluntary cancellation within a week of the decision. From our side, we expect that a fair cancellation demand can only occur after the conditions of part 5(b) and 7(b) have been met, specifically, that all the submitted data have been reviewed alongside all voluntary data submitted by Bayer, plus following a measured dialogue between the scientists.

*Id*.

Thus, it appears that Bayer and Nichino understood and were not troubled by the "fast death" nature of the termination condition; rather, their most pressing concern at the time was instead with the *process* that must occur before the Program could trigger such "fast death" proceedings. That is, Bayer and Nichino wanted to ensure that the Program would not issue an unreasonable adverse effects determination without reviewing all the data submitted by Bayer and Nichino and engaging in a "measured," scientist-to-scientist dialogue with Bayer on the data and the Program's conclusions.

Given the language of the conditional registrations, Bayer and Nichino's affirmative concurrence on that language, and the record of negotiations, we find that Bayer and Nichino willingly agreed to the termination condition, knowing that they were agreeing to an approach that could remove the flubendiamide products from the market rapidly.[28] Having knowingly agreed to this procedure, they cannot contest it now.

2. *May the Board Consider the Lawfulness of a Condition of Registration in a FIFRA Section 6(e) Proceeding?*

The scope of a 6(e) cancellation proceeding is narrowly limited to the following issues: (1) whether the condition was satisfied, and (2) whether the Pesticide Program's determination on the appropriate disposition of the existing stocks of the canceled pesticide is consistent with FIFRA. 7 U.S.C. § 136d(e)(2).

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[28] The Program also argues that Bayer and Nichino's acceptance of the registrations without challenge prevents them from now challenging the validity of the termination condition based on the doctrine of laches. Response Brief of the United States Environmental Protection Agency at 14-15 n.2 ("Resp. Br."). Laches "is an equitable defense applicable where there has been an unreasonable delay in bringing an action, and where the party raising the defense has suffered undue prejudice." *In re Willie P. Burrell*, 15 E.A.D. 679, 691 (EAB 2012) (citing *Costello v. United States*, 365 U.S. 265, 281-82 (1961)). The applicability of the doctrine of laches to this case, particularly on the question of whether the Program was prejudiced by the delay, is unclear. A seemingly more applicable equitable doctrine would be equitable estoppel, which "precludes a party from asserting a right that the party would otherwise enjoy if that party takes actions upon which its adversary reasonably relies to its detriment." *In re BWX Tech., Inc*., 9 E.A.D. 61, 80 (EAB 2000) (citing *Heckler v. Cmty. Health Serv*., 467 U.S. 51, 59 (1984); *Bank v. U.S*., 294 U.S. 120, 124-125 (1935)). However, because the Program has not argued this claim, and the parties have not briefed whether Bayer and Nichino should be estopped from challenging the lawfulness of the condition in this action, the Board does not decide the potential application of the doctrine here.

The legislative history affirms Congress' intent to keep section 6(e) hearings strictly limited: "We strongly believe that * * * any hearing on a [section 6(e)] cancellation should be confined to whether or not the conditions are met and how existing stocks should be handled." H.R. Rep. No. 95-343, at 10-11. Thus, the plain language of section 6(e)(2) and its legislative history would appear to prohibit Bayer and Nichino from collaterally attacking the lawfulness of their registrations' conditions in this section 6(e) cancellation proceeding.

Bayer and Nichino object that the Board cannot evaluate whether they have complied with the conditions of the flubendiamide registrations without "necessarily first consider[ing] whether the conditions are valid." BN Post-Arg. Br. at 2. Bayer and Nichino add that "[b]ecause the EAB stands for the EPA Administrator as the 'final decision-maker' on [the Pesticide Program's] proposed determination, it cannot ignore questions about the lawfulness of a condition." *Id.* at 3. Bayer and Nichino cite no authority for these assertions, and they are not persuasive. Section 6(e), on its face, forecloses collateral attack on a registration's conditions in a cancellation proceeding. Congress is free to define the timing, forum, and procedure for challenges to the denial and cancellation of pesticide registrations, and the Board cannot disregard the statutory scheme that Congress passed and the President signed into law.[29] *See Elgin v. Dep't of the Treasury*, 567 U.S. 1, 8-10 (2012) (concluding that where a statute does not preclude all judicial review, a statutory provision channeling how and where administrative and judicial review is conducted will be upheld if that structure is "fairly discernible in the statutory scheme"); *NRDC v. EPA*, 673 F.2d 400, 406-07 (D.C. Cir. 1982) (upholding the "now or never" judicial review scheme in the Clean Water Act that

[29] Bayer and Nichino also claim that their unlawfulness argument shows that the Board lacks subject matter jurisdiction and thus "EPA has no legal authority to proceed under § 6(e)." BN Post-Arg. Br. at 3. But this argument fails to confront the bar in section 6(e) to the Board's consideration of any issue other than whether Bayer and Nichino have violated a condition of their registrations and whether the Pesticide Program's determination on disposition of existing stocks is consistent with FIFRA. If in a properly-initiated section 6(e) proceeding the Board is prohibited from considering an issue such as a challenge to the lawfulness of the condition allegedly violated, Bayer and Nichino's description of its unlawfulness claim as affecting the Board's subject matter jurisdiction does not, without more, explain why the Board may ignore the Congressional limitation. In the end, we conclude that Bayer's couching of its lawfulness claim as a challenge to the Board's subject matter jurisdiction adds little to Bayer and Nichino's other arguments as to why the Board may consider this claim despite the statutory bar.

requires certain rules and permit decisions to be challenged within ninety days and precludes challenges to such rules and permit decisions in enforcement actions).

In other statutes, Congress has similarly limited the scope of what can be challenged in a particular proceeding. For example, the section 6(e) limitation on the issues that may be raised in a cancellation proceeding is analogous to the Clean Water Act's limit on what issues can be raised in a permit enforcement proceeding. In the Clean Water Act, Congress specified the appropriate forum for challenging an EPA-issued National Pollutant Discharge Elimination System ("NPDES") permit, and then in a separate provision barred any subsequent collateral attack on the permit in an enforcement proceeding. *See* CWA § 509(b)(1), (b)(2), 33 U.S.C. § 1369(b)(1) (requiring permit appeals be filed within 120 days in a United States Circuit Court of Appeals), 1369(b)(2) (barring review in an enforcement proceeding of any action for which review could have been obtained under section 1369(b)(1)). Courts have routinely enforced the Clean Water Act's bar on collateral attack on NPDES permits, even where the permit was granted by an authorized state and not EPA and even where parties claimed the permit provision was unlawful. *GMC v. EPA*, 168 F.3d 1377, 1379, 1383 (D.C. Cir. 1999), *aff'g In re General Motors Corp., CPC-Pontiac Fiero Plant,* 7 E.A.D. 465 (EAB 1997) (denying collateral attack on validity of a state permit as based on mutual mistake and issued without proper authority); *Pub. Interest Research Group v. Powell Duffryn Terminals*, 913 F.2d 64, 77-78 (3d Cir. 1990) (holding that a challenge to lawfulness of the inclusion of certain discharge limits in a state permit was barred in an action enforcing the permit). Claims that such a result violates due process have been rejected as "utterly meritless." *Powell Duffryn Terminals*, 913 F.2d at 78 n.27. As the Third Circuit explained, "[d]ue process was available to [the permittee], in the form of an administrative challenge to the permit. [The permittee] was not denied due process; it simply failed to use the process available to it." *Id.*

Here, too, Bayer and Nichino had ample opportunity to challenge the lawfulness of the termination condition in a timely and permissible way but failed to do so. For example, they could have declined to accept the registration terms that the Pesticide Program offered them in 2008 and then challenged the Program's refusal to grant a conditional registration under terms acceptable to them. In its final letter to Bayer and Nichino proposing terms for a conditional flubendiamide registrations, the Pesticide Program highlighted that option: "[i]f either Nichino or Bayer notifies EPA that it is unwilling to accept any of those conditions [of registration outlined in the preliminary acceptance letter], EPA will commence the appropriate denial process under section 3(c)(6) of FIFRA." PAL, PBNX 8, at PBN0020; *see also* 40 C.F.R. §§ 152.118(a), 164.20. A denial of a general or conditional registration entitles the applicant to "request a hearing in accordance

with FIFRA 6(b)." 40 C.F.R. § 152.118(e). Such a hearing would be identical to a hearing requested by a registrant in response to a section 6(b) notice of intent to cancel, including the same hearing on the record before an administrative law judge, *id*. §§ 164.20(c), .40, the same rights to present and cross-examine witnesses, *id*. § 164.81, the same right to request referral of questions of scientific fact to a committee of the National Academy of Sciences, *id*. § 164.50(e), and the same allowance of participation by affected third parties, *id*. § 164.31. *See* Part II.C above; *see also* 40 C.F.R. §§ 164.3, .20. Bayer and Nichino declined this offer by accepting the conditional registrations.

Moreover, Bayer and Nichino cannot contend that they did not understand the consequences of agreeing to the proposed registrations containing the termination condition rather than taking a denial and contesting the Program's action. As the negotiations on the registrations show, Bayer and Nichino well understood that by accepting what they described as a "fast death" provision, the Pesticide Program could demand voluntary cancellation based on a finding of unreasonable adverse effects without instituting a potentially lengthy section 6(b) cancellation proceeding. Further, the Notices of Registration alerted them that failure to comply with the conditions of their registrations – one of which is the termination condition – made those registrations subject to cancellation under FIFRA section 6(e). And, again, a section 6(e) cancellation proceeding is – by the statute's express terms – sharply limited in scope. Thus, prior to accepting the terms of registration, Bayer and Nichino knew they had waived any right to a section 6(b) cancellation hearing, and knew, or should have known given the clarity of section 6(e), that any objection they had to the condition giving the Pesticide Program the option to effectively require cancellation without instituting a section 6(b) proceeding could not be raised in a section 6(e) cancellation for failure to comply with the termination condition.

Bayer and Nichino characterize the Program's offer to deny their application as a "Hobson's choice of accepting conditions designed to bypass the cancellation process or receiving no registrations at all." App. Br. 14 (footnote omitted). But Bayer and Nichino did not face a Hobson's choice. A Hobson's choice means essentially "no choice at all – either taking what is offered or taking nothing at all." Bryan A. Garner, *Garner's Dictionary of Legal Usage* 410 (2011); *see also Zelman v. Simmons-Harris*, 536 U.S. 639, 707 (2002) (Souter, J., dissenting) (stating that "a Hobson's choice is not a choice"). Bayer and Nichino were offered a real choice, not an illusory or Hobson's choice. In 2008, the Pesticide Program offered them either, (1) a registration with conditions that the Program found necessary to meet the terms of FIFRA, or (2) the opportunity under FIFRA section 6(b) and the applicable regulations to dispute the Program's

conclusion that such conditions were legally required. Thus, Bayer and Nichino had an alternative – the same alternative available to any applicant for a government license: accept the government's decision on its application or challenge the government's determination either administratively or in court.[30]

Bayer and Nichino claim that declining to accept the termination condition and obtaining a denial of their registration applications was not "a realistic or meaningful 'option,'" but would have been merely "a chance to mount a premature, facial challenge to a provision that would only become relevant if EPA chose, years later, to issue a cancellation determination contrary to the data and science." App. Br. at 15. However, there is nothing premature or speculative about a challenge to a denial of a registration application. A denial is an adverse action by the federal government that Bayer and Nichino would have had standing to challenge administratively before EPA under section 6(b), and, if not successful at the administrative level, in federal court. That the application denial would have concerned a condition that might never have been triggered does not mean that the denial would have had an effect that was any less direct, concrete, and adverse.

Aside from accepting and then challenging a denial, Bayer and Nichino had other legal options. Arguably, Bayer and Nichino could have accepted the conditional registrations and then challenged the termination provision directly in federal district court, similar to what the registrants did in *Woodstream v. Jackson.* There, a pesticide registrant challenged various conditions in a conditional registration, including an expiration date. *Woodstream II*, 845 F. Supp. 2d at 179. Similar to Bayer and Nichino's argument in this case, the registrant in the *Woodstream* litigation asserted that the expiration date condition was an unlawful "bypass" of the general cancellation procedures in FIFRA section 6(b). *Id*. at 182. Although the court ruled against the registrant on the merits, the court did not question that it had jurisdiction to hear the case. *See Woodstream I*, 2011 U.S. Dist. LEXIS 151994, at *18-19 (noting that registrant could challenge the expiration condition directly in federal district court). Further, in dismissing the registrant's

[30] Bayer and Nichino also claim that they only accepted the termination condition because they trusted the Program to discuss the science in good faith. ALJ Tr. at 144-45 (testimony of J. Johnson); *see also* EAB Tr. at 14. However, given that such a dialogue is a pre-condition to the Program's unreasonable adverse effects finding under the registrations, Bayer and Nichino had the opportunity in this section 6(e) proceeding for a hearing on that issue but declined to do so. *See* Part V.B.1.a., below.

claim, the court mentioned a third option available to a registrant dissatisfied with the conditions of a FIFRA registration:

> Woodstream could have accepted the conditions, but immediately filed a new request for an amended registration removing the conditions. If the EPA denied the request, as it presumably would, Woodstream would be entitled to the same remedies available under section 6 in the case of a cancellation, including an opportunity for a full administrative hearing.

*Woodstream II*, 845 F. Supp. 2d at 182-83. Finally, Bayer and Nichino could have filed an application to convert their conditional registrations to general registrations. Resp. Br. at 6. If the Program had denied Bayer and Nichino's applications for general registrations, Bayer and Nichino would have been entitled to a full administrative hearing and judicial review of the Agency's decision. FIFRA § 3(c)(6), 7 U.S.C. § 136a(c)(6).

Thus, Bayer and Nichino had several avenues to either challenge the lawfulness of the termination condition or demonstrate they were entitled to general registrations. Instead, Bayer and Nichino chose not to avail themselves of any of these opportunities. Bayer and Nichino's failure to exercise their legal options at the appropriate time does not authorize the Board to depart from the narrow confines of FIFRA section 6(e) to hear their challenge to the lawfulness of their registrations in this proceeding.

Bayer and Nichino are quite clear about what they seek: they claim they are entitled to a full administrative hearing under section 6(b) on whether flubendiamide causes unreasonable adverse effects *before* their registrations can be canceled and flubendiamide removed from the market. If the Pesticide Program had made a previous finding that flubendiamide does not cause unreasonable adverse effects and granted section 3(c)(5) general registrations to Bayer and Nichino, they would have been entitled to a section 6(b) cancellation before the cancellation became effective. But the Program never granted Bayer and Nichino a section 3(c)(5) general registration. Because Bayer and Nichino hold only section 3(c)(7) conditional registrations, their rights are more limited. As shown in Part V.A.1.a above, a registrant that violates a condition of its section 3(c)(7) conditional registration cannot insist that the Pesticide Program nonetheless must initiate cancellation proceedings under section 6(b) rather than section 6(e). Moreover, as discussed in Part V.A.1.b above, Bayer and Nichino are in an especially poor position to demand a pre-cancellation hearing under section 6(b) given their knowing acceptance of the "fast death" provision's elimination of section 6(b)

hearing procedures in exchange for immediate market entrance for flubendiamide products.

Yet, Bayer and Nichino still retain the ability to obtain a full section 6(b) hearing on whether flubendiamide causes unreasonable adverse effects. They can refile general registration applications for flubendiamide, forcing the Program to grant or deny such applications under the applicable statutory procedures (i.e., a section 6(b) hearing for registration denials). Granted, under this approach, a section 6(b) hearing will not take place while Bayer and Nichino still retain registrations legalizing the sale and distribution of flubendiamide. But having accepted section 3(c)(7) conditional registrations and then violated them, Bayer and Nichino cannot insist on the statutory rights accorded registrants holding full section 3(c)(5) general registrations.

In sum, we conclude that the statute precludes Bayer and Nichino from raising a challenge to the lawfulness of the termination condition in this section 6(e) cancellation proceeding. This holding should not be construed as an endorsement of the legality or wisdom of the termination condition. Should the Pesticide Program decide to demand such a condition for a future registration – a course the Program states it does not intend to follow – the applicant can challenge the condition at that time. Neither is anything in this decision a judgment on the risks and benefits of flubendiamide, or on the merits of the challenge that Bayer and Nichino have made as to the Pesticide Program's determination that flubendiamide causes unreasonable adverse effects on the environment. Rather, the Board's decision reflects our reading of section 6(e) as not permitting the broader challenges now raised by Bayer and Nichino. Their challenges to the lawfulness of the termination condition should have come earlier and in a different proceeding. Their arguments concerning whether flubendiamide causes unreasonable adverse effects can be adjudicated if they apply for a section 3(c)(5) general registration.

B. *Resolution of Issues Before the Board in the FIFRA Section 6(e) Cancellation Proceeding*

We now turn to the only two questions properly at issue in this FIFRA section 6(e) cancellation proceeding. First, we consider whether Bayer and Nichino have complied with the conditions of registration. Because it is undisputed that Bayer and Nichino complied with all of the data gathering and data submission requirements, we limit our review to whether they complied with the termination condition. We conclude that they did not. Second, we consider whether the Pesticide Program's determination with respect to the disposition of existing stocks is consistent with FIFRA. With one exception, we conclude that it is.

1. *Did Bayer and Nichino Comply with the Termination Condition of the Flubendiamide Registrations?*

Bayer and Nichino did not comply with their obligation to submit voluntary cancellation requests within one week after the Pesticide Program notified them – on January 29, 2016 – of its determination that flubendiamide causes unreasonable adverse effects. Bayer and Nichino's February 5, 2016 letter affirmatively refusing to request cancellation documents that noncompliance. *Cancellation Refusal*, PBNX 18, at PBN0100. Nonetheless, Bayer and Nichino argue that their failure to request cancellation is excused because the Pesticide Program did not meet an important pre-condition to the termination condition: that the Program engage in a scientific dialogue with Bayer and Nichino on data they submitted and the Program's conclusions. App. Br. at 20-24. Before addressing the merits of that question, we first discuss the Program's argument that Bayer and Nichino waived this objection to the Notice of Intent to Cancel by failing to raise it prior to the evidentiary hearing. [31]

a. *Bayer and Nichino Waived Their Right to Challenge the Pesticide Program's Compliance with Its Obligations under the Flubendiamide Registrations*

If a party files a request for hearing under FIFRA section 6, it must also "file a document stating his objections to the Administrator's * * * intent to cancel the registration." 40 C.F.R. § 164.20(b). This statement of objections "shall clearly and concisely set forth such objections and the basis for each objection, including relevant allegations of fact concerning the pesticide under consideration." *Id*. § 164.22(a). The objections "may be amended at any time *prior to the commencement of the public hearing* by leave of the Administrative Law Judge," which leave shall be freely granted. *Id*. § 164.22(b) (emphasis added). Part 164 does not address how specific the "basis for each objection" must be when a registrant claims it was excused from complying with a registration condition because the Pesticide Program did not meet a condition precedent to the registrant's obligation. However, Rule 9(c) of the Federal Rules of Civil Procedure does address a similar question, stating that "when denying that a condition precedent has occurred or been performed, a party must do so with particularity." Fed. R.

[31] The Program argued in its post-hearing brief that this objection was untimely. Respondent's Post-Hearing Brief at 9. The ALJ agreed but also found, alternatively, that the necessary dialogue had occurred. Init. Dec. at 28.

Civ. P. 9(c).[32] This federal court rule ensures that the opposing party has notice that this defense is being raised so it can prepare accordingly. *See* 5A Charles Alan Wright & Arthur R. Miller, *Fed. Prac. & Proc.* § 1304 (3d ed. 2004) ("Because in most cases no question will be raised as to the satisfaction of conditions precedent, Rule 9(c) has the effect of forcing a defendant to raise the issue when she believes there is actually a question about occurrence or performance."). The Board finds this rationale persuasive, and so we interpret 40 C.F.R. § 164.22 in a similar manner.

Thus, under section 164.22, we look to what Bayer and Nichino argued as a "basis for each objection." We ask whether they argued with sufficient particularity that the condition precedent had not occurred. Our inquiry focuses on whether the Pesticide Program had notice that Bayer and Nichino were relying on this assertion as an element of their challenge to the Notice of Intent to Cancel. Based on our review, we agree that Bayer and Nichino failed to put EPA on notice that they were contesting the adequacy of the scientific dialogue prior to the hearing. Therefore, we find untimely Bayer and Nichino's argument that they were under no obligation to request voluntary cancellation.

(i) *What Arguments Did Bayer and Nichino Raise in Their Request for Hearing and Statement of Objections and Other Filings?*

In various filings with the ALJ prior to the evidentiary hearing, Bayer and Nichino generally alleged that the scientific discussions that took place between the parties lacked transparency. Yet at no point before the evidentiary hearing began did Bayer and Nichino specifically allege that the termination condition was not triggered because the Pesticide Program had failed to comply with its obligation to "engage in dialogue" with Bayer scientists. Rather, Bayer and Nichino's allegations regarding lack of transparency were either included as background information or cited as supporting their arguments that the Pesticide Program's finding of unreasonable adverse effects was erroneous and that the Pesticide

[32] The Board is not bound by the Federal Rules of Civil Procedure and related practice. *See*, e.g., *In re Chempace Corp*., 9 E.A.D. 119, 135 n.22 (EAB 2000). However, the Board may look to federal court decisions on similar procedural rules to inform the Board's interpretation of its administrative rules. *See In re Lazarus, Inc*., 7 E.A.D. 318, 330 (EAB 1997); *see also Chempace*, 9 E.A.D. at 135 n.22. Bayer and Nichino have provided no reasons why federal court decisions interpreting Rule 9 of the Federal Rules of Civil Procedure should not be considered in interpreting the procedural requirements of 40 C.F.R. § 164.22.

Program had not followed the procedures required by FIFRA section 6(b). We examine each of Bayer and Nichino's pre-hearing communications and filings.

In responding to the Pesticide Program's letter informing them of the Program's unreasonable adverse effects determination, Bayer and Nichino set forth three main contentions: (1) the termination condition that required Bayer and Nichino to request voluntary cancellation was unlawful; (2) any cancellation process based on a determination that the flubendiamide products cause unreasonable adverse effects must take place under FIFRA section 6(b); and (3) the continued registration of flubendiamide does not cause unreasonable adverse effects on the environment. *Cancellation Refusal*, PBNX 18, at PBN0098. In explaining the last point, Bayer and Nichino touched on their interactions with the Pesticide Program, noting that there were "meetings and discussions from July through November 2015" to discuss additional data requirements to address remaining uncertainties, but emphasizing both that, (1) "EPA abruptly shifted course and expressed its intent to discount the real world monitoring data," and (2) "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 regulatory analyses and discussions." *Id*. at PBN0099. Significantly, Bayer and Nichino cited these "shifts" in the Pesticide Program's positions to illustrate their claim that the Pesticide Program's unreasonable adverse effects determination was based on "unrealistic" or "[in]appropriate" data. *Id*. at PBN0099-100. Bayer and Nichino, however, did not argue that the Pesticide Program had violated the conditional registrations' dialogue requirement.

After receiving this letter, the Pesticide Program issued the Notice of Intent to Cancel the flubendiamide registrations, expressly stating that "whether the registrants satisfied the condition of registration requiring them to submit timely requests for voluntary cancellation" would be an issue for the hearing, if one were to be requested. 81 Fed. Reg. at 11,561. Despite the Pesticide Program's explicit invitation to raise the issue of compliance with their registrations' conditions, Bayer and Nichino filed a request for hearing without alleging that their failure to satisfy the termination condition was excused because the Pesticide Program had not complied with the condition precedent requiring a scientific dialogue. In their March 31, 2016 Request for Hearing, Bayer and Nichino make the following five objections to the Notice of Intent to Cancel: (1) the Pesticide Program cannot cancel the registrations without undertaking a full FIFRA section 6(b) proceeding; (2) the termination condition is unlawful; (3) the registrants satisfied all of the lawful conditions in their registrations; (4) the continued registration of flubendiamide meets the registration standard because it does not cause unreasonable adverse effects; and (5) EPA's proposed existing stocks determination is inconsistent with

FIFRA. Req. for Hearing at 40-64. On close examination, the actual allegations and claims in the Request for Hearing either do not support or actually undermine Bayer and Nichino's belated assertion during the hearing that their challenge to the Notice of Intent to Cancel also included a claim that they were excused from submitting a voluntary cancellation request because the Pesticide Program failed to engage in the scientific dialogue required by their registrations.

Bayer and Nichino do include many of the factual allegations that now form the basis for their no dialogue defense in the "Background" section of their Request for Hearing. *See id*. at 24-25 (stating that the scientific discussions on December 16, 2015 and thereafter were "based * * * on a different endpoint that appeared to be designed to ensure, after the fact, that registrants' 'final' mitigation proposal would not be sufficient"); *id*. at 25-26 (discussing the aftermath of the December 15, 2015 meeting with the Assistant Administrator); *id*. at 31 (stating that the discussions until December 2015 were based on a level of concern for des-iodo in sediment pore water at 19.5 ppb, but that "at the eleventh hour and after requesting the registrants' final analysis and mitigation proposal, EPA suddenly and remarkably chose to revert to the pore water endpoint of 0.28 ppb"). Also in the Background section, Bayer and Nichino describe the Pesticide Program's commitment in the registrations "to engage in discussion with the registrants about the data and EPA's conclusions." *Id*. at 19. However, the Background section never links the dialogue requirement[33] in the registration with their factual allegations on a lack of transparency. The Pesticide Program was not obliged to ascertain what objections *could be made* based on every factual allegation in the first 139 paragraphs of Bayer and Nichino's sixty-six page Request for Hearing; on the contrary, Bayer and Nichino were required to "concisely set forth such objections *and* the *basis* for *each* objection * * *." 40 C.F.R. § 164.22(a) (emphasis added).

Importantly, when Bayer and Nichino move from the "Background" section to the substance of their filing – which contains their actual objections – they drop all reference to the "dialogue" or "discussion" requirement in the registrations. The absence of a reference to the "dialogue" requirement is most glaring in Bayer and

[33] Bayer and Nichino never use the term "dialogue" in their objections, much less the phrase "measured dialogue" that they used during the negotiations over the registrations. In fact, Bayer and Nichino did not even acknowledge their role in negotiating this term or that the sequential terms of the registration were at issue in the proceeding until after the Pesticide Program introduced this evidence in its opposition to Bayer and Nichino's Motion for an Accelerated Decision on April 18, 2016.

Nichino's third objection. That objection – "The Registrants Have Satisfied All the Lawful Conditions of the Conditional Registration" – is the only one that addressed compliance with the registrations' conditions. Req. for Hearing at 48. However, not only did that objection fail to mention the Pesticide Program's obligation to engage in a scientific dialogue, but it alleges facts that would seem to contradict any claim by Bayer and Nichino that the Program had violated that duty. Specifically, Bayer and Nichino contend that "[t]hroughout 2015, scientists from the registrants and EPA engaged in discussions about both the benefits and the risks of flubendiamide." *Id*. at 49.

Bayer and Nichino's fourth objection further undermines their assertion that they gave notice of their claim that the Program failed to engage in dialogue and, thus, their failure to request voluntary cancellation is excused. In that objection – "Continued Registration of Flubendiamide Meets the Registration Standard" – Bayer and Nichino affirmatively tie their factual allegations regarding a lack of transparency to an objection legally and factually distinct from an objection that the Pesticide Program did not meet the condition precedent to the termination condition because they failed to engage in the required scientific dialogue. The thrust of their objection is that "[i]f afforded a proper section 6(b) hearing * * * Bayer and Nichino would * * * establish[] that EPA's cancellation determination: (1) ignores the most recent and definitive [toxicity] data * * *; (2) ignores the real-world monitoring data * * *; and (3) dismisses without justification the significant benefits of flubendiamide." *Id*. at 51. Bayer and Nichino describe the fourth objection as "summariz[ing]" "the errors in EPA's cancellation determination." *Id*. at 52.

One error, according to Bayer and Nichino, is that Program's "selection of the lower [toxic] endpoint is not consistent with sound science." *Id*. (capitalization omitted). Bayer and Nichino point to the Program's alleged lack of transparency on toxic endpoint selection as evidencing the need for the "regulatory process" of a section 6(b) proceeding that would include "appropriate review" by the FIFRA Scientific Advisory Panel. *Id*. (capitalization omitted). Bayer and Nichino argue that "[s]cientific peer review by the [FIFRA Scientific Advisory Panel] – which EPA goes to great lengths to avoid – would require EPA to confirm and explain its use of the lower endpoint." *Id*. at 54. At no point in this discussion do Bayer and Nichino refer to the requirement in the registrations to engage in a scientific dialogue.

Thus, Bayer and Nichino's lack of transparency allegations in their fourth objection go to the merits of their objection that FIFRA section 6(b) is the appropriate avenue for this proceeding and that the Pesticide Program has reached

an incorrect substantive conclusion regarding whether flubendiamide causes unreasonable adverse effects. Now that the ALJ has conducted the expedited and narrowly-focused hearing required by FIFRA section 6(e), Bayer and Nichino ask the Board to infer that these statements *could also* refer to an objection that they were under no obligation to voluntarily cancel the registrations and, therefore, did not violate the terms of their conditional registrations. Yet, these two distinct objections arise from two entirely different legal bases, and stating one does not preserve the other. *See Mingo Logan Coal Co. v. EPA*, No. 14-5305, 2016 U.S. App. LEXIS 13139, at *30 (D.C. Cir. July 19, 2016) (holding one issue preserved and one waived because they were "different claims supported by different arguments"). As such, the Request for Hearing does not preserve the argument Bayer and Nichino now attempt to advance.

Our view of the Request for Hearing is confirmed by two subsequent pre-hearing filings from Bayer and Nichino. In their prehearing exchange filing, Bayer and Nichino disputed the ALJ's preliminary conclusion that "[t]he issue of whether or not the conditions of registration have been satisfied is not an issue in this proceeding," claiming that they were entitled to challenge their alleged non-compliance with the termination condition at the hearing. Prehearing Exchange of Bayer CropScience LP and Nichino America, Inc. at 2-3 ("Bayer Prehearing Ex."); s*ee also* ALJ Order Scheduling Hearing and Prehearing Procedures at 3. Significantly, Bayer and Nichino advanced a single ground as to why their satisfaction of the termination condition was at issue in the cancellation proceeding. And that ground was not based on an allegation that the Pesticide Program had not engaged in the required scientific dialogue. Rather, Bayer and Nichino argued that "the purported obligation to 'voluntarily' cancel the registrations was never triggered" "because EPA's unreasonable adverse effects determination is unsound and invalid." Bayer Prehearing Ex. at 3. In light of this challenge, they claimed the right to submit evidence rebutting the Pesticide Program's conclusions on flubendiamide's risks and benefits and demonstrating "that EPA did not undertake the multistep process *required under FIFRA* to make a determination that a registration no longer meets the Registration Standard."[34] *Id*. at 6 (emphasis

[34] Bayer and Nichino cite statements by Charlotte Sanson, Director of Registration for Bayer CropScience LP, to support their argument. Her statements indicate that Bayer was referring to a full FIFRA section 6(b) scientific review by outside parties – such as the Scientific Advisory Panel, U.S. Department of Agriculture, and growers – and not the discussions between the scientists from Bayer and the Pesticide Program required by the registration. Bayer Prehearing Ex. at 6 n.9; *see also* Sanson Statement, PBNX 116, at PBN1611-12.

added). Just as they had done in the February 5, 2016 letter and their Request for a Hearing, Bayer and Nichino made a very specific claim concerning lack of transparency but related it to an issue legally distinct from whether the Pesticide Program had engaged in the required dialogue: whether the Pesticide Program complied with the regulatory process *under FIFRA* for making an unreasonable adverse effects finding.

A second notable filing by Bayer and Nichino is their brief opposing the Pesticide Program's motion to limit the scope of testimony. In that pleading, Bayer and Nichino offered five separate arguments as to why the already-submitted risk/benefit statements should be considered as relevant to the two statutorily-designated section 6(e) issues – compliance with the conditions of registration and the Program's determination on existing stocks.[35] Strikingly, despite the fact that Bayer and Nichino's toxicology witness testified as to the Pesticide Program's lack of transparency, Bayer and Nichino did not argue that the toxicologist's testimony was admissible as relevant to the question of whether the Pesticide Program had engaged in the required dialogue. Yet, Bayer and Nichino now cite on appeal to their toxicologist's testimony alleging a lack of transparency as directly bearing on the dialogue question. BN Post-Arg. Br. at 16 n.23.

It was not until the May 10, 2016 hearing before the ALJ that counsel for Bayer and Nichino first articulated their new argument that the condition precedent to voluntary cancellation was not met, stating that "[t]he documentary and testimonial evidence shows that EPA was required to review the Flubendiamide data, and to engage in a measured scientific dialogue with Bayer and Nichino on both the data and EPA's conclusions before making the cancellation demand. The facts show that EPA did not do so." ALJ Tr. at 15. This new argument shifted away from Bayer and Nichino's previous legal objection – that due process requires that they be given the opportunity to contest the Program's underlying scientific determination – to a new objection as to whether the scientific dialogue was adequate under the terms of the registrations. Ostensibly, this tactical shift occurred

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[35] Bayer and Nichino argued that: (1) EPA conceded that risks/benefits were relevant to the existing stocks issue; (2) EPA's request to bar the evidence was contrary to the adversarial nature of the proceedings; (3) EPA's assertions on its unreasonable adverse effects determination in the proceedings undermined its efforts to keep risk/benefit information out of the hearing; (4) EPA's existing stocks policy requires the Agency to consider risks/benefits; and (5) evidence on the risks/benefits of flubendiamide was relevant to EPA's determination on existing stocks. Registrants' Opposition to Respondent's Motion to Limit Scope of Testimony at 3-12 ("Opp. Mot. to Limit").

because "[t]he Tribunal did not agree to allow the registrants to make all of [their section 6(b)] arguments" in the hearing. *Id*. at 14. On the record before us, we conclude that Bayer and Nichino's pre-hearing references to lack of transparent discussions were not simply ambiguous regarding Bayer and Nichino's potential objection that the Program had not met the registration's dialogue requirement, but rather these references affirmatively directed attention to separate and distinct legal objections to the cancellation. Bayer and Nichino do not point to any statement in the record prior to the hearing in which they provide a basis for, let alone assert with particularity, an objection on the question of whether the Pesticide Program adequately engaged in dialogue in satisfaction of the condition precedent.

(ii) *Was the Pesticide Program Prejudiced By a Lack of Notice of the Registrants' Arguments On the Scientific Dialogue Issue?*

Prejudice is a relevant factor in determining whether a claim has been waived. Indications of prejudice to a party include "unfair surprise, *i.e.*, a lack of adequate notice and opportunity to respond to the defense; the need for significant new discovery and/or trial preparation; or, the defense requires inquiry into factual issues." *In re Lazarus, Inc*., 7 E.A.D. 318, 332 (EAB 1997) (footnotes omitted); *cf. Myers v. Cent. Fla. Invs., Inc.*, 592 F.3d 1201, 1225 (11th Cir. 2010) (holding that while technical adherence to FRCP 9(c) is not always required, the denial of a condition precedent must be specific enough to give "ample notice" to the burdened party that the fulfillment of the condition is at issue in the proceeding); *Digital Ally, Inc. v. Z3 Tech, LLC*, 2010 U.S. Dist. LEXIS 103715, *12-14 (D. Kan. Sept. 30, 2010) (stating that a party failing to deny with particularity that a condition precedent has been fulfilled is precluded from subsequently raising that issue if it would "unfairly surprise or prejudice the opposing party").

The regulations direct the ALJ to "freely grant" leave for a party to amend its objections "prior to the commencement of the public hearing," and even contemplate delaying the hearing to give additional time for the parties to prepare for new arguments raised by the amended objections. 40 C.F.R. § 164.22(b). This structure clearly implies that the opportunity to amend the objections ends once the hearing commences. There is a sound reason for requiring the objections to be timely stated "clearly and concisely" before the hearing, particularly in statutorily expedited FIFRA section 6(e) proceedings: the objections serve to put the Pesticide Program on notice of the issues it must address at the hearing to fulfill its burden of going forward. Had Bayer and Nichino wished to amend their statement of

objections to include the factually-intensive legal question of whether the condition precedent was fulfilled, they should have done so prior to the hearing.[36]

Given that Bayer and Nichino chose not to amend their objections prior to the hearing, the Program lacked notice that the hearing would focus on this factually intensive inquiry. The Program was thus unfairly prejudiced because, had it received notice, it could have presented its own contrary evidence. The Pesticide Program did not learn of Bayer and Nichino's new claim until after the hearing had begun. Had the adequacy of the scientific dialogue been put directly at issue earlier, the Pesticide Program would have had the opportunity to amend the written testimony of Susan Lewis (Director of the Registration Division in the Office of Pesticide Programs), prepare testimony from other witnesses, or submit new exhibits. At oral argument, the Program specifically stated that it did not put on evidence at the hearing related to the scientific dialogue in December 2015 and January 2016, and "would have put forward the information that was given to [Bayer and Nichino] in December" had the Program been put on notice of this argument. EAB Tr. at 69, 71; *see also* Program Post-Arg. Br. at 18-19 (describing documents the Program would have included in the record had the scientific dialogue been put at issue before the hearing). By raising its claim late, Bayer and Nichino deprived the Program of the opportunity to respond.

Therefore, it is appropriate to read 40 C.F.R. § 164.22 to preclude a party from subsequently raising new objections at the hearing if it failed to deny a condition precedent with particularity as a "basis of each objection" in a manner which would give EPA ample notice of the arguments it wishes to present. We find that Bayer and Nichino did not, as a basis of any of their objections prior to the hearing, give EPA ample notice of their argument that the pre-condition to the

[36] This could have been done in the week between her May 3, 2016 Order on Respondent's Motion to Limit Scope of Testimony and the hearing on May 10. Further, Bayer and Nichino could have raised this argument in their April 26, 2016 Opposition to Respondent's Motion to Limit Scope of Testimony filed the day after the ALJ's Order on Petitioners' Motion for Accelerated Decision. They did neither. Indeed, the opposite appears to be true. *See* Req. for Hearing at 49 (admitting that a scientific dialogue between the parties occurred "[t]hroughout 2015" without any qualification). EPA has not argued that this was an admission for purposes of the pleadings, and we decline to so decide. However, we believe this sentence is the clearest statement in Bayer and Nichino's objections to the issue of scientific dialogue under the terms of the registration.

termination condition was not met due to an inadequate scientific dialogue. Thus, their argument on this issue is untimely and the Board holds that it has been waived.

b. *Bayer and Nichino Did Not Establish That the Program Failed to Comply With Its Obligations Under the Registrations*

Bayer and Nichino provided no notice that they intended to argue that the Pesticide Program's alleged failure to engage in dialogue concerning the data excused their noncompliance with the termination condition. Thus, in the proceeding before the ALJ, the Pesticide Program did not have a fair opportunity to compile record evidence and testimony on this question. However, we find that even if Bayer and Nichino's argument had not been waived, the record nonetheless demonstrates that the Pesticide Program met its burden of production to show that the requisite dialogue took place. On the other hand, Bayer and Nichino, who bear the ultimate burden of persuasion in this proceeding, offer little more than speculation to support their claim that the Pesticide Program did not engage in these discussions in good faith. Such evidence cannot meet their burden of persuasion on this point.

The flubendiamide conditional registrations contain several pre-conditions that must be satisfied before the obligation to request voluntary cancellation is triggered: (1) the Pesticide Program must "complete the review of the entire required data set and will consider any additional data and supporting information voluntarily submitted by [Bayer and Nichino] * * * by January 31, 2013; (2) scientists from the Pesticide Program and from Bayer "shall engage in dialogue about the data and the Agency's conclusions;" and (3) the Pesticide Program must "make[] a determination that further registration of [] flubendiamide * * * will result in unreasonable adverse effects on the environment." PAL, PBNX 8, at PBN0019.

Bayer and Nichino raise no significant claim that the Pesticide Program failed to review and consider their data submissions, nor do they show that the Program failed to make an unreasonable adverse effects finding as to flubendiamide. The record contains detailed review memoranda by the Program on such critical studies as the Farm Pond Monitoring Study and the Sediment-Spiked Toxicity Study. The Program even completed a short review of the Photolysis Study that Bayer and Nichino did not submit until January 5, 2016, two years after the deadline for review of the submitted data. Similarly, the Program's detailed unreasonable adverse effects finding is contained in the record, and Bayer and Nichino do not dispute that the Program executed this document. At one point prior to the evidentiary hearing, Bayer and Nichino asserted that the Program had not met its obligation to "make a determination" on unreasonable adverse effects

because that determination was substantively incorrect. Bayer Prehearing Ex. at 6. However, they have not renewed that claim on appeal.[37]

The only remaining issue regarding compliance with the pre-conditions is whether the Pesticide Program satisfied its obligation to engage in scientific dialogue with Bayer prior to making the unreasonable adverse effects determination. Bayer and Nichino first assert that no meaningful dialogue occurred. Second, they claim that even if the Program did hold discussions on some issues, it did not engage in dialogue on critical subjects covered under the phrase "the data and the Agency's conclusions." Below, we first consider what subjects the Program was required to discuss with Bayer and Nichino, and then we turn to the question of whether adequate scientific dialogue on those subjects occurred.

(i) *What is Meant by the Phrase "the Data and the Agency's Conclusions"?*

Bayer and Nichino argue that the requirement to engage in dialogue about "the data and the Agency's conclusions" includes every Pesticide Program decision related to the flubendiamide data up through the Program's determination that flubendiamide poses unreasonable adverse effects to the environment. The Pesticide Program contends that it was obligated to discuss its characterizations of flubendiamide risk with the Bayer scientists but not the "intermediate conclusions" underlying its risk characterizations nor its ultimate conclusion regarding unreasonable adverse effects. Critically, Bayer and Nichino disagree with the Program as to whether the Program was required to "engage in dialogue" about the toxic endpoints it selected to assess overall risk. Bayer and Nichino argue that the Program was required to engage in dialogue concerning the toxic endpoints while the Program argues that its selection of endpoints was part of the intermediate analytical process and therefore was not covered by the engage in dialogue requirement. We disagree in part with both sides.

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[37] Bayer and Nichino's pre-hearing argument that the termination condition contemplated that they could substantively dispute the Pesticide Program's unreasonable adverse effects determination in a section 6(e) hearing is inconsistent with the language in the termination condition that simply specifies that a determination be made. In addition, Bayer and Nichino's argument conflicts with both Bayer and Nichino's interpretation of the termination condition as a "fast death" provision, and Bayer and Nichino' primary contention on appeal – that the termination condition was "devis[ed]" by the Program "to ensure that EPA's 'unreasonable adverse effects' determination is not subject to *any* outside review or challenge." BN Post-Arg. Br. at 1.

When the requirement to engage in dialogue on the "data and the Agency's conclusions" is viewed in isolation, the scope of the requirement is not immediately apparent. However, when read in the context of the overall conditions of registration, the scope of "data and the Agency's conclusions" is more clearly delineated. Thus, we begin there.

The termination condition and the pre-conditions are contained in paragraphs 6 and 8 of the Preliminary Acceptance Letter, which serves as the basis for the terms of registration. PAL, PBNX 8, at PBN0018-19. The two paragraphs are substantively identical, except that paragraph 6 applies to Nichino and paragraph 8 applies to Bayer. *See id*. Each paragraph is divided into four subparts, which prescribe a series of steps that the parties must take, with each step having its own deadline. *Id*. We analyze these subparts in order.

Subpart (a) pertains to data submission. It requires Bayer and Nichino to submit all the data required by the registrations on or before July 31, 2012. PAL, PBNX 8, at PBN0018-19 ¶¶ 6(a), 8(a). Subpart (b) establishes two critical pre-conditions to the termination condition. First, the Pesticide Program must complete its data review within six months of the deadline for submission of the data (i.e., by January 31, 2013); and, second, scientists from the Program and from Bayer must engage in dialogue concerning the data and the Pesticide Program's conclusions:

> 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 * * * by January 31, 2013. EPA scientists and Bayer scientists shall engage in dialogue about the data and the Agency's conclusions.

*Id*. at PBN0019 ¶ 8(b); *see also id*. ¶ 6(b) (applicable to Nichino).

Subpart (c) describes the three options available to the Pesticide Program following the data review and dialogue required by subpart (b). The Program was directed to either, (1) grant general registration to the flubendiamide products, (2) agree with Bayer and Nichino regarding the terms for continued or revised conditional registration for the products, or (3) terminate the registrations by accepting voluntary cancellation by Bayer and Nichino. *Id*. ¶ 8(c); *see also id*. ¶ 6(c) (applicable to Nichino). The Program was to choose between these options by September 1, 2013.

The termination condition appears in subpart (d). Expanding on the last provision of subpart (c), the language in subpart (d) specifies that if the Program – "after [its] review of the data as set forth in [subpart] (b) above" – determines that continued registration of the flubendiamide products will result in unreasonable

adverse effects, Bayer and Nichino must request voluntary cancellation. *Id*. ¶ 8(d) (emphasis added); *see also id*. ¶ 6(d) (applicable to Nichino). Subpart (d) also provides that the termination condition will not take effect before September 1, 2013.

Both sides have confirmed our reading that the subparts of paragraphs 6 and 8 apply in sequential order. As Bayer and Nichino note, the subparts are intended to "follow[] in natural chronological order, requiring Registrants to submit the data, EPA to review it, the scientists to engage in the required dialogue, and EPA to then make and implement its registration or cancellation determination." App. Br. at 18; *accord* Resp. Br. at 1 ("If, after reviewing the relevant data, EPA were to make a determination that the Registrants' products cause unreasonable adverse effects, Registrants were required to request voluntary cancellation pursuant to FIFRA section 6(f)."). Thus, the Pesticide Program's data review and the scientific dialogue must occur before the Program can make a determination regarding unreasonable adverse effects. If the Program thereafter determines that continued registration of the products will result in unreasonable adverse effects, Bayer and Nichino must, within one week, request voluntary cancellation.

Bayer and Nichino's contention that "the Agency's conclusions," as set forth in subpart (b), include the Program's determination on unreasonable adverse effects, as set forth in subpart (d), is precluded by its own interpretation that the subparts establish chronological steps to resolve uncertainties associated with the conditional registrations. If subpart (b) – requiring data review and dialogue – precedes subparts (c) and (d) – specifying the Program's ultimate decisional options and the termination procedure for the registrations – then the dialogue required by subpart (b) definitionally cannot include the unreasonable adverse effects finding required in the termination condition. As Bayer and Nichino phrased it, the Pesticide Program is to review the submitted data and engage in dialogue with the scientists, and the Program is "then" required to "make and implement its registration or cancellation determination." App. Br. at 18. This interpretation is confirmed by the language in subpart (d), which directs that the Pesticide Program's unreasonable adverse effects determination is not to be made until "after EPA's review of the data as set forth in [subpart](b)." PAL, PBNX 8, at PBN0018-19.

During the negotiations, the Bayer representative expressed the same view: "a fair cancellation demand can only occur *after the conditions of part [subpart](b) have been met*, specifically, that all the submitted data have been reviewed alongside all voluntary data submitted by Bayer, plus following a measured dialogue between the scientists." *Negotiation E-mails*, RE 4, at RE036 (emphasis added). Moreover, excluding the unreasonable adverse effects determination from

a dialogue between *scientists* about data and the Agency's conclusions makes sense in that a scientific dialogue is clearly appropriate on conclusions regarding scientific data but much less appropriate on an unreasonable adverse effects determination. That determination involves a balancing of multiple considerations addressing matters other than just scientific data. *See* FIFRA § 2(bb), 7 U.S.C. § 136(bb); *see also* William H. Rodgers, Jr., *Environmental Law: Pesticides and Toxic Substances* § 5.8 (1988).[38]

Bayer and Nichino dispute this conclusion, arguing that subpart (d) requires "that EPA disclose and discuss its ultimate unreasonable adverse effects determination before demanding voluntary cancellation." BN Post-Arg. Br. at 9. However, the registration terms do not refer to or require a cancellation demand that is separate and distinct from the unreasonable adverse effects determination. As the registrations state, "[i]f * * * the Agency makes a determination that further registration of [flubendiamide] will result in unreasonable adverse effects on the environment, within one (1) week of *this finding*, * * * [Bayer and Nichino] will submit a request for voluntary cancellation." PAL, PBNX 8, at PBN0019 ¶¶ 6(d), 8(d) (emphasis added). Thus, the unreasonable adverse effects determination itself serves as the trigger for the one-week deadline for Bayer and Nichino to submit voluntary cancellation requests. We agree with Bayer and Nichino that the dialogue requirement is a condition precedent to the triggering event for the termination condition. But because the triggering event is the unreasonable adverse effects

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[38] The Senate Committee on Agriculture and Forestry described the scope of the unreasonable adverse effects judgment in this fashion:

> [T]he balancing of benefit against risk is supposed to take every relevant factor that the Administrator can conceive of into account. * * * [The Administrator] must consider hazards to farmworkers, hazards to birds and animals and children yet unborn. He must consider the need for food and clothing and forest products, forest and grassland cover to keep the rain where it falls, prevent floods, provide clear water. He must consider aesthetic values, the beauty and inspiration of nature, the comfort and health of man. All these factors he must consider, giving each its due. No one should be given undue consideration, no one should be singled out for special attention, no one should be considered a 'vital' criterion.

S. Rep. No. 92-838, at 10 (1972) (Supp. Rep.).

determination, the dialogue requirement as a condition precedent cannot include that determination.

At the same time, we find untenable the Pesticide Program's claim that the underlying "intermediate conclusions" leading up to its characterization of flubendiamide risk are excluded from the term "conclusion." As support for its claim, the Pesticide Program cites its use of the term "conclusion" in a Program guidance document and in the Program's flubendiamide risk assessment memoranda. Resp. Br. at 10. But none of these documents defines the term "conclusion" or suggests that it is a term of art that differentiates between a hierarchy of different scientific conclusions in the risk assessment process. Even more problematically for the Program, the sections in the 2008 flubendiamide risk assessment it cites as listing conclusions do not simply include risk characterization conclusions. To the contrary, those sections contain dozens of conclusions on everything from the "main routes of degradation for flubendiamide" to the NOAEC and LOAEC values for flubendiamide and des-iodo from several different studies involving different test subjects, exposure durations, and test environments. *New Registration Risk Assessment*, PBNX 27, at PBN0464-67.

Three contextual factors inform our consideration of what topics must be discussed under the requirement to engage in dialogue about the data and the Program's conclusions. First, the dialogue must be between scientists, so it follows that the matters to be discussed should be scientific ones. Second, subpart (b), in which the dialogue requirement appears, is focused on data, and the data referred to in the Preliminary Acceptance Letter are all scientific studies. Finally, the data required by the conditional registrations are intended to resolve uncertainties as to the risk posed by flubendiamide so that the Pesticide Program can determine what option to pursue under the terms of the registration (that is, whether to convert the conditional registrations to general registrations, extend the conditional registrations, or make an unreasonable adverse effects determination triggering the termination condition). With this context in mind, we interpret the phrase "the data and the Agency's conclusions" as defining and limiting the scope of the required dialogue to: (1) the validity and results of the scientific studies submitted; and (2) the Program's conclusions regarding the proper use of the results in assessing flubendiamide risk.

Applying this interpretation to the two studies at the center of this dispute – the Farm Pond Monitoring Study and the Sediment-Spiked Toxicity Study – we reach the following conclusions. For the Farm Pond Monitoring Study, a dialogue was required concerning the validity and results of the Study, as well as on what those results suggested as to the reasonableness of the modeling estimates of

flubendiamide exposure. After all, the Farm Pond Monitoring Study was required to provide information that "would address the uncertainty associated with current model limitations." PAL, PBNX 8, at PBN0018. For the Sediment-Spiked Toxicity Study, a dialogue was required concerning the validity of the Study, identification of NOAECs and LOAECs from the Study, and the Program's conclusions on whether the identified NOAECs should be used as toxic endpoints in assessing risk. All of these matters are scientific in nature, focused on an analysis of scientific studies, and essential elements bearing on the assessment of flubendiamide risk.

(ii) *Did the Pesticide Program "Engage in Dialogue" with Bayer and Nichino on the Data and the Program's Conclusions?*

Nowhere in the Preliminary Acceptance Letter do the parties define what they mean by "engage in dialogue," and there is no controlling legal standard for what constitutes a "dialogue." The dictionary definition is "a conversation between two or more persons" or "an exchange of ideas and opinions" or "a discussion between representatives of parties to a conflict that is aimed at resolution." *Merriam-Webster's Collegiate Dictionary* 319 (10th ed. 1999). Further, in the negotiations over the termination condition, Bayer and Nichino indicated that they sought a "measured" dialogue. The Pesticide Program does not object to that characterization, and both sides have interpreted the provision to mean that the parties must engage in a good-faith, scientific discussion of the data and the Program's conclusions. ALJ Tr. at 51 (testimony of S. Lewis), 105 (testimony of C. Sanson).

Significantly, neither the July 28, 2008 Clive Halder email nor anything else in the record concerning the negotiation of the terms of registration suggests that the parties' agreement to engage in dialogue means that they agreed to reach consensus concerning interpreting the data. *See Negotiation E-mails*, RE 4, at RE020-065. Nor is there any indication that the Pesticide Program agreed to defer to Bayer and Nichino's interpretations. While Bayer and Nichino bargained for the right to engage in dialogue with the Agency, the Pesticide Program never relinquished the ultimate authority granted to it under FIFRA to decide what the data mean and to determine whether the conditional registration of the flubendiamide products should continue. Further, the dialogue could have been oral or written. While the term "dialogue" most commonly refers to an oral conversation, in the context of a debate on scientific matters, a scientific dialogue could plausibly refer to either a face-to-face meeting or an exchange of views in writing. Finally, the requirement to engage in dialogue does not require an iterative process. A dialogue could take place in a single meeting in which there is a good

faith back-and-forth discussion. Thus, for purposes of this appeal, the Board considers a dialogue to have occurred if the parties engaged in a good-faith, scientific discussion of the data and the Program's conclusions concerning those data, whether that discussion occurred orally or in writing, whether that discussion occurred at a single meeting or in a single exchange of written comments, and even if no consensus regarding the meaning of the data or the Pesticide Program's conclusions was reached.

The record extensively documents that the Pesticide Program participated in such a dialogue concerning the Farm Pond Monitoring Study, which was the critical study on flubendiamide and des-iodo accumulation. After Bayer and Nichino submitted that Study in December 2014, EPA conducted a detailed review in February 2015 and provided a copy of the review document to the registrants. *Farm Pond Monitoring Study Review*, PBNX 35, at PBN0976. Bayer and Nichino provided two separate sets of comments on that document in June 2015. The Pesticide Program responded to both sets of comments in writing in July 2015. Moreover, the dialogue did not stop there. As Bayer and Nichino concede, discussions with the Pesticide Program continued up until December 2015 concerning "potential mitigation to address EPA's conservative risk assessment."[39] Post-Hearing Brief of Bayer CropScience and Nichino America, Inc. at 3. By late 2015, the scientists were "a bit at loggerheads," apparently on the issue of the persistence of flubendiamide's degradates, ALJ Tr. at 151 (testimony of J. Johnson). However, the registration terms do not require consensus, only a good-faith exchange of views by the parties.

The record does not show as lengthy a dialogue between the Pesticide Program and Bayer and Nichino on the Sediment-Spiked Toxicity Study. Bayer and Nichino submitted that study on their own initiative in 2010, and EPA completed its review of the study in July 2011. However, it was not until December 16, 2015, that the Pesticide Program's use of the Study became a matter of debate. Apparently, Bayer and Nichino assumed that the Program's decision, in the February 2015 review of the Farm Pond Monitoring Study, to use "the registrant-calculated endpoints to avoid diverting focus from the issues the Agency has with the submitted [Farm Pond Monitoring Study] and aquatic exposure

[39] There is nothing in the record to indicate that the Pesticide Program engaged in a dialogue with Bayer and Nichino concerning the Photolysis Study. However, no dialogue was required on this Study given that it was submitted on January 5, 2016, long after the applicable deadline. The Pesticide Program went well beyond what the registration required by reviewing this Study and taking its results into account in its risk assessment.

reports" meant that the Program had decided to use Bayer and Nichino's suggested endpoints for all purposes, even though the Program had used lower endpoints previously. *See Farm Pond Monitoring Study Review*, PBNX 35, at PBN0992. Bayer and Nichino learned that the Program was using the toxic endpoints derived from the Water-Spiked Toxicity Study on December 16, 2015, and immediately protested. Essentially, discussions on toxic endpoint selection for benthic invertebrates began on that date. Accordingly, we have focused on the six-week period between December 16, 2015, and January 29, 2016, when the Program issued its unreasonable adverse effects finding, to determine whether the required dialogue on toxic endpoints occurred. For the reasons discussed below, the Board concludes that the Pesticide Program has met its burden of going forward to show that it engaged in a good faith dialogue with Bayer and Nichino scientists on the toxic endpoint issue raised by the Sediment-spiked Toxicity Study during those six weeks.

The Pesticide Program took several actions between December 16, 2015, and January 29, 2016, to engage in dialogue on its decision to rely on the lower NOAECs from the Water-Spiked Toxicity Study as toxic endpoints rather than the higher NOAECs from the Sediment-Spiked Toxicity Study. First, after Bayer's Vice President protested the Pesticide Program's decision to rely on the 0.28 µg/L NOAEC for sediment pore water in the Water-Spiked Toxicity Study as a toxic endpoint, the Program extended the expiration date of the registrations not once, but twice, first to January 15, 2016, and then to January 29, 2016. Second, in response to a request from Bayer's Vice President, the Pesticide Program provided its risk analysis using the lower toxic endpoint to Bayer and Nichino. *Assessment Addendum*, PBNX 31, at PBN0861; Sanson Statement, PBNX 116, at PBN1609 (noting that following the Bayer email to the Assistant Administrator on December 16, 2015, "registrants intensively reviewed the information provided by EPA over the holidays" prior to the January 6, 2016 meeting). Third, the Pesticide Program scheduled and participated in an all-day meeting with Bayer and Nichino on January 6, 2016. Sanson Statement, PBNX 116, at PBN1609. The morning portion of the meeting was devoted to scientific issues, and the afternoon to regulatory issues. ALJ Tr. at 91 (testimony of S. Lewis). Scientists from both the Pesticide Program and Bayer and Nichino were present for the morning session. *Id*. at 92. Bayer and Nichino admit these discussions occurred. *See* Req. for Hearing at 26. According to Bayer's Director of Registrations, "[a]t the January 6 meeting, EPA presented its scientific position, relying on the lower toxicity endpoint and theoretical modeling to support its position that flubendiamide is accumulating or

will accumulate in vulnerable water bodies above a level of concern."[40] Sanson Statement, PBNX 116, at PBN1609. This record evidence more than carries the Pesticide Program's burden of going forward to show that a good faith dialogue on the toxic endpoint for des-iodo occurred.

In an attempt to rebut this evidence, Bayer and Nichino claim that both the Assistant Administrator and the Pesticide Program regulatory staff and scientists maneuvered "to shield [their critical positions and conclusions] from review and challenge [by Bayer and Nichino] until after a [cancellation] decision was reached." App. Br. at 20. According to Bayer and Nichino, during the fall of 2015, "EPA shifted its focus and began pursuing cancellation from a political level with the Agency, including the Assistant Administrator." *Id.* At that point, Bayer and Nichino claim, "good faith back and forth dialogue * * * seemed to stop." *Id.* But Bayer and Nichino go further than alleging that the Pesticide Program simply stopped communicating with them. They allege that staff from the Pesticide Program "affirmatively withheld" their decision to return to the original, lower toxic endpoint for des-iodo and manipulated the timing and sequence of meetings with the Assistant Administrator, "so that EPA's scientists could brief the Assistant Administrator and obtain approval for cancellation based on the new endpoint [level] before Registrants had a chance to review and challenge EPA's positions." *Id.* at 22.

Bayer and Nichino, however, cite little record evidence to support such allegations. Principally, Bayer and Nichino rely on, (1) testimony by Ms. Sanson that the Pesticide Program's Registration Division Director stated at the January 6th meeting that it was "unfortunate" Bayer and Nichino were not informed earlier of the revision of the endpoint level, and that the decision on cancellation would be made at "a very high level" at the Agency; App. Br. at 20, and (2) speculation by

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[40] Bayer and Nichino's witnesses presented no other testimony as to what took place at the January 6, 2016 meeting regarding the toxic endpoint dispute. Mr. Jeffrey Johnson, Nichino's Chief Executive Officer, testified that at the time of the December 15th and January 6th meetings the scientists were "a bit at loggerheads" and that the "talks broke down." ALJ Tr. at 151 (testimony of J. Johnson). But the Pesticide Program scientists were under no obligation to reach consensus, they were merely required to engage in dialogue. Further, Mr. Johnson stated that the talks broke down because "some of the most relevant points in terms of the degradates and their persistence, or potential persistence were being ignored." *Id.* Thus, Mr. Johnson's testimony does not even address the toxic endpoint issue, which Bayer and Nichino focus on in support of their contention that a dialogue did not take place.

Ms. Sanson and Mr. Johnson that the Pesticide Program's decision to cancel flubendiamide was political, not scientific. ALJ Tr. at 127 (testimony of C. Sanson), 186-87 (testimony of J. Johnson). But a statement that it was "unfortunate" that information was not provided earlier to Bayer and Nichino does not show that the Program affirmatively acted to deprive them of the opportunity for dialogue. Further, it is fully appropriate that major decisions – such as whether to cancel a pesticide registration – be made by high-level, politically-appointed figures at EPA. That a political appointee is the one to make the decision does not mean that such a decision is made on "political" considerations instead of appropriate legal, policy, and scientific ones. If that were true, individuals appointed to run the EPA would be barred from doing the very jobs that they are charged by law with performing. *See* U.S. EPA Delegation of Authority 5-7, *Cancellation and Suspension* (May 11, 1994). Statements by Ms. Sanson and Mr. Johnson that the Program's cancellation decision was "political" appear to be nothing more than unsupported speculation.

More importantly, Bayer and Nichino fail to take into account the Pesticide Program's response following their December 16, 2015 protest that they had not been informed about the Pesticide Program's decision to use the lower endpoint level. In reaction to Bayer and Nichino's protest, the Pesticide Program extended the expiration date for the conditional registrations, provided Bayer and Nichino with the its latest risk analyses, and scheduled and participated in an all-day meeting to discuss science and regulatory issues.[41]

Moreover, our examination of the record indicates that the Pesticide Program continued to take seriously Bayer and Nichino's communications on

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[41] Bayer and Nichino contend that the Pesticide Program did not engage in dialogue on its toxic endpoint selection at the January 6, 2016 meeting but instead stated that it intended to rely on a "'suite' of toxicological endpoints." BN Post-Arg. Br. at 14. Although Bayer and Nichino cited no record evidence for this assertion, it appears reasonable given that the Program's unreasonable adverse effects determination indicates that the Program considered the NOAECs for the overlying water and the sediment pore water from the Water-Spiked Toxicity Study and the same NOAECs from the Sediment-Spiked Toxicity Study in evaluating flubendiamide risk. *Cancellation Decision Memo*, PBNX 30, at PBN0850; *Assessment Addendum*, PBNX 31, PBN0862, 0866-69. But a statement about relying on a "suite of endpoints" does not mean that a scientific dialogue did not occur. From Bayer and Nichino's point of view, the effect should have been the opposite. If Bayer and Nichino objected to any of the possible endpoints in that suite, the Program's statement gave them the opportunity to open a dialogue on the question.

science and risk assessment issues right up until it made its January 29, 2016 unreasonable adverse effects determination. Three events stand out. First, the Pesticide Program reviewed and considered Bayer and Nichino's Photolysis Study, even though that study was not submitted until January 5, 2016. Given that the registrations already had been extended four times by that point and the deadline for submission of data was long past, the Program had no obligation to consider these data at all. Second, Bayer and Nichino submitted a new mitigation proposal on January 8, 2016, and as a result, the Program extended the expiration date in the conditional registrations for two weeks so it could consider the proposal. Letter from Richard Gebken, Product Manager, Registration Division, U.S. EPA, to Nancy Delaney, Regulatory Manager, Authorized Agent for Nichino America, Inc., Bayer CropScience LP, PBNX 16, at PBN0095 (Jan. 14, 2016); *see also Assessment Addendum*, PBNX 31, at PBN0863. Finally, in its final risk assessment on flubendiamide, the Pesticide Program took several steps to respond to data submitted by Bayer and Nichino and arguments made by their scientists: (1) the Pesticide Program adjusted its exposure model to take into account Bayer and Nichino's arguments that the model did not reflect overflow events revealed in the monitoring study; (2) the Pesticide Program incorporated the results of the Photolysis Study into its model, despite significant concerns that the study overstated degradation rates and the fact that the study was not submitted until January 5, 2016; and (3) the Pesticide Program used the NOAECs from both the Water-Spiked Toxicity Study and the Sediment-Spiked Toxicity Study in assessing flubendiamide's risk to benthic aquatic invertebrates.[42] *Assessment Addendum*,

[42] Bayer and Nichino claim that the Program relied solely on the 0.28 μg/L NOAEC for sediment pore water in reaching its unreasonable adverse effects determination. BN Post-Arg. Br. at 12. The record does not support that claim. The memorandum containing the Program's unreasonable adverse effects finding states that the Program considered both the endpoints derived from the Water-Spiked Toxicity Study as well as the "registrant-suggested" endpoints from the Sediment-Spiked Toxicity Study. *Assessment Addendum*, PBNX 31, at PBN0866-69. Moreover, the page that Bayer and Nichino identified in oral argument also contradicts their claim. *See* EAB Tr. at 38. That page contains four graphs plotting des-iodo exposure over a 30-year period compared to a toxic endpoint level. *Assessment Addendum*, PBNX 31, at PBN0903, app. 3, fig.1. Each graph uses a different endpoint: (1) the NOAEC for overlying water from the Water-Spiked Toxicity Study (1.89 μg/L); (2) the NOAEC for sediment pore water from that Study (0.28 μg/L); (3) the NOAEC for overlying water from the Sediment-Spiked Toxicity Study (4.0 μg/L); or (4) the NOAEC for sediment pore water from that Study (19.5 μg/L). *Id.* Three out of the four graphs show des-iodo exposure exceeding the toxic endpoint at some point in the 30-year span.

PBNX 31, at PBN0866-69. The Program took into account Bayer and Nichino's science and risk assessment positions when examining the current registered crops for flubendiamide, Bayer and Nichino's thirteen crops/crop groups mitigation proposal from December 2015, Bayer and Nichino's January 8, 2016 tree-nut mitigation proposal, and a mitigation proposal devised by the Pesticide Program that produced the lowest flubendiamide exposure conceivable. *Id*. Each of these scenarios was examined at an application frequency as low as once per year. *Id*.

Bayer and Nichino also argue that the Pesticide Program failed to engage in the required dialogue on three specific conclusions because the Program did not provide those conclusions to Bayer and Nichino until it released its determination that flubendiamide causes unreasonable adverse effects on January 29, 2016. Bayer and Nichino describe these conclusions as: (1) the unreasonable adverse effects determination itself; (2) risk characterizations based on "revised and new modeling scenarios;" and (3) the decision to rely on the 0.28 μg/L NOAEC from the Water-Spiked Toxicity Study as the toxic endpoint. BN Post-Arg. Br. at 11-12. We disagree.

As to the unreasonable adverse effects determination, as discussed earlier, we have concluded that the registration terms do not require the Program to discuss its ultimate finding regarding unreasonable adverse effects with the Bayer scientists because that finding is not encompassed by the requirement that the Program must "engage in dialogue" about the data and the Program's conclusions. *See* Part V.B.1.b.(i), above. The Pesticide Program's extensive discussions with Bayer and Nichino concerning the submitted data and the Pesticide Program's risk analysis based on that data were sufficient to satisfy the Pesticide Program's obligation under subpart (b) of the conditional registrations. Having fulfilled subpart (b), the Pesticide Program could make an unreasonable adverse effects determination without further consultation with Bayer and Nichino.

We also conclude that the Program was not obligated to engage in a scientific dialogue on new or revised modeling scenarios included in the January 29, 2016 unreasonable adverse effects determination memorandum. First, at the January 6, 2016 meeting, the Program presented its risk estimates on the latest mitigation scenario provided by Bayer and Nichino. That day-long meeting provided an adequate opportunity for dialogue on the Program's latest risk assessments. The principal new scenario examined in the January 29, 2016 memorandum was a mitigation scenario that Bayer and Nichino did not submit until

January 8, 2016.[43] Mitigation scenarios are regulatory proposals, not "data" to be reviewed by scientists, and thus are not covered by the dialogue requirement. Moreover, even if treated as such, the tree-nut mitigation proposal was submitted much too late to trigger subpart (b) review and dialogue requirements. PAL, PBNX 8, at PBN0018-19 (establishing July 31, 2012, as the deadline for submitting required data and requiring the Pesticide Program to review all required data and "consider any additional data and supporting information voluntarily submitted" by January 31, 2013). Other revisions to the January 29, 2016 risk assessments were based on data Bayer and Nichino submitted well after any deadline contained in the conditional registrations for data submission (Photolysis Study submitted on January 5, 2016) or adjustments resulting from a prior scientific dialogue with Bayer and Nichino scientists on earlier submitted data (adjustments to the water exposure model based on comments from Bayer and Nichino on the Program's review of the Farm Pond Monitoring Study).

The record contradicts the assertion by Bayer and Nichino that the Pesticide Program's decision to rely on the 0.28 μg/L NOAEC from the Water-Spiked Toxicity Study as a toxic endpoint was a "new" conclusion in the January 29, 2016 memorandum. In a December 16, 2015 email to the Assistant Administrator of EPA's Office of Chemical Substances and Pollution Prevention, Bayer's Vice President of North American Regulatory Affairs protested the Program's use of this NOAEC as a toxic endpoint. Sargent E-mail, PBNX 14, at PBN0092. That protest led the Program to extend the conditional registrations and to schedule the January 6, 2016 science/regulatory meeting with Bayer and Nichino. To the extent Bayer and Nichino were concerned with the Program's reliance on that NOAEC, they were given the opportunity on January 6, 2016, to make their views known.

In sum, Bayer and Nichino have not carried their burden of demonstrating by a preponderance of the evidence that the Pesticide Program failed to engage in a scientific dialogue on data submitted by Bayer and Nichino and the Program's conclusions. To the contrary, the record shows extensive discussions on scientific issues, including issues that were raised as late as December 16, 2015. We find that neither the language of the conditional registrations nor the record supports the

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[43] The Program also included a risk analysis of a mitigation scenario neither proposed nor approved by Bayer and Nichino that was intended to explore whether any potential mitigation proposal would reduce risks of concern. *See Assessment Addendum*, PBNX 31, at PBN0868-69. The conditional registrations did not require the Program to engage in a scientific dialogue with Bayer and Nichino concerning hypothetical mitigation proposals that Bayer and Nichino did not endorse.

claim by Bayer and Nichino that the Pesticide Program released "new conclusions" on January 29, 2016, without engaging in the required scientific dialogue.

2. *Is the Pesticide Program's Determination with Respect to the Disposition of Existing Stocks Consistent with FIFRA?*

The Pesticide Program may allow the continued sale and use of existing stocks of a pesticide canceled under FIFRA section 6(e). FIFRA § 6(e), 7 U.S.C. § 136d(e). The Program defines existing stocks as "those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the [cancellation] action." *Existing Stocks of Pesticide Products; Statement of Policy*, 56 Fed. Reg. 29,362 (June 26, 1991) ("Existing Stocks Policy" or "Policy") (also introduced in the record as PBNX 52).

For flubendiamide, the Pesticide Program made two separate determinations regarding the sale and use of existing stocks. First, the Program determined that it would be inconsistent with the purposes of FIFRA to allow the sale and distribution of flubendiamide stocks, with limited exceptions.[44] 81 Fed. Reg. at 11,560. Ms. Lewis explained that Bayer and Nichino's refusal "to comply with a specific condition of registration that was material to EPA's approval of the registration" was "inconsistent with the purposes of FIFRA" because "[c]onditions of registration and the associated commitments by registrants to fulfill those conditions are vitally important to the registration process." Written Testimony of Susan T. Lewis, RE 10, at RE109. The Pesticide Program also noted that this determination was consistent with its Existing Stocks Policy that generally recommends allowing the sale and distribution of existing stocks when a registrant violates a "general" condition of registration but not when a registrant violates a "specific" condition. 56 Fed. Reg. at 29,366. A "general" condition is defined by the Policy as a condition that "neither establishes specific data requirements nor specific dates [for data submission]" but rather "requires a registrant to submit required data when all other registrants of the similar product are required to do so." *Id*. A "specific" condition does impose specific data requirements and submission dates that are identified at the time of registration. *Id*. The Pesticide

[44] The Program would allow distribution of the products "to the extent that distribution is for purposes of returning material back up the channels of trade, for purposes of disposal, or for purposes of lawful export." *Id*.

Program concluded the termination condition was a "specific" condition.[45] 81 Fed. Reg. at 11,560.

The Pesticide Program reached the opposite conclusion regarding the use of existing stocks of "end-use flubendiamide products" that are currently in the hands of end users.[46] *Id*. The Pesticide Program explained that:

> [t]he quantity of existing stocks of these products currently in the hands of end users is expected to be sufficiently low that the costs and risks associated with collecting them for disposal would be high compared to those associated with the use of the cancelled product in accordance with its labeling.

*Id*. No party has challenged the Pesticide Program's determination on use of existing stocks by end users.

With one exception, the Board concludes that the Pesticide Program's determination regarding the sale and distribution of existing stocks is consistent with FIFRA. Adoption of the conditional registration system was deemed "imperative" by Congress to provide the Pesticide Program with "flexibility" and to alleviate the "double standard" between existing registrants and new applicants. S. Rep. No. 95-334, at 4 (1977). The Pesticide Program reasonably concluded that it would undermine Congress's purpose in establishing a conditional registration system to allow conditional registrants to knowingly violate a condition of their registrations and yet still be "reward[ed]" with a generous existing stocks provision. *Id*. We agree with the ALJ's reasoning on this point:

> [Not permitting the sale and distribution of existing stocks] is *consistent* with the purpose of FIFRA section 3, which was to allow

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[45] For similar reasons, the Pesticide Program made the same determination as to "use" of the "technical" flubendiamide product, registered to Nichino. *Id*. "Technical products," according to the Pesticide Program, "are used solely for the purpose of manufacturing other pesticide products." *Id*. Likewise, our determination below on the sale and distribution of existing flubendiamide end-use stocks applies equally to the use of existing technical flubendiamide stocks.

[46] The Program identified three insecticides as "end-use flubendiamide products": BELT SC Insecticide, VETICA Insecticide, and TOURISMO Insecticide. *See id*. The fourth Flubendiamide product – FLUBENDIAMIDE Technical – is used exclusively to manufacture the other flubendiamide products and is, therefore, not an end-use product. *Id*.

> the temporary sale of new pesticides, while the registrant stayed in compliance with conditions set under registration. The Petitioners here are intentionally out of compliance, and have no intention of coming into compliance. There is no reason to allow them to continue to sell and distribute their pesticides beyond the effective date of the cancellation.

Init. Dec. at 36.

Denying the sale and distribution of existing stocks does not wrongfully punish Bayer and Nichino for exercising their statutory rights to request a hearing on the Pesticide Program's Notice of Intent to Cancel. The Pesticide Program has denied the sale and distribution of existing stocks because of Bayer and Nichino's violation of the termination condition, not because they requested a section 6(e) cancellation hearing. Granted, Bayer and Nichino, in the circumstances of this case, could not have obtained a section 6(e) cancellation hearing without violating the termination condition. But that was a quandary of their own making. In negotiations with the Pesticide Program concerning their registrations, Bayer and Nichino agreed to a termination process – voluntary cancellation – different from the automatic expiration date initially proposed by the Pesticide Program. They clearly understood that they were agreeing to what they described as a "fast death" provision. They also should have understood that if they violated the termination provision, requesting a hearing on the notice of intent to cancel that was sure to follow would not provide a forum to challenge the lawfulness of the termination condition. As we point out above, the language of section 6(e) explicitly enumerates the only issues that may be raised at the hearing. Finally, to the extent they had doubts about the lawfulness of the termination condition, Bayer and Nichino had several options to challenge that condition, all of which they failed to exercise. In these circumstances, it was reasonable for the Pesticide Program to treat Bayer and Nichino's failure to comply with the termination condition as a deliberate violation of their registrations. Their noncompliance is inconsistent with one of the purposes of FIFRA, which is fair and efficient operation of the conditional registration system.

Bayer and Nichino also argue that the Pesticide Program's existing stocks determination is inconsistent with the Existing Stocks Policy. App. Br. at 36-37. They seize on a single parenthetical in the Policy to argue that the Pesticide Program's practice is to base its existing stocks determination on an examination of the risks and benefits of the pesticide whenever it poses significant risk concerns. We cannot agree that this is a reasonable construction of the Policy. Bayer and Nichino's interpretation renders the Policy internally inconsistent as well as in direct contradiction to section 6(e).

The parenthetical relied on by Bayer and Nichino occurs in the opening sentence of the section of the Policy that discusses the differential treatment of violations of "general" and "specific" conditions:

> Where a conditional registration is canceled *(and the Agency has not identified significant risk concerns)*, the Agency will base its existing stocks decision on the nature of any conditions that have not been met by the registrant.

56 Fed. Reg. at 29,366 (emphasis added). Bayer and Nichino argue that the parenthetical means that in any case where significant risks are identified, it is irrelevant whether a general or specific condition has been violated. Rather, Bayer and Nichino claim that the Policy dictates that the Pesticide Program must evaluate the risks and benefits in making a determination on existing stocks whenever the Pesticide Program has identified a significant risk concern. This is true, according to Bayer and Nichino, even if the sale and use of existing stocks would be barred under the Policy due to a violation of a specific condition in a conditional registration. In other words, Bayer and Nichino read the Policy as holding that a finding of significant risk compels the Pesticide Program to consider allowing the sale and use of existing stocks in circumstances where the sale and use would otherwise be barred. Bayer and Nichino, however, offer no reason for why a finding of significant risk should compel the Pesticide Program to consider allowing *more* sale and use of the pesticide. A more logical reading of the parenthetical is that it was intended to give the Pesticide Program the flexibility to deny the sale and use of existing stocks if significant risks were identified in connection with a pesticide registration canceled due to the registrant's violation of a "general" condition in the registration.

More troubling, Bayer and Nichino's interpretation of the Policy appears to violate the statute. Section 6(e) permits the Pesticide Program to allow the continued sale and use of existing stocks only if the Pesticide Program can conclude *both* that sale and use "is not inconsistent with the purposes of [FIFRA] *and* will not have unreasonable adverse effects on the environment." FIFRA § 6(e)(1), 7 U.S.C. § 136d(e)(1) (emphasis added). The Existing Stocks Policy indicates that allowing the sale and use of existing stocks is inconsistent with the purpose of FIFRA when the pesticide is canceled for violation of a specific condition in a conditional registration. Yet, Bayer and Nichino suggest that the Policy provides that even when the consistency with the purposes of FIFRA prong of the existing stocks test cannot be met, an evaluation of the unreasonable adverse effects prong alone can justify a determination allowing use of existing stocks. In effect, Bayer and Nichino's interpretation of the Policy would amend the statute to change the "and" to an "or" – allowing the Pesticide Program to permit the sale and use of

existing stocks if either sale and use is not inconsistent with FIFRA *or* it would not result in unreasonable adverse effects. We decline to construe the Policy in a manner that so directly conflicts with the statutory language.

However, we do conclude that one aspect of the Pesticide Program's existing stocks determination is not supported by the record. As proposed, the Program's prohibition on the sale and distribution of existing stocks would apply not only to Bayer and Nichino but also to retailers and distributors not affiliated with the registrants. *See* Req. for Hearing at 59-62 (objecting that the ban on the sale and distribution of flubendiamide in the Notice of Intent to Cancel applies to "all persons," including distributors and retailers). The Pesticide Program proposed to bar all sale and distribution of existing stocks based on the conclusion that, given Bayer and Nichino's violation of a specific condition of their conditional registration, such sale and distribution was not consistent with the purposes of FIFRA. But, the Program's rationale for denying the sale and distribution of existing stocks by Bayer and Nichino – because they violated the terms of their conditional registrations – has limited, if any, applicability to non-registrants. *See* Brief of Amicus Curiae Agricultural Retailers Association at 5-6 ("EPA has not alleged any conduct by pesticide distributors and retailers that warrant 'punishment,' yet its existing stocks determination would punish these companies by prohibiting their sale or distribution of flubendiamide products that they have already purchased."). At oral argument, the Program's counsel admitted there was no record evidence supporting assertions that Bayer and Nichino would benefit by allowing non-registrants to sell and distribute the stocks of flubendiamide they had already purchased. EAB Tr. at 83. Thus, the Program's rationale for denying the sale and distribution of existing stocks to non-registrants falls apart.

Instead of remanding the existing stocks determination back to the Program, our final order canceling the flubendiamide registrations modifies the Program's existing stocks determination consistent with our authority delegated from the Administrator. *See* U.S. EPA Delegation of Authority 5-7, *Cancellation and Suspension* (May 11, 1994) (reserving "final decisions following hearings" to the Board); *see also* FIFRA § 6(e)(2), 7 U.S.C. § 136d(e)(2). We amend the existing stocks determination described in the Notice of Intent to Cancel to allow distributors and retailers other than Bayer and Nichino to sell and distribute end-use flubendiamide products that have been formulated, packaged, and labeled for use and have been shipped or released into commerce to distributors on or before the date of this Final Decision and Order, until those stocks are exhausted. *See* 56 Fed. Reg. at 29,366. The Program should provide appropriate notice of this modification to affected stakeholders.

This modification is consistent with the Administrator's authority to allow the continued sale and use of existing stocks under section 6(e). The Program did not make a specific unreasonable adverse effects determination with regard to flubendiamide existing stocks based on its conclusion regarding inconsistency with the purposes of FIFRA was, alone, enough to deny the sale and distribution of such stocks. Mot. to Limit at 4-5. However, the Program did opine that if its grounds for denying existing stocks were overturned, it would not oppose the sale and distribution of existing stocks. *See id*. at 4. The Program's position was that it would not be "appropriate to further delay the cancellation of flubendiamide * * * to prepare for and litigate complicated risk-benefit issues in the context of an existing stocks determination." *Id*. Two United States Courts of Appeals decisions have approved similar pragmatic determinations on the allowance of existing stocks. *Northwest Food Processors Ass'n v. Reilly*, 886 F.2d 1075, 1080 (9th Cir. 1989) (approving a pesticide cancellation settlement allowing for sale and use of existing stocks because the "Administrator could reasonably conclude" that the settlement, even with the existing stocks provision, would result in a lower level of pesticide use than if the matter continued to be litigated); *National Coalition Against Misuse of Pesticides v. EPA*, 867 F.2d 636, 640 (D.C. Cir. 1989) (approving an "existing stocks settlement provision [that] rested principally on the notion that formal cancellation (and suspension) proceedings would allow much larger quantities of chlordane to be introduced into the environment"). While those cases involved settlements of cancellation proceedings, the principle of those holdings applies here: the Pesticide Program should not be forced to litigate over whether the pesticide poses unreasonable adverse effects if that litigation may reasonably be expected to lead to overall greater use of the pesticide than under the existing stocks determination. Here, litigation of unreasonable adverse effects could not be resolved quickly given the complexity of the scientific issues involved. Moreover, our modification of the existing stocks determination only allows sale and distribution of a subset of what the Program had already determined should reasonably be allowed to avoid a delay in a cancellation determination. Thus, we conclude that modification complies with the statute.

C. *Resolution of Challenges to Decisions by the Administrative Law Judge*

In addition to challenging the Initial Decision, Bayer and Nichino also challenge the ALJ's April 25, 2016 order denying their Motion for Accelerated Decision and her May 3, 2016 order granting the Pesticide Program's Motion to Limit. App. Br. at 1. Further, Bayer and Nichino now move the Board to reopen the hearing. Mot. to Reopen at 1. We address each of these challenges in turn.

1. *Motion for Accelerated Decision*

On April 11, 2016, Bayer and Nichino moved for an accelerated decision asking the ALJ to find unlawful and deny the Pesticide Program's proposed cancellation of the flubendiamide registrations. Mot. for Acc. Dec. at 3-4. For the same reasons we detailed in Part V.A.1 above, we conclude that the ALJ correctly ruled that this proceeding was properly brought under FIFRA section 6(e).

2. *Motion to Limit Scope of Testimony*

On April 18, 2016, before the ALJ had ruled on the Motion for Accelerated Decision, the Pesticide Program moved to limit the scope of testimony at the hearing. Mot. to Limit at 6. Specifically, the Program asked the ALJ to exclude testimony related to whether flubendiamide causes unreasonable adverse effects on the environment, reasoning that such evidence is irrelevant to the narrow scope of this FIFRA section 6(e) proceeding. *Id*. at 4-6. The Program did concede that such evidence could be relevant to a determination regarding existing stocks, but only if such determination were based upon a risk/benefit analysis or other scientific issues. *Id*. at 3. But, the Program argued that in this instance, the existing stocks determination and other scientific issues were not based on a risk/benefit analysis, so any evidence related to any unreasonable adverse effects was irrelevant. *Id*. The ALJ granted the motion on May 3, 2016, a full week before the hearing began. Order Limiting Scope at 10.

We agree with the ALJ that the excluded evidence on the risks and benefits of flubendiamide is not relevant to the Program's existing stocks determination. In this appeal, Bayer and Nichino argue that the excluded evidence is relevant to three issues: (1) their challenge to the lawfulness of the 'voluntary' cancellation provisions, (2) EPA's compliance with the provisions of the registration, and (3) EPA's determination to prohibit all sale and distribution of existing stocks of flubendiamide. App. Br. at 26-27. We have already held that the lawfulness of a condition contained in a conditional registration is outside of the scope of a FIFRA section 6(e) hearing. *See* Part V.A.2, above. We have also already held that the Program's existing stocks determination is not inconsistent with the purposes of FIFRA both because of Bayer and Nichino's willful violation of the termination condition and because the Agency's Existing Stocks Policy allows the Program to make an existing stocks determination when a registrant has violated the specific terms of its conditional registration without first evaluating the risks and benefits of the pesticide. *See* Part V.B.2, above. Nor does Bayer and Nichino's proffered risk and benefit information pertain to our decision on, and amendment of, the existing stocks determination as to retailers and distributors other than Bayer and Nichino. The Board's determination was based on a pragmatic conclusion about

overall use of flubendiamide and not on a specific evaluation of risk and benefit information. Finally, we address and deem waived Bayer and Nichino's new argument on appeal that this evidence was relevant to the scientific dialogue issue in the next section. *See* Part V.C.3, below.

Finding no error in the ALJ's Order Limiting Scope, we affirm the exclusion of all of the documents sought to be entered into the record by Bayer and Nichino as irrelevant to this narrow FIFRA 6(e) proceeding.

3. *Motion to Reopen the Hearing*

Bayer and Nichino argue that the hearing should be reopened for the limited purpose of admitting the previously excluded evidence as well as other evidence excluded by the ALJ at the hearing.[47] Mot. to Reopen at 1. Additionally, during the hearing, counsel for Bayer and Nichino moved into the record several of EPA's risk assessments, decision memoranda, and Bayer's responses to those assessments after the Program's counsel clarified that these documents were not being introduced "to go to the substantive merits, [] just to go to the agency's process" and counsel for Bayer agreed they were offered "within the judge's ruling." ALJ Tr. at 116-17.[48] Bayer and Nichino argue on appeal that the ALJ improperly used the contents of these excluded documents as a basis for her Initial Decision without the benefit of their own, contrary evidence. App. Br. at 29-30.

As an initial matter, we note that Bayer and Nichino are unable to articulate a fixed set of reasons why this evidence is admissible.[49] Indeed, for the first time, Bayer and Nichino now argue on appeal that the excluded evidence is relevant to

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[47] The excluded evidence includes PBNX 37-51, 80-115, and 119-22, as well as portions of the admitted Verified Witness Statements of C. Sanson, L. Hall, and J. Johnson. Offer of Proof at 2-3. The ALJ also excluded PBNX 124-126, pertaining to the *Reckitt* administrative proceedings in 2013, as irrelevant to the flubendiamide cancellation proceedings after Bayer and Nichino offered them during cross-examination of Ms. Lewis. ALJ Tr. at 63-64.

[48] These exhibits were PBNX 22-25, 27-32, and 34-36.

[49] In the span of less than two months, Bayer and Nichino offered five reasons for admissibility of this evidence in their Opposition to the Motion to Limit filed on April 26, five different reasons in their Offer of Proof filed on May 19, three reasons in their Appeal Brief filed on June 13, and five reasons (with a possible sixth) in their Motion to Reopen filed on the same day. Opp. Mot. to Limit at 3-8; Offer of Proof at 3; App. Br. at 26-27; Mot. to Reopen at 2.

the question of whether the parties engaged in scientific dialogue before the Program issued its unreasonable adverse effects determination.[50] *See* App. Br. at 25. We rule that this issue is waived, as Bayer and Nichino cannot point to any place in the record where they raised this issue below. *See In re Martex Farms, S.E.*, 13 E.A.D. 464, 478 (EAB 2008) ("We have consistently held that arguments raised for the first time on appeal are deemed to have been waived."); *see also Mingo Logan Coal Co. v. EPA*, No. 14-5305, 2016 U.S. App. LEXIS 13139, at *31 (D.C. Cir. July 19, 2016) (declining to consider the company's claim made "for the first time on appeal").

Bayer and Nichino also challenge the ALJ's exclusion of three documents from a prior administrative proceeding in *Reckitt* to show that the Program recently sought to cancel other conditional registrations through a full FIFRA section 6(b) proceeding. App. Br. at 11-12; *see also* PBNX 124-26. The ALJ was correct in determining that this proffered evidence should be excluded from the FIFRA section 6(e) hearing on the flubendiamide registrations. As stated earlier in Part V.A.1 above, if the Program has not determined that any of the conditions of a conditional registration have been violated, it may still initiate a 6(b) cancellation proceeding if it believes that the pesticide causes unreasonable adverse effects on the environment. Bayer and Nichino intended the excluded evidence to show that the Program proposed to cancel all of Reckitt Benckiser's registrations, even six conditional registrations, under FIFRA section 6(b) due to the 2008 Risk Mitigation Decision for Ten Rodenticides. App. Br. at 12. Tellingly, Bayer and Nichino make no effort to relate the conditions in Reckitt Benckiser's conditional registrations to those in the flubendiamide registrations, nor does any of the excluded evidence show that Reckitt Benckiser violated a condition of its registration as Bayer and

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[50] Of the five arguments that Bayer and Nichino made in opposition to the Motion to Limit, they did not argue that the evidence was relevant to the sequence of events required by the registration. *See* notes 35-36, above, and accompanying text. Nor did Bayer and Nichino preserve this argument for the record in their Offer of Proof to the ALJ. There, they argued that the excluded evidence is relevant to five issues: (1) the "substantive merits" of EPA's cancellation decision and whether it is consistent with FIFRA's Registration Standard; (2) the merits of EPA's existing stocks determination for flubendiamide; (3) the claim that the termination condition was unlawful; (4) the consequences of the cancellation determination and existing stocks determination; and (5) as a response to substantive statements throughout the record on the risks/benefits of flubendiamide. Offer of Proof at 3. Conspicuously absent from these filings is any argument that the evidence is relevant to EPA's compliance with the terms of the registration.

Nichino did here. *See id*. (admitting that these documents are only relevant to the "scope and nature of EPA's authority" and to "facts that the ALJ found relevant and cited in support of the ruling finding EPA's cancellation approach lawful").

We have already ruled that a determination on the lawfulness of a condition in a conditional registration is outside the scope of this FIFRA section 6(e) proceeding. Given the statutory structure of FIFRA section 6, we are not persuaded by the argument that how the Program chooses to proceed in one case under one unique set of circumstances binds it in another case under a completely different set of circumstances. Indeed, the proffered evidence appears to lend credence to our interpretation of the interplay between FIFRA sections 6(b) and 6(e). Under this lens, the excluded evidence should have been admitted only if it was deemed relevant to at least one of the two issues in this FIFRA section 6(e) proceeding. On examination, the *Reckitt* evidence has no bearing on the flubendiamide existing stocks determination, and the documents are irrelevant and immaterial as to whether Bayer and Nichino complied with the conditions of *their own* registrations. *See* FIFRA § 6(e)(2), 7 U.S.C. § 136d(e)(2) (limiting the issues at the hearing to only whether "the registrant" has failed to initiate and pursue appropriate action toward fulfilling a condition and the Agency's existing stocks determination).

Additionally, Bayer and Nichino attack the ALJ, and thus the Initial Decision, for "backtrack[ing] on her commitment not to entertain arguments regarding the merits of EPA's scientific decision-making * * *." App. Br. at 29. As support for this assertion, they accuse her of "uncritically recit[ing] in substantive detail EPA's analysis and conclusions with respect to flubendiamide's risks." *Id*. However, in each of the cited instances, the ALJ used these documents for their offered purpose: "to go to the agency's process." *See* ALJ Tr. at 116. Such use was thus "within the judge's ruling," and was not improper. Had Bayer and Nichino been concerned with the content of these documents being "recited" or "described," they should not have offered the documents into the record through their own witness. *See id*. at 116-17 (exchange and admission of documents during testimony of C. Sanson). Bayer and Nichino do not specify in any concrete way where a recitation of the facts contained in the risk analyses and decision documents altered the ALJ's Initial Decision or prior orders on the two issues allowed at the hearing by the statutory language of FIFRA section 6(e).

For these reasons, we hereby deny Bayer and Nichino's Motion to Reopen the Hearing for the purpose of including in the record documents that were previously excluded.

## VI. *FINDINGS OF FACT AND CONCLUSIONS OF LAW*

In accordance with FIFRA section 6(d), 7 U.S.C. § 136d(d), the Board sets forth the following findings of fact and conclusions of law upon which this order is based:

1. The Pesticide Program registered the following pesticide products, each containing the active ingredient flubendiamide, under special circumstances pursuant to FIFRA section 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C): BELT SC Insecticide (EPA Reg. No. 264-1025), FLUBENDIAMIDE Technical (EPA Reg. No. 71711-26), VETICA Insecticide (EPA Reg. No. 71711-32), and TOURISMO Insecticide (EPA Reg. No. 71711-33) (collectively, "Flubendiamide Products").

2. Appellants Bayer and Nichino are the sole registrants for the Flubendiamide Products.

3. The Pesticide Program issued the Flubendiamide Product registrations subject to a number of conditions, including the following requirements: (a) Bayer and Nichino must collect and submit to the Program various forms of data related to the toxicity, persistence and migration of flubendiamide and its primary degradate, des-iodo; (b) the Program must review the required data set and must consider any additional data and supporting information voluntarily submitted by Bayer and Nichino; (c) the Program must "engage in dialogue" about the data, as well as its conclusions, with scientists from Bayer; and (d) the Program must ultimately either approve general registration of the Flubendiamide Products, reach agreement with Bayer and Nichino regarding terms for further conditional registration of the Flubendiamide Products, or accept voluntary cancellation of the Flubendiamide Product registrations.

4. As a condition of registration, Bayer and Nichino agreed that if the Pesticide Program, after reviewing all the data and engaging in the required scientific dialogue, were to make a determination that further registration of the Flubendiamide Products would result in unreasonable adverse effects on the environment, Bayer and Nichino would, within one week, submit a request for voluntary cancellation of the Flubendiamide Products.

5. Bayer and Nichino knowingly agreed to and accepted all of the conditions of registration for the Flubendiamide Products.

6. Bayer and Nichino knowingly agreed that if they failed to comply with any of the conditions of registration, the Flubendiamide Products would be subject to cancellation under FIFRA section 6(e), 7 U.S.C. § 136d(e).

7. Bayer and Nichino timely complied with all of the data requirements included in the Flubendiamide Product registrations.

8. The Pesticide Program timely reviewed all of the data required by the Flubendiamide Product registrations, and the Program also considered additional data and supporting information voluntarily submitted by Bayer and Nichino.

9. Bayer and Nichino failed to establish by a preponderance of the evidence that the Program did not "engage in dialogue" with Bayer scientists regarding the data and the Program's conclusions.

10. After reviewing the data and engaging in dialogue, the Pesticide Program determined that further registration of the Flubendiamide Products would result in unreasonable adverse effects on the environment.

11. By letter dated January 29, 2016, the Pesticide Program notified Bayer and Nichino that further registration of the Flubendiamide Products would result in unreasonable adverse effects and that they were obligated to submit an appropriate request for voluntary cancellation within one week's time.

12. Pursuant to the terms of the Flubendiamide Product registrations, Bayer and Nichino were required to submit a request for voluntary cancellation of the Flubendiamide Product registrations to the Program on or before February 5, 2016.

13. By letter dated February 5, 2016, Bayer and Nichino notified the Pesticide Program that they declined to request voluntary cancellation of the Flubendiamide Product registrations.

14. By declining to request voluntary cancellation of the Flubendiamide Product registrations pursuant to FIFRA section 6(f)(1), 7 U.S.C. § 136d(f)(1), Bayer and Nichino failed to satisfy a condition of registration of the Flubendiamide Products.

15. The Pesticide Program issued a Notice of Intent to Cancel the Flubendiamide Product registrations based on the failure by Bayer and Nichino to satisfy a condition of registration.

16. The Pesticide Program made a determination to prohibit, with limited exceptions, the further sale, distribution or use of existing stocks of the Flubendiamide Products upon cancellation of the Flubendiamide Product registrations, except that the Program would allow end users currently holding existing stocks of BELT SC Insecticide, VETICA Insecticide and TOURISMO Insecticide to continue using those stocks until depleted.

17. The Pesticide Program appropriately commenced this proceeding under FIFRA section 6(e), 7 U.S.C. § 136d(e), rather than under FIFRA section 6(b), 7 U.S.C. § 136d(b).

18. Pursuant to FIFRA section 6(e)(2), 7 U.S.C. § 136d(e)(2), Bayer and Nichino timely requested a hearing.

19. The scope of a cancellation hearing under FIFRA section 6(e), 7 U.S.C. § 136d(e)(2), is narrowly limited to the resolution of two issues: (a) whether registrants have complied with the conditions of registration (or have initiated and pursued appropriate action toward fulfilling those conditions), and (b) whether the Pesticide Program's determination with respect to the continued sale and use of existing stocks is consistent with FIFRA.

20. In this proceeding under FIFRA section 6(e), 7 U.S.C. § 136d(e), Bayer and Nichino may not challenge the lawfulness of the termination condition of registration for the Flubendiamide Products, which requires them to submit a request for voluntary cancellation within one week of a determination by the Pesticide Program that further registration of the Flubendiamide Products would result in unreasonable adverse effects on the environment.

21. Bayer and Nichino did not timely object or argue with sufficient particularity that the Program failed to comply with a condition of the Flubendiamide Product registrations by failing to "engage in dialogue" with Bayer scientists regarding the data and the Program's conclusions.

22. Bayer and Nichino are now, in this FIFRA section 6(e) hearing, precluded from raising the argument that the Program failed to comply with a condition of the Flubendiamide Product registrations by failing to "engage in dialogue" with Bayer scientists regarding the data and the Program's conclusions.

23. The Pesticide Program's determination to prohibit Bayer and Nichino's continued *sale and distribution of* existing stocks of Flubendiamide Products is *consistent* with FIFRA.

24. The Pesticide Program's determination to prohibit the continued *sale, distribution and use* of existing stocks of FLUBENDIAMIDE Technical is *consistent* with FIFRA.

25. The Pesticide Program's determination to prohibit the continued *sale and distribution of* existing stocks of BELT SC Insecticide, VETICA Insecticide and

TOURISMO Insecticide by distributors and retailers *other than* Bayer and Nichino is not supported by the record.

## VII. *ORDER*

In accordance with the foregoing Final Decision, the registrations issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. §§ 136-136y), for BELT SC Insecticide (EPA Reg. No. 264-1025), FLUBENDIAMIDE Technical (EPA Reg. No. 71711-26), VETICA Insecticide (EPA Reg. No. 71711-32), and TOURISMO Insecticide (EPA Reg. No. 71711-33) (collectively, "Flubendiamide Products") are hereby canceled.

All sale, distribution, and use of Flubendiamide Products by Bayer CropScience LP and Nichino America, Inc. is hereby prohibited in accordance with the terms set forth in the Notice of Intent to Cancel, 81 Fed. Reg. at 11,560. The sale and distribution of existing stocks of BELT SC Insecticide, VETICA Insecticide, and TOURISMO Insecticide that have been formulated, packaged, and labeled for use and have been shipped or released into commerce to distributors and retailers other than Bayer CropScience LP and Nichino America, Inc., on or before the date of this Final Decision and Order, is allowed until those stocks are exhausted. The use of existing stocks of BELT SC Insecticide, VETICA Insecticide, and TOURISMO Insecticide in the hands of end users as of the date of this Order is allowed until those stocks are exhausted.

So ordered.