ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

In re:	)	
	)	
Bayer CropScience LP, and	)	FIFRA Appeal No. 16-(01)
Nichino America, Inc.	)	
	)	
Docket No. FIFRA-HQ-2016-0001	)	

POST-ARGUMENT BRIEF OF BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

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I. INTRODUCTION

In its June 23, 2016 Order on Post-Argument Briefing, the Environmental Appeals Board ("EAB" or "the Board") asked the parties to address a series of questions the Board identified during oral argument. Registrants appreciate the opportunity to provide their responses below.

The central issue in this proceeding is whether it is lawful for the United States Environmental Protection Agency ("EPA" or "the Agency") to devise and employ forced "voluntary" cancellation provisions that allow EPA to bypass statutory due process requirements under Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y ("FIFRA") and the "detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration." *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011) (emphasis in original). EPA's purposes in devising and implementing the provisions are twofold: to ensure that EPA's "unreasonable adverse effects" determination is not subject to *any* outside review or challenge, and to avoid the risks and burdens of undergoing the cancellation and suspension process required by FIFRA §§ 6(b) & (c). EPA claims the right to demand immediate "voluntary" cancellation of flubendiamide based on an "unreasonable adverse effects" determination that can be contested only through a FIFRA § 6(e) hearing in which EPA claims Registrants cannot challenge the lawfulness of EPA's process, the merits of EPA's decision, or the substance of EPA's existing stocks determination. Finding this lawful would allow EPA to cancel a highly beneficial insecticide without any review, and would embolden the Agency to take a similar approach for any registration it wishes going forward, rendering the required cancellation process available only at EPA's sole discretion. The Board should deny EPA's proposed cancellation and require EPA to pursue cancellation and suspension, if it wishes, through the process required by FIFRA §§ 6(b) & (c).

II. RESPONSES TO QUESTIONS POSED BY THE BOARD.

1. The Board Has the Authority to Address the Lawfulness of the Forced "Voluntary" Cancellation Provisions EPA Devised to Bypass Statutory Cancellation Process.

Registrants respectfully submit that the more appropriate question is: under what authority could the Board ignore the lawfulness of the conditions it is asked to enforce? The plain language of FIFRA § 6(e) and the EAB's inherent obligation to assess its subject matter jurisdiction over this dispute provide the Board the authority to rule on the lawfulness of the "voluntary" cancellation provisions.

a. The EAB must resolve questions about the lawfulness of a condition of registration in determining whether the condition has been violated and to ensure that it has jurisdiction over this proceeding.

This is the first FIFRA § 6(e) cancellation proceeding ever held, and as a result, there is no federal or administrative case law interpreting the scope of the EAB's review of the Office of Pesticide Programs' ("OPP") proposed cancellation determination. Thus, the Board should look to and give logical effect to the plain language of § 6(e). For the EAB to determine "whether the . . . conditions have been satisfied within the time provided" under FIFRA § 6(e)(2), the Board must necessarily first consider whether the conditions are valid. OPP has conceded that there are legal limits on the conditions it may impose upon pesticide registrants,[1] and has never claimed (nor could it) that a registrant is obligated to comply with an unlawful condition. If the only condition that Registrants are alleged to have violated is unlawful, then Registrants have complied with all valid conditions and there are no grounds for cancellation under § 6(e).

The Board does not merely review OPP's determination; it enters the final cancellation order, regardless of whether the ALJ's initial decision has been appealed. 40 C.F.R. § 164.101(b) (authorizing EAB review of the initial decision even "when no exceptions are filed").

[1] *See* EAB Oral Argument Tr. ("EAB Tr.") 86:6-87:2.

This final decision "constitutes the 'consummation of the agency's decision-making process' and is determinative of the rights of the parties." *See* EAB Practice Manual at 6 (quoting *City of San Diego v. Whitman*, 242 F.3d 1097, 1101 (9th Cir. 2001)). Because the EAB stands for the EPA Administrator as the "final decision-maker" on OPP's proposed determination, it cannot ignore questions about the lawfulness of a condition. Such a narrow reading of the EAB's jurisdiction would imply that the Board has no choice but to cancel a registration for a registrant's failure to satisfy an indisputably illegal condition of registration (*e.g.*, the payment of a bribe to EPA).

Moreover, Registrants' challenge to the lawfulness of the voluntary cancellation provisions is a challenge to the ALJ's and EAB's subject matter jurisdiction over this proceeding, the resolution of which is part of the Board's inherent authority. EPA's voluntary cancellation provisions purport to establish § 6(e) jurisdiction for a cancellation that is properly governed by § 6(b)&(c)[2] to avoid subjecting EPA's unreasonable adverse effects finding to review by other agencies and independent scientific authorities, or to challenge on the merits in a § 6(b) hearing. If the provisions are unlawful, then EPA has no legal authority to proceed with cancellation under § 6(e), the Administrative Law Judge ("ALJ") and EAB lack subject matter jurisdiction, and the matter should be remanded to OPP to proceed under § 6(b)&(c) if it wishes.

As the Board has previously held, "an administrative tribunal may make the legal and/or factual findings necessary to assure itself that it has subject matter jurisdiction over the case before it." *In re Julie's Limousine & Coachworks, Inc.*, 11 E.A.D. 498, 508 (EAB 2004) (citing *In re Lyon Cty. Landfill*, 8 E.A.D. 559, 567-68 (EAB 1999)). *In re Lyon County Landfill* involved a challenge to an administrative enforcement action brought by EPA under the Clean

[2] In the most recent contested cancellation proceeding, EPA avowed that cancellations and suspensions based on risk-benefit determinations are "governed" by the §§ 6(b)&(c) process, not § 6(e). PBNX 126 at PBN1765 (public filing excluded by the ALJ as "irrelevant").

Air Act. The ALJ dismissed EPA's action for lack of jurisdiction, finding that the Agency lacked the statutory authority to issue the penalty order through an administrative action and should have pursued a judicial action instead. *Id.* at 563-64. EPA appealed, challenging the ALJ's authority to independently assess its jurisdiction over a proceeding that EPA had already determined to be lawfully initiated. *Id.* at 564-65. The EAB rejected EPA's arguments, finding that it was appropriate for the ALJ to first determine whether the governing statute permitted the action brought by EPA, and that an ALJ "who independently reviews the jurisdictional basis of a case is not superseding [EPA's] role," but simply ensuring that EPA's authority is "legally available." *Id.* at 567-68. Here, the EAB is presented with a similar attempt by EPA to avoid a statutorily required proceeding and similar claims from OPP that the ALJ and EAB lack the authority to question OPP's claim that jurisdiction is proper. The EAB should find that it lacks subject matter jurisdiction to administer this dispute and remand to OPP.

b. The Board's authority to consider the lawfulness of a condition of registration does not give third parties broad rights to challenge the lawfulness of the condition or all aspects of the registration.

FIFRA § 6(e) provides that "a person adversely affected by the notice" can request a hearing. 7 U.S.C. § 136d(e)(2). The EAB need not be concerned that permitting the present challenge to the lawfulness of a condition of registration will result in a multitude of third-party challenges to the lawfulness of EPA cancellation determinations. Third parties do not have a right under § 6(e) to challenge any aspect of the registration they wish. Their challenge must relate to the proposed cancellation and would be limited to addressing the lawfulness of EPA's invocation of the § 6(e) process (which will not be an issue if EPA follows the process), and contesting whether the conditions were met and the existing stocks determination under § 6(e)(2). Moreover, federal courts have found that a third party's right to challenge a cancellation notice is limited in situations in which the registrants have agreed to cancel the

registrations. *Nw. Food Processors Ass'n v. Reilly*, 886 F.2d 1075, 1079 (9th Cir. 1989) (holding that FIFRA does not give nonregistrant users the right to continue contesting cancellation in an administrative hearing once the registrants have agreed to abandon their registrations).

c. Striking the voluntary cancellation provisions would not invalidate the registrations.

If the Board concludes that the voluntary cancellation provisions are unlawful, they can be stricken from the registrations and the registrations may continue without consequence other than ensuring that EPA cannot pursue an unlawful process.[3] What would remain are conditional registrations for which all conditions of registration have already been satisfied.[4]

OPP's sole witness and its counsel repeatedly claimed that the voluntary cancellation conditions were "necessary" and "essential" to the Agency's decision to grant the registrations,[5] and counsel for EPA asserted at oral argument that EPA's authority to impose "other conditions" of registration under FIFRA § 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C), is limited to conditions that EPA finds "necessary" to support the registration.[6] Yet EPA's only stated explanation for why the cancellation provisions are "necessary" – that they allow the Agency to promptly cancel the registrations if it determines that flubendiamide causes unreasonable adverse effects on the environment – demonstrates that the condition is purely procedural and wholly unnecessary.

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[3] *See* Reply in Support of Mot. for Accelerated Decision (ALJ Dkt. #19) at 17-20.

[4] EPA recognized that as of July 31, 2012, Bayer "ha[d] submitted all data required by the original conditions of registration for flubendiamide." PBNX 10.

[5] RE 10 at 200101 (Ms. Lewis characterizing the conditions as "necessary in order for EPA to be able to make a no unreasonable adverse effects determination"); Opposition to Mot. for Accelerated Decision ("MAD Opp.," ALJ Dkt. #17) at 38-39 (describing the voluntary cancellation condition as "the condition EPA determined was essential when it granted the registration in 2008"); EAB Tr. 88:18-20 ("[T]he voluntary cancellation condition, was an essential part of making the unreasonable adverse effects finding."); *id.* 90:4-6 ("[T]he Agency maintains that this condition was essential to issuing the registration to begin with.").

[6] EAB Tr. 86:13-22 ("It would have to be something that is based on what the administrator would deem would be something necessary for this particular product and mitigation measure.").

The condition is purely procedural because it purports to apply a standard that already governs all pesticide registrations[7] while altering the statutory process that governs cancellations under that standard. It is unnecessary because EPA can and must achieve such a result by following processes set out by law. If EPA wishes to cancel the flubendiamide registrations based upon an unreasonable adverse effects finding, it must do so by following the FIFRA § 6(b) cancellation process. If EPA wishes to quickly remove flubendiamide products from the marketplace to avoid environmental harm that could occur during the cancellation process, it must do so by following the suspension process mandated by § 6(c). Remarkably, EPA provided no arguments as to why the voluntary cancellation provisions are necessary in light of § 6(c). EPA ignored § 6(c) throughout this proceeding and did not even mention it in its Response Brief.

EPA will presumably continue to assert that if the voluntary cancellation provisions are found unlawful, the registrations must be invalidated. *See, e.g.*, MAD Opp. at 40. EPA cites no legal authority for this proposition. EPA's unifying principle in this proceeding is that no matter what path Registrants take, and no matter what conclusion the ALJ and EAB may reach, the result must always be the same – cancellation of the flubendiamide registrations. To "comply" with the unlawful condition, Registrants would have to voluntarily cancel their registrations under FIFRA § 6(f). Because Registrants refused to comply with the unlawful provisions, EPA claims the registrations must be cancelled under FIFRA § 6(e). Finally, if Registrants successfully challenge the legality of the provisions, EPA claims the registrations must be vacated. When an agency claims it can achieve the desired result whether its demand is

[7] FIFRA provides that EPA "shall register" a pesticide if EPA determines, among other things, that the product "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*." FIFRA § 3(c)(5)(C)-(D), 7 U.S.C. § 136a(c)(5)(C)-(D) (emphasis added).

complied with, challenged, or found unlawful, the lawfulness of the demand is inherently suspect. Registrants urge the EAB, as the final arbiter of EPA's cancellation determination, to strike the unlawful condition from the registrations and order that if EPA still wishes to proceed with cancellation, it must do so under FIFRA §§ 6(b) & (c).

2. The Preponderance of the Evidence Standard of Proof Applies to Orders Issued by the EAB After a § 6(e) Hearing.

Hearings conducted pursuant to § 6(e) are governed by § 6(d), which provides that the final order issued after the hearing "shall be based only on substantial evidence of record of such hearing." The Board asked what standard of proof this provision requires, taking into account the reference to a "substantial evidence" standard in FIFRA § 16(b), 7 U.S.C. § 136n(b), and the *Steadman v. SEC* Supreme Court decision. *Steadman v. SEC* confirms that "substantial evidence" as used in § 6(d) requires EPA (and thus the EAB) to support any order issued after a § 6(e) hearing by a "preponderance of the evidence." 450 U.S. 91, 102 (1981).

In *Steadman*, the Supreme Court affirmed a hearing decision by the Securities and Exchange Commission ("SEC") finding by a preponderance of the evidence that the petitioner violated antifraud laws. *Id*. at 93-94, 103-04. The Court considered Administrative Procedure Act ("APA") § 7(c), 5 U.S.C. § 556(d), which applies to adjudicatory proceedings unless superseded by specific statutory provisions, and states in part: "A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by *and in accordance with* the reliable, probative, and *substantial evidence*." *Id*. at 98 (emphasis in original). The Court held that this "establish[ed] a standard of proof" that "is the traditional preponderance-of-the-evidence standard." *Id*. at 102.

FIFRA § 6(e) cancellation hearings are on-the-record adjudicatory proceedings required by statute and subject to APA § 7(c), 5 U.S.C. § 556(d). Consistent with *Steadman*, "substantial

evidence" as used in § 6(d) establishes a preponderance-of-the-evidence standard of proof. *See also* 2 Richard J. Pierce, Jr., Administrative Law Treatise 972-73 (5th ed. 2010) (*Steadman* "suggest[s] that the preponderance of the evidence standard of proof applies to the vast majority of agency actions."). Thus, factual findings in final orders issued by the EAB after § 6(e) hearings must be supported by a preponderance of the evidence in the record.

The reference to "substantial evidence" in FIFRA § 16(b) serves a different purpose. It provides the standard of *review* that Courts of Appeals must apply to findings of fact on appeal of a final order issued after a § 6(e) hearing. Certain circuit courts, including the Fourth and D.C. Circuits, generally equate the "substantial evidence" standard of review with "arbitrary and capricious" review.[8] Other circuit courts, such as the Fifth and Ninth Circuits, have interpreted the "substantial evidence" standard to require a somewhat more stringent review.[9]

3. The Requirement to Engage in "Dialogue About the Data and the Agency's 'Conclusions'" Includes the Agency's Unreasonable Adverse Effects Determination and Decisions on Toxicological Endpoints.

The "voluntary" cancellation provisions require EPA to engage in dialogue with Registrants "about the data *and the Agency's conclusions*" before demanding "voluntary" cancellation based on an unreasonable adverse effects determination. PBNX 8 at PBN0019

[8] *See GTE S., Inc. v. Morrison*, 199 F.3d 733, 745 n.5 (4th Cir. 1999) ("With respect to review of fact findings, there is no meaningful difference between" the two standards.); *James City County v. EPA*, 12 F.3d 1330, 1338 n.4 (4th Cir. 1993) ("It is widely held that there is now little difference in the application of the two standards."); *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 745 F.2d 677, 683-84 (D.C. Cir. 1984) (describing "the emerging consensus" that there is "no *substantive* difference between" the two standards).

[9] *See Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1214 (5th Cir. 1991) ("Congress put the substantial evidence test in the [TSCA] statute because it wanted the courts to scrutinize the Commission's actions more closely than an 'arbitrary and capricious' standard would allow."); *Pollinator Stewardship Council v. U.S. EPA*, 806 F.3d 520, 533 (9th Cir. 2015) (Smith, J., concurring) ("The substantial evidence standard affords an agency less deference than the arbitrary and capricious standard" and "allow[s] greater scrutiny."); *but see Bonnichsen v. United States*, 367 F.3d 864, 880 n.19 (9th Cir. 2004) ("there is no substantive difference").

(Preliminary Acceptance Letter ("PAL") sections 6(b) & 8(b)) (emphasis added). The reference to "conclusions" is not a term of art; consistent with the standard dictionary meaning, a "conclusion" is "a final decision or judgment: an opinion or decision that is formed after a period of thought or research."[10] Thus, the provisions require EPA to not only engage in general dialogue about the data, but also to disclose and engage in dialogue about the Agency's final decisions and judgments about the data and whether they support continued registration.

Read naturally within the multi-step "voluntary" cancellation provisions, the requirement to engage in dialogue about "the Agency's conclusions" necessitates that EPA disclose and discuss its ultimate unreasonable adverse effects determination before demanding voluntary cancellation under PAL sections 6(d) & 8(d). It makes sense that a condition requiring good-faith dialogue before demanding cancellation based on an unreasonable adverse effects determination would include dialogue about the final determination. In this case, EPA precluded any opportunity for such dialogue by issuing its determination on the same day as its cancellation demand.[11] In their February 5, 2016 letter declining the "voluntary" cancellation demand, Registrants outlined numerous scientific problems in EPA's approach that they identified in a preliminary review, and indicated that they "remain available to address the science in a transparent and methodical way." PBNX 18 at PBN0100. EPA announced its Notice of Intent to Cancel ("NOIC") on March 1, 2016 without any further dialogue. PBNX 19.

Even if the requirement to engage in dialogue about "the Agency's conclusions" somehow does not include the unreasonable adverse effects determination, it must require dialogue on the critical scientific conclusions that form the basis for EPA's determination. Two

[10] *Conclusion*, Merriam-Webster, http://www.merriam-webster.com/dictionary/conclusion.

[11] PBNX 17 at PBN0097 (January 29, 2016 cancellation demand letter); PBNX 30 (January 29, 2016 Decision Memorandum); PBNX 31 (January 28, 2016 Ecological Risk Assessment Addendum, provided on January 29, 2016).

critical decisions the Agency must make to justify a cancellation determination based on potential ecotoxicological effects are (i) what the applicable toxicological endpoint is (typically, a "no observed adverse effect" concentration below which adverse effects are not expected to occur), and (ii) whether exposures at or above that level are occurring or are expected to occur based on the data.[12] A transparent scientific dialogue about the Agency's conclusions thus must include disclosure and discussion of the Agency's conclusion as to the toxicological endpoint it will use to make the cancellation determination.

Conclusions regarding toxicological endpoints often require decisions about the weight to give endpoints derived from different studies and which endpoints to use in the registration or cancellation determination. Here, EPA had to decide whether to use a 0.28 ppb (parts per billion) sediment pore water endpoint that EPA calculated from a spiked water study submitted in 2006, or a 19.5 ppb sediment pore water endpoint based on a spiked sediment study that Registrants submitted in 2010, which EPA agrees is the "prefer[red]" type of study for establishing a sediment pore water endpoint. [13] As discussed below, EPA chose at the eleventh hour to revert to the 0.28 ppb endpoint to justify cancellation rather than the more relevant and scientifically sound 19.5 ppb endpoint from the spiked sediment study, a final decision that it is scientifically unsound and that EPA has refused to engage in scientific dialogue about and did

[12] PBNX 116 at 15:2-16:23 (Ms. Sanson's testimony addressing the interplay between the endpoint and exposure decisions); PBNX 119 (Dr. Engel's expert testimony on exposure issues) (excluded as irrelevant); PBNX 120 (Dr. Moore's expert testimony on the toxicological endpoint selected by EPA) (excluded as irrelevant).

[13] PBNX 33 at PBN0912 (EPA review of the spiked water study identifying as a "Major Guideline Deviation" the fact that "[o]verlying water was spiked, prefer that the sediment is spiked"); PBNX 120 at 14:1-26:19 (Dr. Moore's testimony describing the guidance regarding spiked water and spiked sediment studies and their different purposes; why EPA's decision to use the spiked water study endpoint over the scientifically more relevant and robust spiked sediment study endpoint was unsound; and how this led to an incorrect risk assessment and cancellation determination) (excluded as irrelevant).

not explain – in fact, deliberately obscured – in the documents released on January 29, 2016.

4. EPA Presented New Conclusions in the January 29, 2016 Documents That Were Not Discussed with Registrants.

In the Decision Memorandum and the supporting documents that EPA released on January 29, 2016 with its cancellation demand, EPA presented at least three conclusions that were not previously disclosed. EPA did not engage in the required dialogue on these conclusions before attempting to implement the voluntary cancellation provisions.

First, EPA disclosed for the first time on January 29, 2016 its determination that "continued use of flubendiamide as currently registered . . . will result in unreasonable adverse effects to the environment." PBNX 30 at PBN0852.[14] This final risk-benefit determination was not provided to Registrants at or after the January 6, 2016 meeting or before the January 29, 2016 decision and cancellation demand.[15]

Second, throughout the Decision Memorandum, EPA refers to its conclusions that exposure concentrations based on EPA's theoretical modeling exceed or will exceed "Agency LOCs [levels of concern]" within certain time periods based on unspecified toxicological endpoints. EPA relied on theoretical modeling rather than the real-world monitoring data Registrants were required to generate as a condition of registration, and the claimed exceedances are based on revised and new modeling scenarios EPA chose not to disclose until January 29,

[14] The January 29, 2016 letter announces that "[t]he Agency has made a determination that the continued use of the currently registered flubendiamide products will result in unreasonable adverse effects on the environment," and that "[t]hese *conclusions* are contained within the attached documents. " PBNX 17 at PBN0097 (emphasis added).

[15] *See* PBNX 116 at 17:17-23 (Ms. Sanson testifying that EPA acknowledged at the January 6, 2016 meeting that things were "very dynamic" and that EPA "did not provide its ultimate finding at [that] time"). EPA's withholding of its unreasonable adverse effects determination precluded the dialogue required by the "voluntary" cancellation conditions and invalidates its cancellation demand.

2016.[16] Registrants could not engage in dialogue with EPA about the modeling or the Agency's conclusions when EPA was relying on modeling results that had not been previously disclosed.

Third, and perhaps most critically, the Decision Memorandum and supporting documents contain buried within them EPA's decision to adopt the 0.28 ppb sediment pore water endpoint from the spiked water study, which had been superseded by an endpoint from the scientifically more relevant and sound spiked sediment study, as the sole basis for its cancellation determination. The Board asked the parties to identify "where in the record" new conclusions "are . . . detailed." June 23, 2016 Order on Post-Argument Briefing at 2. Doing so for EPA's decision to use and rely solely on the 0.28 ppb endpoint is a complex task because EPA went to great lengths to avoid dialogue on this decision and to obscure in its final documents the fact that it had even made such a choice. Nonetheless, the chronology of EPA's decision to base the cancellation decision on the 0.28 ppb endpoint has been established through record evidence and undisputed testimony, and is discussed in detail in the next section.

5. EPA Deliberately Thwarted Dialogue on the Use of the 0.28 ppb Endpoint and Did Not Disclose Its Final Decision Until January 29, 2016.

EPA's cancellation determination relies on a decision to adopt the 0.28 ppb sediment pore water endpoint from the spiked water study as the definitive endpoint for assessing potential effects of flubendiamide's degradate des-iodo on benthic aquatic invertebrates, and to justify cancellation based on exceedances of that endpoint alone. In doing so, without discussion or explanation, EPA discredited and ignored the 19.5 ppb endpoint derived from the scientifically more relevant spiked sediment study. *See supra* note 13.

The record evidence establishes the following chronology regarding EPA's endpoint

[16] PBNX 31 at PBN0871-879 (new modeling for multiple crop scenarios which includes the effects of pond outflow); *id.* at PBN0903-904 (new modeling for tree nut and cucurbit scenarios which includes the effects of the photolysis half-life and a 30-foot buffer).

positions, discussions, and disclosures. In support of the original flubendiamide registrations, Registrants submitted a spiked *water* study, in which the test substance is introduced directly into the overlying water of the test system, to provide information on the potential toxicity of des-iodo to benthic aquatic invertebrates. PBNX 116 at 15:15-21. In its May 2008 review of this study, EPA concluded that the spiked water study could be used to calculate a sediment pore water endpoint, but identified the fact that the "[o]verlying water was spiked" as a "Major Guideline Deviation" and noted that the Agency "prefer[s] that the sediment is spiked." PBNX 33 at PBN0912. Using a time-weighted average ("TWA") approach, EPA calculated a 0.28 ppb sediment pore water endpoint for des-iodo from this study. *Id.* at PBN0925 (Table 1, fourth column, seventh row). EPA's 2008 risk assessment noted that the spiked water study did not "follow[] sediment toxicity guidelines which require the sediment to be spiked as opposed to the overlying water," but concluded there was "sufficient information to reach a risk conclusion for benthic invertebrates." PBNX 27 at PBN0455.

Responding to EPA's guidance, Registrants submitted a spiked *sediment* study in 2010. In a spiked sediment study, the test substance is introduced into the sediment and the system is allowed to equilibrate before the study is run. This study better assesses the potential chronic effects of accumulation of residues over time in sediment pore water. PBNX 116 at 15:13-21.[17] EPA reviewed the spiked sediment study in July 2011 and concluded that it supported a TWA pore water sediment endpoint of 19.5 ppb. PBNX 34 at PBN0943. This endpoint was the basis

[17] *See also* PBNX 120 at 14:1-21:18 (Dr. Moore's testimony describing the difference between spiked water and spiked sediment studies, why the spiked sediment approach is the more relevant method for testing potential effects of accumulation of residues in sediment pore water over time, and that EPA's use of the spiked water endpoint instead of the spiked sediment endpoint is not scientifically sound and inconsistent with OECD guidance and EPA's prior conclusions) (excluded as irrelevant).

for the discussions between the parties going forward until December 2015.[18]

On December 16, 2015, the day after a high level meeting attended by the Assistant Administrator and the CEOs of both Bayer and Nichino at which Registrants were told that the Agency would reach a cancellation decision by December 18, 2015 and that they should immediately provide their "best, final mitigation proposal," Registrants learned that EPA scientists had briefed the Assistant Administrator on the case for cancellation using the 0.28 ppb endpoint. PBNX 116 at 14:1-22; PBNX 14. By withholding from Registrants its analysis based on that endpoint and an apparent change in endpoint selection, EPA actively manipulated the process to preclude the required dialogue on this critical issue at what the Agency intended to be the final meeting on flubendiamide. Registrants immediately objected to EPA's lack of transparency and the refusal to engage in good-faith scientific dialogue. PBNX 14.

At a subsequent meeting on January 6, 2016, Registrants sought to engage in a scientific dialogue with EPA on its apparent decision to use the lower endpoint, but EPA responded by denying it had made such a decision and presented the 0.28 ppb endpoint as one endpoint among a "suite" of toxicological endpoints, an approach it carried over into the Decision Memorandum and the Ecological Risk Assessment Addendum ("Addendum") it released with the cancellation demand on January 29, 2016.[19] Neither document provides any discussion of EPA's evaluation

[18] For example, in a February 2015 review of the monitoring studies EPA required Registrants to conduct, EPA's Environmental Fate and Effects Division ("EFED") listed the endpoints that Registrants believed were applicable, including the 19.5 ppb des-iodo sediment pore water endpoint, noted that "[s]ome of these registrant-calculated endpoints *differ slightly* from the Agency determined endpoints," and advised that the Agency "will use the registrant-calculated endpoints" in evaluating the implications of the monitoring studies. PBNX 35 at PBN0992 (emphasis added). EFED makes no mention of the superseded 0.28 ppb endpoint from the spiked water study, which was 70 times lower and not a "slight" difference. *Id.*

[19] PBNX 30 at PBN0847 (Table 1, "Final Suite of Available Effects Toxicity Endpoints," listing both the 0.28 ppb des-iodo pore water endpoint from the spiked water study and the 19.5 ppb endpoint from the spiked sediment study); PBNX 31 at PBN0862 (Table 5, same).

of the spiked water versus spiked sediment study endpoints, and both documents refer vaguely to exceedances of "Agency LOCs" without specifying which particular endpoints EPA used to determine levels of concern and whether and to what extent the Agency was relying on the superseded 0.28 ppb endpoint.[20]

Only by laborious comparison of EPA's characterization of the exceedances to the graphs provided in the appendices is it possible to discern that EPA decided to ignore the more relevant and scientifically sound 19.5 ppb endpoint it previously adopted and to revert to the unsound, 0.28 ppb endpoint to justify its cancellation determination.[21] There is no discussion or explanation in either document of EPA's decision to use the superseded 0.28 ppb endpoint to justify cancellation, even though Registrants had disputed that potential choice since first learning of the possible reversion to the 0.28 ppb endpoint on December 16, 2015.[22]

In short, the record shows that OPP chose not to notify Registrants at a putative final meeting on December 15, 2015 that it had decided to revert to the 0.28 ppb endpoint; briefed the Assistant Administrator on the case for cancellation using analysis employing that endpoint the

[20] *See, e.g.*, PBNX 30 at PBN0849-851 (repeatedly asserting that scenarios "exceed Agency LOCs" without specifying which particular endpoints were used to determine levels of concern); PBNX 31 at PBN0865-69 (same).

[21] *Compare, e.g.*, PBNX 30 at PBN0850 (asserting that "[t]he tree nut scenario proposed by [Registrants] exceeds Agency LOCs in 2 years at three applications per year and 3 years at two or one application(s) per year"), *with* PBNX 31 at PBN0903 (upper right graph showing that based on EPA's theoretical modeling, the 0.28 ppb endpoint (indicated by the lower dashed red line) is exceeded in 2 or 3 years depending on the number of applications, but the 19.5 ppb endpoint (indicated by the blue dashed line at the top of the graph) is not exceeded in 30 years).

[22] The Addendum misleadingly "compares" the "current" des-iodo endpoint of 0.28 ppb from the spiked water study with the same endpoint as used in the June 2008, May 2010, and December 2010 risk assessments, suggesting a false consistency while ignoring the 19.5 ppb endpoint from the spiked sediment study the Agency adopted in the interim after its July 2011 review of that study. PBNX 31 at PBN0861 (Table 4); PBNX 34. The Decision Memorandum likewise provides a short "Comparison of EPA Use of Flubendiamide and Des-iodo Toxicity Endpoints in Previous Risk Assessments" that avoids any reference to the Agency's prior use of the 19.5 ppb endpoint and the sudden reversion to the 0.28 ppb endpoint that drove EPA's cancellation determination. PBNX 30 at PBN0847; PBNX 35 at PBN0992; PBNX 14.

very next day; precluded meaningful discussion of the use of the lower endpoint by denying the Agency had made that decision at the January 6, 2016 meeting and presenting the lower endpoint as one endpoint among a "suite" of available endpoints; and deliberately obscured its reliance on the unsound endpoint in its final decision documents issued on the same day as the cancellation demand – which do not even mention the choice, let alone provide the scientific basis for it.[23]

EPA's steadfast refusal to engage in dialogue on the choice of endpoints persisted through the oral argument, where EPA counsel refused or was unable to provide any substantive response to the EAB's questions about the lack of dialogue on the use of the endpoint, and instead responded by raising Registrants' purported failure to object on this issue even after the Board asked for a response on the substance and by asserting, without explanation, that the choice of endpoint was not one of "the Agency's conclusions" that it was required to discuss. EAB Tr. 67:14-75:1. Despite claiming an absence of record evidence, EPA has not moved to reopen the hearing to enter any further evidence on this point into the record. *Id.* 73:3-10.

6. If Registrants Had Requested Voluntary Cancellation Under § 6(f), They Could Not Have Effectively Challenged EPA's Unreasonable Adverse Effects Determination During the Notice-and-Comment Period.

The EAB need look no further than EPA's own statements in this proceeding to see that EPA's purported "voluntary" cancellation provisions were intended to preclude Registrants from challenging its unreasonable adverse effects determination. The purpose of FIFRA § 6(f), 7 U.S.C. § 136d(f), is to allow registrants who no longer wish to maintain a registration to cancel the registration on *their own initiative*. Because a registration cannot be maintained without a willing registrant, § 6(f) provides the public a right to notice and comment, but nothing more. At

[23] In testimony the ALJ excluded as "irrelevant," Dr. Moore, who has 17 years of experience conducting risk assessments, including for EPA and Environment Canada, found EPA's "lack of discussion" of the critical endpoint selection "striking" and its "lack of transparency about how and why that endpoint was selected . . . troubling." PBNX 120 at 27:1-28:9.

a minimum, it would be incongruous to require Registrants to voluntarily cancel their own registrations in order to comment on EPA's scientific determination regarding the environmental profile of those products. More fundamentally, it would unfairly require Registrants to accept administrative rights to dispute the merits of EPA's decisions that are plainly inferior to those available in the FIFRA § 6(e) hearing into which Registrants were forced, let alone the FIFRA § 6(b) process in which they properly belong.

FIFRA § 6(f) permits a registrant to request voluntary cancellation of its own registration at any time and for any reason.[24] As a result, it does not require EPA to provide any scientific justification for its decision to grant voluntary cancellation. The only administrative process required under § 6(f) is "a 30-day period in which the *public* may comment," with the potential for a 180-day comment period for voluntary cancellation of minor agricultural uses unless EPA determines that a waiver of that longer period is warranted. FIFRA § 6(f)(1)(B)-(C) (emphasis added). Having voluntarily initiated the § 6(f) cancellation process, the registrant seeking cancellation is unsurprisingly presumed to support cancellation. The basic notice-and-comment rights provided under § 6(f) are intended to be exercised not by the registrant, but by interested stakeholders, such as growers or grower advocacy groups who wish to preserve a certain registered use[25] or environmental advocacy groups who wish to more quickly foreclose the continued production or sale of the product.[26]

At most, FIFRA § 6(f) would have provided Registrants a token opportunity to submit comments disputing the scientific conclusions in EPA's unreasonable adverse effects

[24] For example, Bayer recently requested voluntary cancellation of certain other flubendiamide registrations, not because of any concerns regarding their environmental impacts, but because those products were no longer in commercial use. *See* 81 Fed. Reg. 21,344, 21,344 (Apr. 11, 2016); Corrected ALJ Hearing Tr. (ALJ Dkt. #32) 136:4-21.

[25] *See, e.g.*, 78 Fed. Reg. 40,136, 40,136-37 (July 3, 2013).

[26] *See, e.g.*, 79 Fed. Reg. 16,793, 16,794 (Mar. 26, 2014).

determination. Because cancellation would have been "voluntary", EPA would be under no obligation to do more than acknowledge the comment in its cancellation order, and respond only to the extent the comment was deemed relevant to its decision to grant voluntary cancellation.[27] Given EPA's unwavering position in this § 6(e) hearing that the merits of its unreasonable adverse effects determination are irrelevant to the entry of its proposed cancellation order, the Agency cannot in good faith now claim that it would have considered that determination relevant to its cancellation order under § 6(f). Registrants would have had no right to respond to EPA's response to their comments, no matter how cursory. Once the cancellation order was final, Registrants would have had no right to seek administrative review before an ALJ and the EAB. Finally, Registrants would have faced substantial challenges in asking a court to entertain their appeal of a final cancellation order granting them the very relief they "voluntarily" requested.

Registrants would furthermore have been foreclosed from exercising the *only* substantive recourse that § 6(f) provides registrants who believe that cancellation is unjustified – the withdrawal of the voluntary cancellation request. In publishing its notices of receipt of a request to voluntarily cancel a registration as required under § 6(f), EPA sets out a process by which the registrant may withdraw its request.[28] Registrants have historically exercised this right to withdraw cancellation requests made in error,[29] although they are not precluded from withdrawing a cancellation request over a substantive dispute. Here, however, the challenged provisions not only require Registrants to submit a request for voluntary cancellation, but also to

[27] EPA's voluntary cancellation notices explain that "EPA intends to grant [the] requests at the close of the comment period" unless the Agency determines that further review is necessary or the registrants withdraw their requests. *See, e.g.*, 81 Fed. Reg. 27,439, 27,439 (May 6, 2016).

[28] *See, e.g.*, 81 Fed. Reg. at 27,441 ("Registrants who choose to withdraw a request for product cancellation or use deletion should submit the withdrawal in writing to [EPA].").

[29] *See, e.g.*, 81 Fed. Reg. 3792, 3798 (Jan. 22, 2016) (in which a registrant commented on its own voluntary cancellation request to explain that the request had been made in error, and EPA agreed to retain the registration).

"include a statement that [registrant] recognizes and agrees that the cancellation request is irrevocable." PBNX 8 at PBN0019. Thus, Registrants could not have withdrawn their voluntary cancellation request without EPA alleging a violation of the PAL, triggering cancellation under § 6(e). It is in part for this reason that Registrants argued before the ALJ that the "voluntary" cancellation provision that EPA imposed upon Registrants was voluntary in name only. *See* Mot. for Accelerated Decision (ALJ Dkt. #12) at 52-55.

In summary, in exchange for the opportunity to submit public comments criticizing the lack of scientific support for EPA's unreasonable adverse effects determination, Registrants would have had to cancel products that they believe should properly remain registered, forgo their statutory rights to a cancellation decision that is subject to interagency review by the Secretary of Agriculture and scientific peer review by the Scientific Advisory Panel and that can be challenged in an administrative proceeding, and, in doing so, potentially jeopardize their ability to seek and obtain judicial review of that decision. No registrant should be forced to sacrifice its statutory and due process rights in order to raise scientific concerns that EPA is free to ignore. Nor should registrants be held to have lost their rights to challenge the conditions by failing to pursue such an unfavorable path, particularly when the conditions of registration at issue themselves point to the right to invoke and seek relief through the § 6(e) process.

7. The Doctrine of Laches Does Not Apply Here, There Was No Unreasonable Delay by Registrants, and There Is No Prejudice to EPA.

EPA asserts that laches bars Registrants from challenging the lawfulness of the "voluntary" cancellation provisions. Response Br. at 14-15 n.2. Laches is an affirmative defense against an action on the grounds that there was a "lack of diligence" by the claimant in bringing the action that caused "prejudice" to the defendant. *Menominee Indian Tribe of Wis. v. United States*, 614 F.3d 519, 531-32 (D.C. Cir. 2010). The laches doctrine does not limit or

preclude *defenses* a party may raise in opposing an action brought against it, and thus does not preclude Registrants from challenging the "voluntary" cancellation provisions as unlawful as a defense to the cancellation action. EPA has not cited any cases suggesting otherwise. To the contrary, courts have recognized that parties can raise substantive objections to an agency rule or other administrative action of continuing application when the agency applies the rule or action against the party, even if the parties could have done so much earlier.[30]

Even if applicable here, laches would not preclude Registrants from challenging the lawfulness of the "voluntary" cancellation provisions. Laches is an equitable doctrine, requiring a consideration of the facts and a finding that there was an "unjustifiabl[e]," "inexcusabl[e]," or "unreasonabl[e]" delay that prejudiced the other party. *Id*. at 531-32. The facts here show that any "delay" by Registrants was reasonable, and that Registrants were justified in not pursuing any of the purported options for an earlier challenge that EPA claims were available:

- No reasonable commercial actor in Registrants' shoes would have declined the registrations, disrupting the launch and forgoing years of sales of a product in which they had invested more than $125 million, to obtain a formal denial and bring a costly and burdensome court action to challenge the voluntary cancellation provisions on the off chance that EPA might use the provisions years later to force cancellation that was not supported by the data Registrants were collecting.
- If Registrants had accepted the registrations and immediately applied to amend the registrations to remove the unlawful provisions,[31] they would have antagonized EPA,

[30] *See, e.g.*, *Indep. Cmty. Bankers of Am. v. Bd. of Governors of Fed. Reserve Sys.*, 195 F.3d 28, 33-34 (D.C. Cir. 1999) ("We have frequently said that a party against whom a rule is applied may, at the time of application, pursue substantive objections to the rule, *including claims that an agency lacked the statutory authority to adopt the rule*, even where the petitioner had notice and opportunity to bring a direct challenge within statutory time limits.") (emphasis added); *Functional Music, Inc. v. FCC*, 274 F.2d 543, 546 n.9 (D.C. Cir. 1958) ("[C]onforming to the dictates of invalid administrative action does not estop a party from subsequently contesting that very action.").

[31] In asserting that Registrants had numerous options for precipitating an earlier challenge to the voluntary cancellation provisions, EPA glosses over the substantial PRIA fees associated with applying for and amending pesticide registrations. Despite having already paid a $498,750 PRIA fee for their initial application (the analogous fee was $516,300 in 2008, and is $627,568

the regulatory agency with pervasive authority over all their products, to obtain, at best, the right to bring a costly and burdensome legal challenge to provisions the Agency might never use. This approach would also have jeopardized the existing registrations, as EPA would likely claim that seeking removal of the unlawful provisions voided the registrations under the terms of the PAL.[32]

- An immediate court action challenging the unlawful provisions would have caused similar burdens and repercussions and prompted EPA to argue that Registrants had failed to exhaust administrative remedies by not requesting and challenging a denial decision and/or that the action was not ripe, since the data had not been generated and there was no indication that EPA would act under the disputed provisions.

Instead, Registrants chose to generate the required data and satisfy the substantive conditions of registration, trusting that if the data did not show evidence of accumulation to levels of concern (which they did not), EPA would follow the science and the terms of the PAL and grant unconditional flubendiamide registrations. PBNX 116 at 8:10-9:2. That trust was reinforced in August 2015, when EPA proposed a "path forward" that included a three-year extension of the registrations. PBNX 11. Registrants' course of action was justified and reasonable, and provides no equitable basis to preclude Registrants from challenging the legality of the provisions.

There is likewise no evidence of prejudice. EPA claims that it was prejudiced by the passage of time because the record is unclear whether EPA would have granted the registrations without the disputed provisions and because participants in the discussions about the registration no longer work for EPA or Registrants. Response Br. at 15 n.2. To the contrary, the record shows that EPA *refused* to grant the registrations without the contested provisions, which EPA has repeatedly claimed were "essential" and "necessary." *See supra* note 5. Whether it was

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today), EPA suggests that Registrants should have either refused the conditions (squandering the entire fee) or accepted the conditions only to immediately apply for an amendment to remove the conditions. The additional PRIA fee for such an amendment, which would have entailed a request that EPA conduct a refined ecological assessment, was $155,300 in 2008. EPA would have had Registrants incur these fees while acknowledging it would have denied every request.

[32] *See* PBNX 8 at PBN0020 ("If either Nichino or Bayer does not agree with any of the conditions of registration, they should consider any such registration to be null and void.").

lawful for EPA to bypass statutory cancellation and suspension requirements under §§ 6(b) & (c) is a question of law that does not turn on the views of the parties involved in the registration negotiations. Finally, EPA cannot claim it was prejudiced by relying on Registrants' agreement to the voluntary cancellation provisions because it had and still has the statutory authority to "quickly remove[]" the product "from the marketplace," Response Br. at 2, through a suspension order under § 6(c). There is no "prejudice" in being required to follow statutory due process.

The Board noted that it routinely receives appeals from parties challenging provisions of their permits, and that parties typically cannot reopen permits to challenge their terms years later. EAB Tr. 102:8-103:9. The Board is very familiar with appeals of permits issued under the Clean Water Act, the Clean Air Act, and the Resource Conservation and Recovery Act ("RCRA"). Thus, for example, 40 C.F.R. § 124.19 provides that any party (including the permittee) that wishes to challenge a RCRA, National Pollutant Discharge Elimination System ("NPDES"), or Prevention of Significant Deterioration ("PSD") permit must do so within 30 days of the issuance of that permit, and that such challenges are limited to issues raised during the public comment period that preceded the issuance of the final permit. 40 C.F.R. § 124.19(a)(3), (a)(4)(ii). A permittee must timely exhaust this right to an administrative appeal as a "prerequisite to seeking judicial review of the final agency action," 40 C.F.R. § 124.19(l)(1), which must in turn be brought within 120 days from the date of the challenged final determination, 33 U.S.C. § 1369(b)(1). Because a permittee is expressly provided a window of opportunity to seek administrative and then judicial review of the terms of its permit, the permittee is precluded by statute from later challenging those same terms in defense of an enforcement action brought by EPA. *See, e.g., United States v. CPS Chem. Co.*, 779 F. Supp. 437, 441 (E.D. Ark. 1991) (holding that because the statutory right to review NPDES limitations

"arises at the time of the issuance of the permit," the statute "precludes judicial review of permit limits in proceedings brought for their enforcement").

Unlike these statutes, FIFRA does not require public notice and comment on a proposed registration decision, and EPA did provide that for flubendiamide. FIFRA does not expressly limit legal challenges to issues raised in comments, or provide a statutory window for registrants to challenge selected conditions of a registration. Instead, FIFRA provides a "take it or leave it" choice. Registrants must ultimately accept the registration EPA offers or forgo registration, request a denial order, and pursue administrative remedies under § 3(c)(6) and § 6. In granting registrations, EPA takes pains to preclude registrants from pursuing other options.[33]

Finally, Registrants should not be equitably barred from contesting lawfulness when they followed the administrative path that EPA signaled was available. EPA recognized Registrants' right to an administrative hearing to contest cancellation (even if it identified the wrong type of hearing) when it issued the registrations in 2008[34] and again in its 2016 NOIC,[35] and Registrants should not be punished for having exercised that right here.

8. Registrants Provided EPA More Than Sufficient Notice That They Objected to Cancellation Because of EPA's Failure to Engage in the Required Scientific Dialogue.

The Board asked Registrants to provide record citations showing where Registrants raised legal objections to the adequacy of the scientific dialogue in their Request for Hearing and

[33] *See, e.g.*, PBNX 7 at PBN0002 (Notice of Registration, "release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the [PAL]"); PBNX 8 at PBN0020 (PAL, "release for shipment . . . constitutes acceptance of the conditions" and "[i]f either Nichino or Bayer does not agree with *any* of the conditions of registration, they should consider any such registration *to be null and void*.") (emphasis added).

[34] PBNX 7 at PBN0002 ("[T]he registration will be subject to cancellation in accordance with section 6(e) of FIFRA.").

[35] PBNX 20 at PBN0103 ("If a hearing is requested by an adversely affected party, a hearing shall be conducted in accordance with FIFRA section 6(d) and 40 CFR part 164.").

Statement of Objections ("Objections," ALJ Dkt. #1). As detailed on pages 23-24 of Registrants' Appeal Brief, the Objections allege that EPA "committed [through the PAL] to review the data generated and submitted by the registrants, and to engage in discussion with the registrants about the data and EPA's conclusions," Objections ¶ 71; contain detailed allegations regarding EPA's withholding of information at the December 15, 2016 "final" meeting and the Agency's sudden disclosure that it was reverting to the 0.28 ppb endpoint the very next day, *id.* ¶¶ 87-92, 111-112; describe and attach the December 16, 2015 email from Registrants objecting to the lack of transparency, *id.* ¶ 93; and allege that EPA acknowledged its own lack of transparency and "unfortunate" timing at the January 6, 2016 meeting, *id.* ¶ 96.

In addition, Registrants identified as a legal objection in the Statement of Objections portion of its filing that "The Sudden Switch to the Lower Endpoint Undermined Transparency and Precluded Appropriate Review." *Id.* at 52. That section describes in detail how EPA's lack of transparency and "maneuvering" "undermined a years-long transparent process of scientific review and exchange . . . and *precluded the registrants from addressing EPA's most critical scientific position before it was presented to the Assistant Administrator*," detailed EPA's efforts to obscure and shield from review its endpoint positions in the Decision Memorandum, and concluded that "[t]his level of obfuscation is antithetical to scientific and regulatory transparency." *Id.* ¶¶ 175-181 (emphasis added). These allegations and objections put EPA on notice that Registrants were raising legal objections to the adequacy of the scientific dialogue and satisfied the requirements of 40 C.F.R. § 164.22(a) to "clearly and concisely set forth such objections and the basis for each objection, including relevant allegations of fact concerning the pesticide under consideration."

In the face of these detailed objections, EPA contends that Registrants did not "assemble

those factual contentions into a claim upon which relief could be granted" and did not articulate "a cause of action." Response Br. at 26. This misses the mark. Registrants were stating objections to the NOIC, not filing a complaint. Likewise, the special pleading rules for stating defenses based on a denial that conditions precedent were met under Fed. R. Civ. P. 9(c), on which the ALJ relied, do not apply to objections under 40 C.F.R. § 164.22(a). Even if they did, they are not as stringent as EPA and the ALJ suggest and would not preclude Registrants' argument that EPA failed to engage in the dialogue required under the voluntary cancellation provision. *See, e.g.*, *Myers v. Cent. Fla. Invs., Inc.*, 592 F.3d 1201, 1224-25 (11th Cir. 2010) (rejecting a technical argument regarding noncompliance with Rule 9(c) and looking to allegations throughout the answer to conclude that the failure to satisfy the condition precedent was stated with sufficient particularity).

CONCLUSION

At oral argument, the Board acknowledged the "importance and complexity of the issues in this case." EAB Tr. 6:16-20. The complexity is a result of EPA's actions in devising the "voluntary" cancellation provisions to circumvent required cancellation process; reaching a cancellation determination that ignored sound science, including the very data it required Registrants to generate; thwarting transparency by withholding and obscuring its conclusions; and contorting the facts, law, and process in self-serving arguments in an effort to avoid ever having to defend the substance of its cancellation and existing stocks determinations and the lawfulness of its cancellation approach on the merits. The resolution, however, is simple. The Board should follow the plain language of FIFRA § 6, find the "voluntary" cancellation provisions unlawful, and remand the case to EPA to pursue cancellation and suspension, if it wishes, through §§ 6(b) & (c).

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 1st day of July, 2016, a true and correct copy of the foregoing Post-Argument Brief of Bayer CropScience LP and Nichino America, Inc. was filed electronically using the EPA EAB eFiling System; and served in the following manner to the below addressees:

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