UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

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

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INTRODUCTION

The Registrants requested this hearing to challenge EPA's proposed cancellation of flubendiamide registrations through a "voluntary" cancellation condition EPA imposed as part of a multi-step condition of the registrations. Based on the Tribunal's prehearing rulings, the issues to be resolved before this matter proceeds to review by the Environmental Appeals Board are: (i) whether EPA fulfilled its obligations to engage in measured scientific dialogue on the data and EPA's conclusions before demanding that the Registrants request voluntary cancellation, and (ii) whether EPA's proposed existing stocks provision is consistent with FIFRA.

The Agency did not engage in the required transparent, measured scientific dialogue. Instead, EPA withheld critical information from the Registrants and provided its conclusions, including new modeling and analysis implementing a revised endpoint, on the same day as its cancellation demand. Thus, the "voluntary" cancellation condition was never properly triggered and the Agency's proposed cancellation must be denied.

EPA's proposed existing stocks provision is contrary to its own existing stocks policy, is based on an unlawful intent to punish Registrants for invoking statutory rights provided by FIFRA, was made without any effort to gather relevant information on existing stocks, and relies on an assertion by EPA that it did not consider risks and benefits that is neither consistent with FIFRA nor credible. If cancellation is approved despite Registrants' challenge, the Tribunal should find that the evidence supports allowing the limited amount of existing stocks to move through the channels of trade to avoid the risks and costs of collection and disposal without beneficial use.

ARGUMENT

I. EPA DID NOT FULFILL OBLIGATIONS THAT WERE REQUIRED AS A PREREQUISITE TO ISSUING A VOLUNTARY CANCELLATION DEMAND.

A. EPA Was Required to Engage in Open, Measured Scientific Dialogue Before Demanding Cancellation.

Throughout this proceeding, EPA has treated the forced "voluntary" cancellation condition as if it were a stand-alone provision requiring the Registrants to voluntarily cancel the registrations within one week upon notice that EPA had determined that continued registration of flubendiamide would cause unreasonable adverse effects. The parallel cancellation provisions at Sections 6(d) & 8(d) are, in fact, part of the larger, multi-step process described in Sections 6 and 8 of the Preliminary Acceptance Letter ("PAL"). PBNX 8 at PBN0018-20.

This process, as Ms. Lewis confirmed on cross-examination, imposes certain obligations on EPA, including requiring the Agency to "complete its review" of the data required by the PAL and "any additional data and supporting information voluntarily submitted" by the Registrants, and requiring that "EPA scientists and Bayer scientists shall engage in dialogue about the data and the Agency's conclusions." *Id.* at PBN0019; Hearing Transcript ("Tr.") 43:8-44:20. The 2008 email correspondence between EPA and Bayer confirmed that the voluntary cancellation demand "can only occur after the conditions of part 5(b) and 7(b) [which became Sections 6(b) and 8(b)] have been met," including "a **measured** dialogue between the scientists." RE 4 at 200036 (emphasis in original); *see also* Tr. 51:16-52:2 (Ms. Lewis confirming that "we must have measured dialogue . . . during the process," including "discussion of any issue or concern between scientists").

The testimony and evidence show that EPA did not engage in a good faith, "measured dialogue" among scientists regarding the data and EPA's conclusions, and had no intent to do so once the Agency decided to proceed toward cancellation. Thus, the voluntary cancellation demand was not properly made. EPA refused to engage in transparent scientific dialogue and refused to present its unreasonable adverse effects conclusions for discussion, likely because it

feared that open scientific discussion of its conclusions would undermine the cancellation action EPA wished to take, regardless of the science.

B. EPA Did Not Engage in a Measured Dialogue on the Data.

A measured dialogue is impossible without transparency. The fact that meetings occurred between EPA and Bayer scientists does not show that the required scientific dialogue occurred. As Ms. Sanson testified, until December 2015, discussions between EPA and Bayer were focused on EPA's plan to extend the registrations for three more years, the data EPA would require the Registrants to generate during that time, and potential mitigation to address EPA's conservative risk assessment. PBNX 116 at 10:14-17, 11:7-12:12, 13:18-23. EPA did not engage in similar discussions regarding its decision to cancel. Instead, in the Fall of 2015, the discussions changed from a decision following the science, to the science following the decision.

Notably, EPA held a high level meeting on December 15, 2015 between the Registrants and Assistant Administrator Jones and asked the Registrants to prepare a final mitigation proposal for the Agency's consideration, without telling the Registrants that EPA was reverting to a toxicity endpoint that was 70 times lower than the one which had been the basis of the parties' ongoing discussions. On *the very next day*, EPA discussed the new endpoint *without* the Registrants at a separate, internal meeting. PBNX 116 at 14:4-22; PBNX 14; Tr. 126:9-16 (Ms. Sanson). As Bayer objected at the time, the "benthic organism endpoint was the basis of our many meetings and discussions thus far" and "the foundation for all the risk analyses Bayer prepared and EPA reviewed and discussed with Bayer." PBNX 14. EPA "never told Bayer that it was changing the endpoint or even that EPA was reevaluating the endpoint." *Id.* This "lack of clarity and disclosure undercuts the integrity of our prolonged scientific discussions and renders them useless." *Id.* EPA did not respond to Bayer's email inquiry, and the endpoint choice and method in which it was used were not discernable until *after* EPA made its cancellation demand.

EPA's decision to actively withhold relevant information in meetings held on the eve of EPA's proposed cancellation action confirms that the Agency had no intent to engage in the open, measured scientific discussion required by the PAL. Instead, this sudden, undisclosed change was undertaken "to ensure that EPA could continue to 'predict' exceedances of levels of concern even after making overdue and necessary corrections to its theoretical modeling," and to achieve the "preordained, political result" of cancelling the flubendiamide registrations, regardless of the science. PBNX 116 at 16:21-17:4; PBNX 14.

The January 6, 2016 final meetings between EPA and the Registrants were an effort by EPA to paper the record after the fact and do not cure the lack of dialogue. On January 6, EPA belatedly presented part of its ultimate position, relying on the new lower endpoint among other levels of concern and on its overly conservative theoretical modeling. EPA acknowledged that "things were 'very dynamic' and the timing of its change was 'unfortunate,'" and tried to explain why its activities "had not been visible to the registrants or any other stakeholders." PBNX 116 at 17:19-23. At an afternoon regulatory meeting, the Registrants requested a "level playing field" and expressed their concerns about the lack of transparency. In response, Ms. Lewis indicated that the "decision to cancel" was "a very high level decision" being made at the political level. Tr. 71:17-72:9, 91:16-92:2 (Ms. Lewis); *id.* 127:1-5 (Ms. Sanson).

Neither meeting provided the required good faith scientific dialogue. As Mr. Johnson testified, the discussion on extending the registrations "got abruptly stopped in late September, early October," the endpoint discussion "was not a transparent discussion at all," and the "good faith back and forth dialogue" typical of conditional registrations "seemed to stop . . . almost like a light switch" once the decision became political and EPA turned off the scientific discussion and turned on its cancellation engine. *Id.* 185:1-13, 186:1-187:1, 189:4-10. Ms. Sanson likewise

testified that "the expiration date was moved out to December, and that's when suddenly we found out that the science division of EPA, they're assessing us using a decision endpoint that . . . was suddenly lower, 70 times, . . . and it changed everything, and it just wasn't transparent to us. There was no communication to us that that was going to happen." *Id.* 126:8-16.

In the February 5, 2016 letter declining EPA's cancellation demand, the Registrants objected not only to EPA's efforts to implement the unlawful forced "voluntary" cancellation condition, but also that EPA had "abruptly shifted course," was "ignoring" the relevant study in favor of a lower endpoint, was "discount[ing] the real world monitoring data, conducted as EPA directed and required," which showed no exceedances of even the potential new lower level of concern, and was "ignor[ing] the significant benefits flubendiamide provides." PBNX 18 at 2-3. The Registrants expressed their continued willingness to "address the science in a transparent and methodical way," *id.* at 3, an offer that EPA declined by announcing its Notice of Intent to Cancel ("NOIC") on March 1, 2016 without any further discussions.

C. EPA Did Not Engage in a Measured Dialogue on Its Conclusions.

A measured dialogue on conclusions is impossible when the conclusions are not revealed until the conversation is over. The record reflects that EPA failed to provide Registrants with its conclusions and its unreasonable adverse effects determination for open scientific discussion before demanding voluntary cancellation.[1] At the December 15, 2015 meeting, Assistant

[1] EPA also did not discuss its evaluation of the benefits of flubendiamide or its cancellation decision with IR-4, USDA's Office of Pest Management and Policy, or any of the specialty crop commodity associations before issuing its January 29, 2016 cancellation demand or its March 4, 2016 NOIC. PBNX 26 at 1 (March 28, 2016 Letter from IR-4 to EPA). IR-4 is "a unique federal/state cooperative research program in the United States that is funded by the US Congress to develop data to support registrations of crop protection products on specialty crops and minor uses." *Id.* IR-4 received 21 Requests for Assistance to expand the flubendiamide registrations and has invested significant resources to support expansion of flubendiamide registrations. *Id.* at 1-2. Most recently, flubendiamide related projects were designated "highest priority" by growers through a formal priority-setting process managed by IR-4. IR-4 had

Administrator Jones indicated that EPA would provide its cancellation decision "by the end of the day on December 18, 2015," and stated that EPA could choose to allow the registrations to expire automatically on December 18 absent any further action by EPA. PBNX 116 at 14:1-15. Thus, EPA's decision-makers either were not aware of or did not feel bound by the Agency's obligation to engage in measured dialogue on its conclusions before demanding cancellation.

Contrary to the cancellation provisions, EPA ultimately provided its conclusions, in the form of the unreasonable adverse effects determination *and* its demand that Registrants voluntarily cancel their registrations, both on the very same day, thus foreclosing any meaningful dialogue on EPA's conclusions. PBNX 30 (Decision Memorandum (Jan. 29, 2016)); PBNX 17 (Demand Letter (Jan. 29, 2016)). On the same day, EPA provided a 52-page Ecological Risk Assessment Addendum ("ERAA") dated January 28, 2016 that contained new analysis, conclusions, and modeling by the Agency (PBNX 31), and a January 29, 2016 Addendum to Clarify Invertebrate Terminology, which sought to redefine and broaden the scope of EPA's stated concerns regarding aquatic invertebrates (PBNX 32). The Registrants were in the process of reviewing this new information and analysis on February 5, 2016, when they were required to respond to EPA's request to voluntarily cancel. PBNX 18.

The January 28, 2016 ERAA presented and relied on new modeling data and results that had not previously been disclosed to the Registrants. PBNX 31 at PBN0871-79 (App. 1). Moreover, the Decision Memorandum and ERAA provide no explanation or justification for the Agency's sudden decision to revert to the 70 times lower toxicological endpoint, despite the

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embarked on a $1.2 million research project and had already begun studies when EPA announced its January 2016 cancellation decision. *Id.* at 2. Yet EPA did not discuss its evaluation of the benefits of flubendiamide or its cancellation determination with IR-4. Ms. Lewis, EPA's sole witness and the author of the January 29, 2016 Decision Memorandum recommending cancellation, was not even aware of IR-4's letter objecting to EPA's cancellation decision and lack of consultation. Tr. 93:3-8.

significance of the change and the Registrants' objections that EPA was acting without transparency or opportunity for discussion. PBNX 14. The 0.28 ppb endpoint from the des-iodo spiked water study that drove the cancellation decision is simply identified by EPA as one of a "Final Suite of Available Effects Endpoints," alongside the scientifically more appropriate endpoint from the des-iodo spiked sediment study of 19.5 ppb. PBNX 30 at PBN0847 (Table 1); PBNX 31 at PBN0862 (Table 5); PBNX 116 at 15:10-16:23. Only by examining the underlying modeling and comparing it to EPA's statements regarding exceedances can one discern that EPA actually based its cancellation decision on the 0.28 ppb endpoint.[2] That EPA's lack of transparency on a central scientific issue extended to the very document that purported to explain the basis for its conclusions is the antithesis of open, measured, scientific dialogue and confirms that EPA has not complied with the provisions of the voluntary cancellation condition.

D. There Must Be Some Limit on EPA's Discretion to Demand Cancellation.

The Registrants requested this hearing to challenge, among other things, whether EPA's unique and unprecedented insistence that the Registrants either accept the "voluntary" cancellation condition or be denied registration was an unlawful circumvention of required statutory suspension and cancellation process under FIFRA § 6, 7 U.S.C. § 136d. The Tribunal found EPA's approach lawful, and if that ruling stands, EPA could require a similar "voluntary" cancellation condition as a prerequisite to issuing almost every registration going forward.[3] In that case, the provision requiring the Agency to review all data and engage in open, measured scientific dialogue on the data and conclusions before demanding cancellation will be the only

[2] *Compare, e.g.*, PBNX 30 at PBN0850 (contending that "[t]he tree nut scenario proposed by the [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 (tree nut assessment showing claimed exceedances based on 0.28 ppb endpoint in upper right graph).

[3] *See, e.g.*, Tr. 143:22-144:3 (Mr. Johnson) ("[F]rom my experience with Nichino America, all of our registrations have been conditional.").

restraint on EPA's discretion to cancel registrations on the Agency's whim and say-so, regardless of the science. These provisions therefore must be implemented and enforced in a substantive fashion. Where, as here, EPA actively withholds information from the Registrants that is critical to its cancellation decision, provides its conclusions, analysis, and modeling simultaneously with its cancellation demand, and does not explain or even describe a change in the critical endpoint driving the cancellation determination in its decision document, the Agency cannot be permitted to invoke and enforce the voluntary cancellation condition.

II. EPA'S PROPOSED EXISTING STOCKS DETERMINATION IS CONTRARY TO EPA'S POLICY, ARBITRARY AND CAPRICIOUS, AND NOT CONSISTENT WITH FIFRA.

A. EPA Did Not Follow Its Own Existing Stocks Policy.

The evidence presented at the hearing proves that EPA's existing stocks proposal, which prohibits any sale or distribution of existing stocks held by the Registrants, distributors, or retailers, is inconsistent with EPA's Existing Stocks Policy (PBNX 52, the "Policy"). Ms. Lewis testified that the Agency's prohibition is consistent with EPA's policy providing that "if a registrant fails to comply with a specific condition . . . the Agency does not believe it is generally appropriate to allow any further sale and distribution by the registrant after the registration is canceled." RE 10 at 14. However, that is EPA's policy for cancellations for failure to comply with obligations of registration "where the agency *does not have significant risk concerns* with respect to the cancelled pesticide." PBNX 52 at PBN1554 (emphasis added). Under Section III.A.1, governing all "[c]ancellations where [EPA] has identified particular risk concerns," the Policy calls for a "case-by-case" determination and directs EPA to conduct "an analysis of the risks and benefits of the distribution, sale, and use of existing stocks." *Id.* at PBN1553; Request for Hearing and Statement of Objections ¶¶ 205-10; Opp. to Mot. to Limit Scope of Testimony at 6-7. EPA's failure to even acknowledge this portion of its own Policy, let alone explain its

departure from the Policy to punish Registrants for exercising their statutory rights, is an abuse of discretion.[4]

Registrants understand that the Tribunal previously ruled that FIFRA permits but does not require EPA to take risks and benefits into account when reaching an existing stocks determination. Registrants respectfully disagree. While the Policy provides some discretion as to which particular risk-benefit "criteria" the Agency "may" consider, it directs that the "risk/benefit analysis *will be an important factor* in the Agency's determination of *whether or not* to allow distribution, sale, and use of existing stocks of cancelled pesticides raising risk concerns." PBNX 52 at PBN1553 (emphasis added). EPA does not have the discretion to ignore risks and benefits in its existing stocks determination for a product for which the Agency has identified risk concerns.[5] EPA's existing stocks determination, which purports to ignore risk-benefit considerations altogether, is therefore inconsistent with EPA's Policy.

B. EPA's Punitive Existing Stocks Determination Is Arbitrary and Capricious.

EPA's decision to base its existing stocks determination on a desire to punish Registrants for exercising their statutory rights was arbitrary and capricious and should be overruled. The evidence reflects that: (i) Registrants had a good faith basis to contest EPA's cancellation determination; (ii) EPA never sought information from Registrants on the amount of flubendiamide available at the time cancellation was sought; (iii) EPA could have made a risk-benefit based existing stocks determination without delay; (iv) EPA instead ignored entirely the impact that its existing stocks determination would have on growers who depend upon the product; and (v) EPA declined to exercise the only lawful means for immediately stopping

[4] *See Ravulapalli v. Napolitano*, 773 F. Supp. 2d 41, 53 (D.D.C. 2011) ("An administrative agency may be said to have acted arbitrarily or capriciously when it disregards its established policy without adequate explanation.") (citing *INS v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1996)).

[5] This portion of the Policy is *not* limited to the cancellation of unconditional registrations.

Registrants from selling flubendiamide while the cancellation proceeding was pending, a suspension order under FIFRA § 6(c), 7 U.S.C. § 136d(c).

While EPA never asked Registrants to stop producing and selling flubendiamide during the cancellation proceeding, EPA now seeks to punish Registrants for their lawful sale of flubendiamide during that process. What EPA disparages as "delay" is in fact the Registrants' lawful exercise of their statutory rights in defense of their registrations.[6] EPA did not and could not have denied Registrants the right to seek this hearing and challenge the cancellation and existing stocks determinations because that is a right guaranteed by law. EPA acknowledged this in discussions and communications with Registrants in January 2016 and again in the NOIC.[7]

EPA argues that a risk-benefit analysis of its existing stocks determination would have been too time and resource intensive and would have delayed "closing the tap" on further production and sale of flubendiamide, when the evidence suggests otherwise. At the time EPA made its existing stocks determination, the Agency had *already* undertaken and completed a risk-benefit analysis as part of its determination that flubendiamide presented unreasonable risks of adverse effects on the environment. Ms. Lewis was both the author of that risk-benefit analysis and the EPA official responsible for the existing stocks determination.[8] Ms. Lewis never

[6] In a troubling exchange during cross-examination of Nichino's President, Jeffrey Johnson, EPA's counsel went even further, asserting that the Agency would be justified in holding Bayer and Nichino to a different and more stringent standard than other registrants going forward because of their refusal to voluntarily cancel here. *See, e.g.*, Tr. 158:17-159:2 ("Now, if Nichino came in today with an application similar, one that showed promise but in which the Agency saw significant potential risks . . . do you think that EPA would be less likely to [grant] that registration than yours in 2008?"); *see also id.* 169:13-19 (suggesting that EPA should take Bayer and Nichino's refusal to request cancellation into account when establishing future existing stocks provisions for the companies' registered products).

[7] PBNX 116 at 17:16-18:11; PBNX 20 at PBN0103 ("If a hearing is requested by an adversely affected party, a hearing shall be conducted.").

[8] *See* PBNX 30 (Decision Memorandum); RE 10 at 13 ("I made the determination for how to handle the existing stocks of flubendiamide with the OCSSP management team.").

explained what the delay would have been in applying the risk-benefit analysis from her Decision Memorandum to the question of existing stocks.

Tellingly, when EPA made its existing stocks determination, it had not sought any of the types of production and sales information from Registrants that would have addressed its unfounded concerns that Registrants would flood the market while cancellation proceeded. Tr. 52:12-53:13 (Ms. Lewis). Had the Agency done so, it would have learned that Nichino had ceased production in September 2015 and that Bayer had placed one final order in February 2016 and would be able to produce somewhat less flubendiamide in 2016 than in 2015. Tr. 173:19-174:14 (Mr. Johnson); PBNX 116 at 22:11-16. Far from flooding the marketplace, both Registrants were proceeding with caution in anticipation that EPA might cancel the registrations. Nor did EPA consider at all the extent to which a punitive existing stocks determination would harm the growers who depend upon the product for insect control. Tr. 54:2-9 (Ms. Lewis).

If EPA's aim was truly to stop flubendiamide production, speeding through an existing stocks determination without any substantive deliberation is not the appropriate way to do so. Congress provided EPA a mechanism for promptly "closing the tap" on a pesticide – suspension under FIFRA § 6(c) – but it is only available when the Agency makes an "imminent hazard" finding, and not when the Agency decides to threaten punitive action. EPA had just completed its unreasonable adverse effects determination, including the Decision Memorandum and supporting documents, and if the Agency believed that the harm it predicted from further use of flubendiamide was "imminent," it could and should have sought a suspension order.

EPA's arbitrary and capricious decision in the NOIC to punish Registrants for taking actions that it concedes are lawful, based on unsubstantiated accusations of delay that Registrants could easily have disproven had they been provided the opportunity, should be rejected as

inconsistent with FIFRA. The actual impact – and thus the presumed intent – of EPA's existing stocks determination, if allowed to stand, will be to discourage aggrieved registrants from exercising their statutory rights under FIFRA. Registrants will face the false choice of forgoing their right under FIFRA to a § 6 hearing or becoming a target for punishment for contesting a cancellation demand. Neither result is what Congress intended when it established the § 6 hearing process for the express purpose of reviewing EPA cancellation determinations.[9]

C. EPA's Claim That It Did Not Consider the Risks and Benefits of Sale and Distribution of Existing Stocks Is Not Credible.

EPA seeks to exclude risk-benefit considerations from the existing stocks determination based on Ms. Lewis's testimony that the decision to ban sale and distribution of existing stocks was based "solely" on EPA's determination that "Registrants intentionally reneged on a commitment to cancel their registrations." RE 10 at 14, 16. This exclusion is artificial. As a practical matter, Ms. Lewis and other EPA decision-makers could not erase from their minds EPA's unsound determinations that use of flubendiamide results in unreasonable adverse effects, is already causing "adverse impacts," and provides minimal, if any, benefits compared to alternatives. PBNX 30 at 9-10. Further, the claim that EPA "solely" considered its punitive goals is not credible because it is contradicted by Ms. Lewis's own testimony and EPA's representations to this Tribunal.[10]

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[9] When Congress intends to empower a federal agency with the discretion to take actions that will not be subject to judicial review for abuse of discretion, it does so explicitly. *See, e.g.*, 21 U.S.C. § 346a (establishing that the Administrator's determination of priorities for the review of pesticide tolerances established before passage of the Food Quality Protection Act of 1996 "shall not be subject to judicial review" other than for a failure to act).

[10] *See* RE 10 at 13 (stating that the punitive purpose was "*[a]mong the reasons* we determined not to allow any further sale or distribution") (emphasis added); Tr. 56:13-14 (Ms. Lewis) ("The rationale *we put in* [the NOIC] was we did not want to reward additional production.") (emphasis added); *see also* Motion to Limit at 3 (contending in successive paragraphs that EPA "has made no determination in regard to the risks posed by existing stocks" other than stocks held by end users, and that EPA "*believes* that use of flubendiamide causes

EPA has a strong incentive to contend that it did not consider risks and benefits in prohibiting sale and distribution – to shield its evaluation of flubendiamide from even the streamlined review that could occur in a FIFRA § 6(e) hearing on an existing stocks provision. However, the distinction EPA seeks to draw is undermined by EPA's own conflicting statements and the impossibility of ignoring its own beliefs in reaching that conclusion.

D. EPA's Existing Stocks Determination Is Inconsistent with FIFRA.

EPA's decision to pursue a punitive existing stocks determination is not just at odds with governing Agency policy, it is inconsistent with the plain language of FIFRA. FIFRA is a risk-benefit statute. The Registration Standard established by Congress requires EPA to consider and weigh the health and environmental risks of a pesticide against potential economic, social, and environmental benefits.[11] When a conditionally registered product is cancelled, the statute permits the continued sale and use of existing stocks of that product "if the Administrator determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment." FIFRA § 6(e)(1), 7 U.S.C. § 136d(e)(1).

The fact that the existing stocks provision is permissive, *see* § 6(e)(1) ("The Administrator may permit the continued sale and use of existing stocks . . ."), does not mean that EPA has unreviewable discretion to craft existing stocks provisions, or can lawfully issue an existing stocks provision that is arbitrary and capricious or inconsistent with FIFRA. Here, EPA chose to exercise its discretion and permit the use of products in the hands of end users, while prohibiting sale or distribution of other existing stocks. For EPA to draw that line on existing stocks without considering the risks and benefits of the product is arbitrary and capricious and

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unreasonable adverse effects on the environment and *that sale and distribution of existing stocks would not pass the risk-benefit test under FIFRA*") (emphasis added).

[11] *See, e.g.*, *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005) (citing *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 532 (9th Cir. 2001)).

contrary to FIFRA's core standard and the express language of § 6(e)(1).

E. Registrants Were Prejudiced in Their Ability to Contest EPA's Existing Stocks Determination.

Based in part on EPA's representations that the Agency did not consider flubendiamide's risks and benefits in determining to prohibit sale of existing stocks to or by retailers and distributors after cancellation,[12] the Tribunal excluded the testimony of all four of Registrants' expert witnesses, portions of the testimony of their fact witnesses, and a number of related exhibits as irrelevant to the § 6(e) cancellation hearing. Among the evidence excluded were the substantive findings of EPA's Biological and Economic Analysis Division's review of Registrants' benefits submission, the Registrants' expert testimony assessing the flaws of that analysis, and fact and opinion testimony demonstrating that a proper weighing of risks and benefits would warrant a broader existing stocks determination.

Having successfully excluded evidence on the risks and benefits of its existing stocks provision, Respondent then offered testimony on these same subjects. During redirect, counsel for Respondent directed Ms. Lewis to explain her conclusion that cancellation would leave little product in the hands of growers. For the first time, Ms. Lewis admitted that EPA had "consulted with our experts in the Biological and Economic Analysis Division" on its existing stocks proposal, despite prior representations that the proposal was purely punitive. Tr. 80:3-4 (Ms. Lewis).[13] If EPA did consider risks and benefits information in determining to prohibit sale and distribution of existing stocks, then under the Tribunal's Order, the Agency opened the door to a hearing on that issue, and Registrants' previously excluded evidence should be admitted.

[12] *See, e.g.*, Motion to Limit at 3 (representing that EPA "did not base the existing stocks determination in the Notice of Intent to Cancel *on risk-benefit or scientific issues*, and will not be offering *any testimony* in this proceeding on whether the sale and distribution of existing stocks would cause unreasonable adverse effects on the environment") (emphasis added).

[13] Counsel for Registrants objected to this testimony about a risk-benefit analysis EPA claimed not to have considered, that Registrants were precluded from challenging. Tr. 80:7-12.

Otherwise, Registrants will have been denied the ability to present evidence on the risks and benefits of permitting the continued sale of existing stocks, when EPA was not.

F. The Agency Should Permit Sale and Distribution of Existing Stocks in the Hands of the Registrants, Distributors, and Retailers.

Because risk-benefit evidence and considerations of disruption to growers and harvests were excluded, the only relevant information on existing stocks provided at the hearing was: (i) that the Registrants did not pack the channels of distribution, but instead limited production for 2016 to levels that were less than 2015, resulting in a limited amount of product to move through the channels of trade, PBNX 116 at 22:11-16; PBNX 117 at 15:1-9; PBNX 118 at 3:20-21; Tr. 173:19-175:6 (Mr. Johnson), and (ii) that Nichino's existing stocks are not registered for sale outside the United States and will need to be collected and disposed of as waste, creating additional environmental risk that will not be offset by beneficial use. Tr. 173:12-15, 174:19-175:1.[14] These facts alone justify an existing stocks provision allowing for sale, distribution, and use of the limited existing stocks available at the time of cancellation.

CONCLUSION

For the reasons stated above, the Tribunal should find that EPA did not engage in the measured, transparent scientific dialogue on the data and the Agency's conclusions required by the PAL, and should deny EPA's proposed cancellation of flubendiamide. In the alternative, the Tribunal should find EPA's proposed existing stocks determination contrary to EPA's policy, arbitrary and capricious, and inconsistent with FIFRA, and should allow distribution, sale, and use of the limited existing stocks in the hands of the Registrants, distributors, retailers, and growers as of the date of cancellation, to allow for an orderly transition and avoid environmental risks caused by collection and disposal of the product without beneficial use.

[14] A similar question was not posed to Bayer's witnesses.

Dated: May 19, 2016

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 19th day of May, 2016, a true and correct copy of the foregoing Post-hearing Brief of Bayer CropScience LP and Nichino America, Inc. was filed electronically using the EPA OALJ e-filing system; and served in the following manner to the below addressees:

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