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All,

Please find attached the Notice of Exceptions and Appeal Brief filed by Bayer and Nichino today before the Environmental Appeals Board in the above-captioned matter.

Regards,

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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	)	

APPEAL BRIEF OF
BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

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INTRODUCTION

Bayer CropScience LP and Nichino America, Inc. (collectively, "Registrants" or "Appellants") seek reversal of a remarkable series of extreme Administrative Law Judge ("ALJ") rulings. These rulings not only condoned the Environmental Protection Agency's ("EPA," "Appellee," or "the Agency") unlawful and unjustified proposed cancellation of flubendiamide, but also would ensure that Registrants, other stakeholders here, and future petitioners upon whom similar registration conditions are imposed, are barred at every stage from arguing the merits or presenting substantive evidence challenging EPA's cancellation determination and existing stocks provision, and that EPA can take substantial regulatory actions affecting numerous stakeholder rights and interests without any transparency or review. As specified in the Notice of Exceptions, Registrants appeal:

(i) the ALJ's April 25, 2016 Order denying Appellants' Motion for Accelerated Decision and finding lawful forced "voluntary" cancellation provisions that EPA imposed to circumvent statutory due process and cancel the flubendiamide registrations based on an unsound unreasonable adverse effects determination ("MAD Order," ALJ Dkt. #24);

(ii) the ALJ's May 3, 2016 Order granting Appellee's Motion to Limit Scope of Testimony and excluding as irrelevant evidence Registrants sought to enter regarding the risks and benefits of flubendiamide, despite the ALJ's subsequent reliance on EPA's determinations on those issues in the Initial Decision ("MTL Order," ALJ Dkt. #27); and

(iii) the ALJ's June 3, 2016 Corrected Initial Decision finding Registrants did not comply with the "voluntary" cancellation provisions and that EPA's determination limiting the use of existing stocks was consistent with FIFRA ("Initial Decision" or "CID," ALJ Dkt. #39).

Unless reversed, these rulings will allow EPA to proceed with cancellation of flubendiamide based on unsound regulatory and scientific determinations that have not been and will not be subject to *any* independent scientific, administrative, or judicial review. Such a result is contrary to the rigorous cancellation and suspension process Congress required under § 6, 7 U.S.C.

§ 136d, of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and would undermine the integrity and reliability of EPA's cancellation process.

EPA's proposed cancellation of the flubendiamide registrations is also not consistent with FIFRA's substantive no "unreasonable adverse effects" risk-benefit Registration Standard and would not survive review on the merits. FIFRA §§ 3(c)(5)(C)-(D) & 2(bb), 7 U.S.C. §§ 136a(c)(5)(C)-(D) & 136(bb). Flubendiamide products provide excellent, selective (targeted) control of lepidopteran pests (caterpillars), are critical tools for Insect Resistance Management ("IRM") and Integrated Pest Management ("IPM"), have low toxicity to beneficial insects and most other taxa, and have an excellent environmental and human health safety profile in their own right and compared to existing alternatives. Flubendiamide's cancellation as proposed by EPA would abruptly remove from growers' toolset a targeted, effective insecticide that they rely on to protect their crops and will encourage the use of more costly and disruptive alternatives.

Moreover, the ALJ's rulings would embolden EPA to impose and require other forced "voluntary" cancellation provisions and to make similar punitive existing stocks determinations that ignore EPA policy and pertinent facts, yet are unchallengeable. This would render the cancellation, suspension, and existing stocks due process protections established under § 6 available only at EPA's whim, which is utterly contrary to basic principles of due process. For the reasons stated below, the Environmental Appeals Board ("EAB") should reverse the ALJ's rulings, deny the proposed cancellation of the flubendiamide registrations, and require EPA to follow the cancellation process outlined under FIFRA §§ 6(b)&(d), 7 U.S.C. §§ 136d(b)&(d), if

the Agency wishes to cancel the registrations based on its unreasonable adverse effects determination.[1]

ISSUES PRESENTED FOR REVIEW

A. May EPA lawfully force registrants to accept "voluntary" cancellation provisions as a condition of registration that are designed to allow EPA to evade statutory due process and cancel registrations based on a subsequent unreasonable adverse effects determination, without following the process Congress required under FIFRA §§ 6(b),(c),&(d), 7 U.S.C. §§ 136d(b),(c),&(d), and without subjecting its cancellation determination to any independent scientific or administrative review?

B. If found lawful, did EPA comply with the provisions requiring the Agency to engage in measured scientific dialogue with Registrants on the data and its conclusions before demanding cancellation, when EPA withheld crucial aspects of its position on the data and toxicological endpoints in its discussions and issued its non-transparent conclusions simultaneously with the cancellation determination?

C. Did the ALJ err in finding irrelevant and excluding evidence related to the risks and benefits of flubendiamide products, where EPA based its cancellation on an express unreasonable adverse effects determination, where Registrants prepared evidence and testimony on the scientific unsoundness of that determination in a streamlined form compatible with the

[1] Registrants' concerns and objections are shared by the broader community of pesticide registrants who rely on the procedural protections guaranteed by FIFRA and depend on transparent and lawful registration and cancellation procedures, as well as growers who rely on flubendiamide and other pesticide products and depend on scientifically sound decisions based on the risks and benefits of their products. *See* CropLife Amicus Br. (ALJ Dkt. #10); Growers' Amicus Br. (ALJ Dkt. #8). The ALJ's rulings ignore the concerns articulated by CropLife about the broader implications of EPA's cancellation rulings and the detailed information the Growers provided regarding the benefits of flubendiamide, its positive environmental and human health safety profile, and the disruption and harm that would be caused by its sudden removal from the marketplace.

accelerated FIFRA § 6(e), 7 U.S.C. § 136d(e), hearing schedule, and where the ALJ's Initial Decision nonetheless repeatedly cites and relies on EPA's unreasonable adverse effects findings to justify EPA's cancellation determination and approach?

D. Did the ALJ err in excluding documents and cross-examination regarding the fact that many registrations held by Reckitt Benckiser that EPA sought to cancel through a § 6(b) proceeding were conditional, contradicting the ALJ's ruling that the *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011), decision prohibiting EPA from evading statutory cancellation process is distinguishable because it "involve[d] general registrations, not conditional registrations" and finding that cancellations of conditional registrations can occur "only under FIFRA Section 6(e)"? MAD Order at 23 & 24 n.21.

E. Is EPA's existing stocks determination, which would allow use of existing stocks in the hands of end-users but prohibit sale and distribution by anyone to "punish" Registrants for their "noncompliance," consistent with FIFRA, where EPA misapplied its own policy, failed to obtain any relevant information on the quantity and location of existing stocks, and did not consider the risks and benefits of allowing further sale and distribution of the limited existing stocks and the agricultural harm the sale and distribution ban would cause?

F. Did the ALJ err in concluding that, when EPA issues an existing stocks determination, stakeholders have no right to challenge it as too restrictive, despite the fact that "whether the Administrator's determination with respect to the disposition of existing stocks is consistent with" FIFRA is a "matter[] for resolution" in a FIFRA § 6(e) hearing?

FACTUAL AND PROCEDURAL BACKGROUND

The factual and procedural background, including flubendiamide's regulatory history and pertinent FIFRA statutory provisions, is set forth in detail in Registrants' Motion for Accelerated

Decision ("MAD," ALJ Dkt. #12) at 4-55 and the written testimony of Ms. Sanson, PBNX 116 at 2:18-20:13.

ARGUMENT

I. THE FORCED "VOLUNTARY" CANCELLATION PROVISIONS ARE UNLAWFUL.

The fundamental question in this proceeding is whether EPA can devise and impose "voluntary" cancellation provisions as purported conditions of registration that allow EPA to cancel registrations based on a subsequent unreasonable adverse effects determination without following the process required by FIFRA §§ 6(b),(c),&(d). The unlawful cancellation scheme EPA seeks to implement through this proceeding would evade FIFRA's requirements for independent scientific peer review and interagency consultation and preclude challenge or review of the merits of the Agency's decision by registrants, growers, other stakeholders, this Tribunal, and the federal courts. Shielding EPA's scientific and regulatory determinations from required review not only denies due process rights guaranteed by law, it undermines the integrity of the regulatory process and the goals of FIFRA by allowing the Agency to announce and enforce cancellation of pesticide products based on determinations that are inconsistent with the science and the FIFRA Registration Standard and would not survive objective review. Federal courts have rejected similar attempts to circumvent required cancellation process and the EAB must do the same here.[2]

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[2] *See, e.g.*, *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1136 (D.C. Cir. 2010) (finding that the district court had jurisdiction to review whether EPA could "bypass[] cancellation proceedings" by deeming registered products "misbranded" and subject to enforcement actions); *Reckitt Benckiser*, 762 F. Supp. 2d at 43, 49 (ruling that EPA cannot use the misbranding scheme to "bypass" FIFRA § 6 requirements); Request for Hearing and Statement of Objections ("Objections") Exhibit 26 (ALJ Dkt. #1.02) at 3-7, 9-11 (registrant's December 7, 2015 brief in *NRDC v. EPA*, No. 14-73353, objecting to EPA's attempt to "short-circuit" the cancellation process by asking the Ninth Circuit to summarily vacate certain pesticide registrations);

A. EPA Cannot Cancel Registrations Based on an Unreasonable Adverse Effects Determination Without Following the Process Required by FIFRA §§ 6(b),(c)&(d).

Courts have recognized that registrants hold property rights in their registrations, and that registrations cannot be cancelled without due process of law, including the specific statutory cancellation procedures Congress established under FIFRA §§ 6(b)-(e), 7 U.S.C. §§ 136d(b)-(e). *See* MAD at 16-19, 46-47; *Reckitt Benckiser*, 613 F.3d at 1133 ("A FIFRA registration is a product-specific license."); *Bell v. Burson*, 402 U.S. 535, 539 (1971) (property interests cannot be annulled without due process of law). FIFRA's cancellation requirements are not optional and go beyond the minimum rights guaranteed under general due process law. Congress "establish[ed] a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration." *See Reckitt Benckiser*, 762 F. Supp. 2d at 42 (emphasis in original).

By the plain terms of FIFRA § 6, if EPA determines that registrations should be cancelled because their use "generally causes unreasonable adverse effects on the environment" (the "Registration Standard"), EPA *must* issue a notice of intent to cancel ("NOIC") and follow the process provided by Congress in FIFRA §§ 6(b)&(d) and 25(d), 7 U.S.C. §§ 136d(b)&(d) and 136w(d), including consulting with the United States Department of Agriculture and providing EPA's determination for independent scientific peer review by the Scientific Advisory Panel, all *before* issuing the NOIC, and providing registrants the right to contest the determination *on the merits* in a full administrative hearing. MAD at 17-18, 47. These statutory provisions are "not ambiguous" and creative approaches EPA may devise to "bypass[] cancellation proceedings" are entitled to no deference. *Reckitt Benckiser*, 762 F. Supp. 2d at 43, 49 (quoting *Reckitt Benckiser*, 613 F.3d at 1136).

Objections Exhibit 27 (Ninth Circuit's January 25, 2016 Order denying vacatur and remanding for administrative proceedings).

It is undisputed that EPA seeks to cancel flubendiamide based on a substantive – albeit incorrect – determination that "the risks of allowing the continued use of flubendiamide outweigh the benefits, and will result in unreasonable adverse effects to the environment." PBNX 30 at PBN0852. By statute, EPA must proceed with the full §§ 6(b)&(d) cancellation process if it wishes to cancel flubendiamide based on those grounds. EPA has refused to do so, and has sought to evade any independent scientific or administrative review of the merits of its cancellation determination, showing an utter disregard for its obligation to provide the hearing process and rights required by law. If the ALJ's Order finding EPA's "voluntary" cancellation provisions lawful is confirmed, EPA would be free to take advantage of its great power over applicants and to adopt this approach for any registration it wishes in the future, rendering the statutory right to § 6(b) cancellation proceedings available only at the Agency's discretion.

B. EPA's Use of the "Voluntary" Cancellation Provisions Is an Unlawful Attempt to Evade Statutory Process.

EPA seeks to implement its cancellation action through forced "voluntary" cancellation provisions that EPA imposed on Registrants by refusing to grant the registrations without them. These provisions were devised to allow EPA to demand immediate cancellation of flubendiamide based on a future unreasonable adverse effects determination, and if Registrants refused, to convert EPA's cancellation determination into a failure by Registrants to satisfy a condition of registration, which the Agency could then pursue through § 6(e)'s streamlined cancellation provisions. EPA would thereby evade required peer review, avoid input from other stakeholders, including federal agencies, and deny the substantive hearing on the merits to which Registrants are entitled under § 6(b).

EPA's unlawful approach is designed to achieve quick cancellation without any opportunity for substantive challenge, whether Registrants chose to comply with a "voluntary"

cancellation demand (and thereby lose their registrations) or object (and face cancellation under § 6(e) for failure to comply with a purported condition of registration). EPA even claims that if the provisions are found unlawful, the registrations should be found void in their entirety (and thus effectively cancelled). MAD Opp. (ALJ Dkt. #17) at 38. In their essence, the provisions are a deliberate and unlawful EPA effort to evade statutorily required process.

EPA claims that the provisions were necessary to "allow the product to be quickly removed from the market-place if EPA's concerns were unresolved" and that "the ability to quickly cancel the registration[s] was an important factor in EPA's decision to grant the registration[s]." RE 10 at 200100. EPA's claim that the provisions were needed to protect the environment is a pretext. Neither EPA nor the ALJ offers *any* response to Registrants' repeated argument that the provisions are unnecessary and unjustified, particularly in light of FIFRA § 6(c), 7 U.S.C. § 136d(c), which allows EPA to issue an order "suspend[ing] the registration of the pesticide immediately" when necessary to prevent an "imminent hazard" during the time needed to complete the cancellation process, provides a *faster* way to remove products from the marketplace than EPA's scheme, and dictates the process EPA *must follow* to remove products before cancellation is completed. Objections ¶¶ 61-63, 156-58, 212; MAD at 19, 53, 67; MAD Reply (ALJ Dkt. #19) at 5-7. EPA's briefs and its sole witness ignore the existence and significance of the § 6(c) suspension provisions entirely. The ALJ mentions Registrants' suspension argument only in passing, and does not respond to it or explain how the "voluntary" cancellation scheme could be necessary or lawful in light of the statutory suspension provisions. MAD Order at 14 n.16; CID at 33.

The actual rationale for EPA's scheme is quite different – the Agency feels that the statutory suspension and cancellation process is too time-consuming and burdensome, and would

subject it to the risks attendant to a substantive challenge. MAD Opp. at 53 (§ 6(b) cancellation "is slow and resource-intensive compared to a FIFRA section 6(e) proceeding"); PBNX 128 at PBN1911 ("[D]eclar[ing] an imminent hazard" would "either raise unnecessary legal risks or would require significant amounts of time and agency resources when compared with the section 6(e) hearing process we are pursuing."). EPA cannot deny statutory due process and shield its determinations from required public transparency and review because it finds following the law too risky and burdensome.

The ALJ's rulings affirming EPA's approach wrongly rely on EPA's unsupported claim that the "voluntary" cancellation scheme was necessary to protect the environment from potential harm and ignore the existence of § 6(c) and its requirements. They also deny Registrants the right to present their substantive evidence and testimony, as Registrants could under a proper suspension and cancellation proceeding, showing that EPA's adverse effects determination is wrong on the science and that flubendiamide poses no actual current, imminent, or future unreasonable adverse effects on the environment.

C. EPA Lacks Authority to Impose "Conditions" of Registration That Require Registrants to Give Up Cancellation Rights.

The ALJ's superficial analysis concludes that EPA has authority to impose the "voluntary" cancellation provisions based on FIFRA § 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C), which authorizes EPA to issue registrations conditioned on the generation and submission of additional data, on the condition that the data must not "exceed risk criteria enumerated in regulations . . . , *and on such other conditions as the Administrator may prescribe*." MAD Order at 24 (emphasis added by ALJ). However far EPA's discretion to impose "other conditions"

under FIFRA § 3(c)(7)(C) may extend,[3] it must fall short of the ability to demand the right to circumvent specific statutory cancellation rights and procedures and deny registrants, other stakeholders, and even the ALJ, EAB, and federal courts the right to challenge or review EPA's cancellation determination as Congress intended. MAD at 48; MAD Reply at 8.

Instead of acknowledging any bounds to this general discretion, the ALJ takes the extreme position that "[t]he term 'other conditions' in the statute is *in no way limited*," and thus that EPA's discretion to devise and impose conditions of registration is unlimited and unreviewable. MAD Order at 24 (emphasis added). This cannot be correct. EPA could not, for example, decide that the application fees specified by Congress in FIFRA § 33, 7 U.S.C. § 136w-8, were too small to address budget shortfalls, and impose conditions of registration requiring applicants to pay twice the specified fees or forgo registration. So too the Agency cannot devise and require applicants to accept conditions giving EPA the right to achieve future cancellation on demand, where Congress has established a detailed cancellation process and requirements, including a suspension provision to specifically address any need to "quickly remove" products from the market that could pose an imminent environmental hazard.

D. The ALJ Bases Its Ruling on the False Conclusion That Conditional Registrations Can Only Be Cancelled Under § 6(e).

The ALJ asserts that § 6(b) "makes no mention of conditional registrations," that "conditional registrations are not entitled to the same lengthy procedures for cancellation under Section 6(b)," that "[c]ancellations of conditioned registrations fall under Section 6(e)," and that

[3] Despite the lengthy discussion in the MAD Order at 24-27, and unlike the plaintiffs in *Woodstream Corp. v. Jackson*, Civil Action No. 11-867 (JEB), 2011 WL 8883395, at *5 (D.D.C. June 3, 2011), Registrants do not contend that EPA's authority to impose conditions is strictly limited to conditions requiring the submission of data. That does not mean EPA's discretion is boundless or that EPA can exercise it in ways that contradict and undermine its statutory obligations. EPA's forced "voluntary" cancellation provisions here go beyond what Congress authorized because, among other things, they are non-substantive and impose a purported condition that Registrants cannot satisfy without relinquishing their registrations.

"the plain language of the statute entitles Petitioners to a cancellation proceeding only under FIFRA Section 6(e)." MAD Order at 22, 24 & n.21 (citing *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174, 177 (D.D.C. 2012)). The ALJ further contends that "[t]he few cases that Petitioners cite to support their claim that EPA is required to go through a Section 6(b) proceeding . . . are all clearly distinguishable from the facts of this case because they involve general registrations, not conditional registrations." *Id.* at 23.

These conclusions are apparently drawn from the Amicus Brief filed by the Center for Biological Diversity ("CBD"), which has no practical familiarity with FIFRA registration and cancellation provisions, and the *Woodstream* decision, which, among other things, misunderstands the facts of *Reckitt Benckiser*. They go beyond anything EPA has advocated,[4] and are contradicted by EPA's prior practice, including in a recent ALJ cancellation proceeding that EPA initiated as required by the *Reckitt Benckiser* decisions. If correct, the ALJ's interpretation of the statute would have perverse results – it would leave EPA with no means of cancelling a conditional registration for grounds independent from existing conditions of registration, such as evidence that real-world use was causing unanticipated adverse effects. Registrants' Resp. to CBD Amicus Br. (ALJ Dkt. #23) at 3-4.

At the hearing, Registrants sought to cross-examine Ms. Lewis using documents confirming that EPA pursued cancellation of at least six conditional registrations held by Reckitt Benckiser under § 6(b), and to question Ms. Lewis about those facts based on her personal experience with that matter and about EPA's position on its authority to cancel conditional registrations under § 6(b), but the ALJ sustained an objection to the exhibits and cross-

[4] *See* MAD Opp. at 49-50 (contending that EPA has "discretionary authority" to cancel conditional registrations through § 6(b) *or* § 6(e), which begs the question of why EPA would ever choose the more onerous approach). EPA did not file a response to CBD's brief to correct CBD's inaccurate assertions.

examination on the Reckitt Benckiser proceeding as "irrelevant." Corrected Hearing Tr. ("Tr.") (ALJ Dkt. #32) 60:10-67:7. At the ALJ's direction, Registrants provided the proposed exhibits for the ALJ's review during the hearing. Registrants also provided oral and written offers of proof explaining that the documents confirm, among other things, that half of the registrations at issue in the Reckitt Benckiser proceeding were conditional, that EPA nonetheless sought cancellation under § 6(b), and that the *Reckitt Benckiser* decisions and cancellation proceedings cannot be distinguished on the grounds that they involved "general registrations, not conditional registrations." Tr. 64:17-67:8; Offer of Proof (ALJ Dkt. #34) at 18-20; PBNX 124-126 (excluded as irrelevant).

The excluded documents and cross-examination are plainly relevant to the scope and nature of EPA's authority to cancel conditional registrations under §§ 6(b) & 6(e), which is a fundamental issue in this proceeding. They relate to, and correct, facts that the ALJ found relevant and cited in support of the ruling finding EPA's cancellation approach lawful. If admitted, they would have shed light on EPA's shifting positions regarding its cancellation authority, and on their face they undermine the ALJ's novel position that EPA's approach was lawful because cancellation of the conditional flubendiamide registrations could *only* proceed under § 6(e). It was a plain and prejudicial error for the ALJ to exclude the exhibits and cross-examination and to fail to revisit that ruling or the erroneous MAD Order after reviewing the documents.

E. The Statutory Language and EPA's Prior Representations Confirm That Cancellations Based on Unreasonable Adverse Effects Determinations Are Governed by § 6(b).

Contrary to the ALJ's reading, the statute by its plain terms does not limit § 6(b) to unconditional registrations. Instead, it provides that a decision to cancel any type of registration based on a determination by EPA that use of the pesticide "generally causes unreasonable

adverse effects on the environment" will proceed under § 6(b), while § 6(e) provides the process for cancellation of conditional registrations where EPA "determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed . . . or . . . at the end of the period provided for satisfaction of any condition imposed, that condition has not been met." FIFRA §§ 6(b)&(e). The different procedures exist not because conditional registrations are, as the ALJ wrongly infers, inherently suspect,[5] but because § 6(b) cancellations involve complex EPA scientific and regulatory determinations that are beyond a registrant's control, go to the core of the FIFRA risk-benefit Registration Standard, and merit peer review, consultation, and a full hearing on the merits, while § 6(e) cancellations involve a registrant's own actions and purported failure to comply with specific requirements, and are thus typically amenable to more streamlined review.

EPA itself recognized in statements to the ALJ in the Reckitt Benckiser proceeding that the cancellation procedures under FIFRA are differentiated by the nature and grounds for the cancellation proceeding, not the registration's status as conditional or unconditional. In a brief in that proceeding, EPA recognized that "the provisions governing risk-based cancellations and

[5] *See, e.g.*, MAD Order at 24 (finding that "a 'conditional registration' is not equivalent to a full registration; it is a stop-gap status" that is "analogous to obtaining a learner's permit"); CID at 36 (contending that "the Administrator took a leap of faith and took advantage of the 'middle ground' by allowing flubendiamide to be conditionally registered . . . to Petitioners' clear benefit, as the Administrator could have simply denied the application based on then-existing data that suggested environmental risk"). The flubendiamide registrations were not granted "on a leap of faith," but based on consideration of the risks *and* benefits of the product and the required express findings that "use of the pesticide is in the public interest" and *will not* cause "any unreasonable adverse effect on the environment" while the conditions are being satisfied and additional data generated. FIFRA § 3(c)(7)(C); PBNX 21 at PBN0106, 110. Conditional registrations must meet the same health and safety standards under FIFRA, and EPA routinely grants conditional registrations to obtain additional data or impose required mitigation and safety measures. *See, e.g.*, PBNX 116 at 2:19-6:12 (Ms. Sanson, describing EPA's affirmative findings in issuing the registrations); Tr. 143:21-144:3 (Mr. Johnson, noting he did not find "anything unusual" in the conditional registrations because "from my experience with Nichino America, all of our registrations have been conditional").

suspensions" are found in §§ 6(b) & (c), and that "products cancelled pursuant to section 6(b) have been determined to pose unreasonable risks to man or the environment that require that they be removed from commerce," while "a section 6(e) cancellation is about the *registrant's* failure to meet its obligations, and not about a problem with *the pesticide product itself*."[6] EPA's "voluntary" cancellation provisions obliterate this distinction and would allow streamlined cancellation based on a unilateral EPA unreasonable adverse effects determination about a product's risks and benefits, while precluding any substantive review of the merits of EPA's cancellation decision. Neither EPA nor the ALJ has explained how that result can be squared with EPA's prior representations to the ALJ.

F. Registrants Are Not Required to Vindicate Their Due Process Rights Through Premature Challenges or Straw Man Applications.

Despite the ALJ's unexplained assertions to the contrary, EPA's refusal to grant the registrations without the "voluntary" cancellation provisions presented Registrants with a Hobson's choice[7] of accepting conditions designed to bypass the cancellation process or receiving no registrations at all. MAD at 52; MAD Order at 27. Having invested more than $125 million to develop and obtain the flubendiamide registrations,[8] Registrants had no realistic choice but to accept the conditions and trust that EPA would base any future registration or

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[6] EPA's Conditional Opposition to CropLife America's Motion to File Amicus Brief at 4 n.2 & 5, Dkt. #24, *In re Reckitt Benckiser*, FIFRA Dkt. #661 (May 6, 2013) (excerpted at PBNX 126) (available in public docket, excluded from hearing as irrelevant) (emphasis in original).

[7] A Hobson's choice is a purported "choice" that involves taking what is offered or taking nothing, named after a livery stable owner that offered customers the "choice" of taking the horse in the stall nearest the door or taking none at all. Hobson's Choice, https://en.wikipedia.org/wiki/Hobson%27s_choice.

[8] The ALJ downplays this investment by suggesting that "[t]he record is unclear" whether the amounts invested by Bayer and Nichino "are shared or overlap one another." CID at 8 n.18. The written testimony is clear that the $60 million in sunk costs by Bayer and the $65 million in sunk costs by Nichino and its parent were "spent" by each entity and do not overlap. PBNX 117 at 3:20-22; PBNX 118 at 2:21-23.

cancellation determination on the science it was requiring Registrants to develop.[9] The alternative EPA and the ALJ propose – that Registrants should have asked EPA to deny the registrations, forgoing what would likely be years of sales of an innovative new product for the chance to mount a premature, facial challenge to a provision that would only become relevant if EPA chose, years later, to issue a cancellation determination contrary to the data and science – is not a realistic or meaningful "option."[10] Registrants should not be found to have forfeited their rights based on an optimistic view of EPA's commitment to sound science and transparent cancellation determinations.

The MAD Order and the *Woodstream* decision on which it relies fail to confront the inherent contradiction between their rulings approving EPA's cancellation shortcuts and the fundamental principle confirmed in the *Reckitt Benckiser* decisions that EPA cannot invent and implement "creative" cancellation approaches to bypass specific cancellation processes required by FIFRA. *See Reckitt Benckiser*, 762 F. Supp. 2d at 42, 49; *Reckitt Benckiser*, 613 F.3d at 1136. Although the automatic expiration conditions considered in *Woodstream* are not at issue here, *Woodstream* never addresses why imposing such conditions on existing registrations to achieve cancellation based on an unreasonable adverse effects determination without required cancellation process is any more lawful than the "misbranding" scheme concocted by EPA and

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[9] The fact that Registrants "played an active part in drafting the conditions," MAD Order at 27, and were able to successfully negotiate away from the even more draconian automatic "expiration" provision EPA first proposed, MAD Reply at 10-12; RE 4 at 200020-43, does not change the utter disparity in bargaining power between a regulated entity and a regulatory agency threatening to withhold a license that entity needs to market its innovative new product, or the fundamental nature of EPA's requirement that Registrants accept a "fast death" cancellation provision or receive no registrations at all.

[10] EPA could only invoke the condition based on a future unreasonable adverse effects determination, and, as Ms. Sanson testified, Bayer would have voluntarily cancelled the registrations if the science supported EPA's unreasonable adverse effects determination. PBNX 116 at 8:7-9:2.

rejected by the *Reckitt Benckiser* decisions. The MAD Order and the *Woodstream* decision likewise fail to explain why registrants should be required to file straw man applications to defend due process rights in registrations they already hold, or why it would serve administrative or judicial efficiency to require them to do so.

Finally, the ALJ wrongly assumes that EPA would have made good on its due process obligations had Registrants sought to vindicate their rights in some other fashion. *See, e.g.*, MAD Order at 27 (finding that Registrants were not denied cancellation rights because they could have accepted the registrations with the conditions and then submitted a request to amend the registrations to remove them, or sought immediate judicial review of the conditions imposed under FIFRA § 16, 7 U.S.C. § 136n. The record suggests otherwise. When faced with a registrant invoking due process rights, EPA routinely seeks to sidestep its obligations, typically by asserting that the rights claimed are only available in some other proceeding or at some other time.

For example, EPA argued in the Reckitt Benckiser cancellation proceeding before the ALJ that registrants' right to challenge existing stocks provisions is limited only to § 6(e) cancellation proceedings based on failure to comply with a required condition of registration. PBNX 126 at 4 n.2. The ALJ agreed.[11] Faced with such a hearing, EPA now claims that where there is an allegation that registrants failed to meet required conditions, as will always be the case in a § 6(e) hearing, the Agency has unreviewable discretion to ban sale and distribution of existing stocks without regard to any risk-benefit considerations as a punitive measure and to encourage compliance. Motion to Limit ("MTL") (ALJ Dkt. #18) at 3. If the ALJ's ruling approving this approach is not reversed, EPA and the ALJ will have assured that there is no

[11] Order on Reckitt Benckiser's Motion for an Expedited Determination at 18-19, Dkt. #41, *In re Reckitt Benckiser*, FIFRA Dkt. #661 (Feb. 3, 2014).

situation in which stakeholders could meaningfully invoke their statutory right to challenge an existing stocks provision, effectively eliminating an explicit statutory right for the Agency's convenience.

Similarly, the briefs in *Woodstream* make clear that Woodstream in fact asked EPA *twice* to amend its registrations. Rather than providing a path to a denial hearing under FIFRA § 3(c)(6), 7 U.S.C. § 136a(c)(6), EPA simply ignored the requests and did not respond. MAD Reply at 15 & n.6. There is no reason to believe that EPA would have treated similar efforts by Registrants any differently. Finally, had Registrants sought immediate judicial review under FIFRA § 16, as the ALJ suggests, EPA no doubt would have argued that such an action was barred by their failure to exhaust administrative remedies (by refusing to accept the registrations and demanding a denial hearing) and the lack of final agency action in the form of an order enforcing the condition. Here, where Registrants quickly invoked their administrative rights upon EPA's issuance of the NOIC, and are seeking final agency action before any judicial review, EPA asserts that their challenge is untimely, outside the statute of limitations, and barred by laches. MAD Opp. at 63-65.

The EAB should reject EPA's evasive tactics, apply the statutory provisions as Congress intended, and require EPA to provide the required statutory process if it wishes to cancel the flubendiamide registrations.

II. EPA DID NOT ENGAGE IN MEASURED SCIENTIFIC DIALOGUE ON THE DATA AND ITS CONCLUSIONS AS REQUIRED BY THE CANCELLATION PROVISIONS.

The "voluntary" cancellation provisions EPA invoked to demand cancellation are not stand-alone provisions; they are part of a larger, multi-step process that imposes certain obligations EPA must satisfy before it can demand cancellation. Registrants' Post-Hearing Brief ("RPHB") (ALJ Dkt. #33) at 2; Preliminary Acceptance Letter ("PAL"), PBNX 8 at PBN0018-

20. These include the requirements laid out in the PAL that EPA must "complete its review" of the required data and any other data and information the Registrants submit and "engage in dialogue about the data and the Agency's conclusions" before demanding cancellation. RPHB at 2; PBNX 8 at PBN0019. Because EPA did not engage in good faith in the required scientific dialogue, and instead withheld crucial aspects of its position on the data and toxicological endpoints and issued its non-transparent conclusions using the data in a new way simultaneously with the cancellation determination and demand, EPA's cancellation demand was not properly made and its proposed cancellation should be rejected.

A. The Parties Agree That the Cancellation Provisions Required Open, Measured Scientific Dialogue on the Data and EPA's Conclusions Before the EPA Demands Cancellation.

The ALJ's Initial Decision discounts the impact of the provisions requiring EPA to engage in dialogue on the data and its conclusions through an outcome-driven reading that undermines the provisions' plain purpose, is contradicted by record evidence, testimony and the parties' clear understanding of the provisions' meaning, and only makes sense as a means to uphold EPA's proposed cancellation.

First, the ALJ claims that the provisions do not require the dialogue to occur before EPA makes its cancellation determination, on the thin grounds that PAL provisions 6(d) and 8(d) only explicitly require that EPA's cancellation determination come "*after* EPA's review of *the data*." CID at 30 (emphasis in original). This ignores that each subsection follows in natural chronological order, requiring Registrants to submit the data, EPA to review it, the scientists to engage in the required dialogue, and EPA to then make and implement its registration or cancellation determination. PBNX 8 at PBN0018-20. The ALJ's reading also contradicts the parties' express understanding and the evidence. In a 2008 email, Mr. Halder, then Bayer's Director of Regulatory Affairs, made Bayer's position clear that "a fair cancellation demand *can*

only occur after the conditions of part 5(b) and 7(b) [which became 6(b) and 8(b)] have been met" and EPA did not object. RE 4 at 200036 (emphasis added). At the hearing, EPA's witness Ms. Lewis agreed that the Agency could not issue an unreasonable adverse effects determination and demand cancellation "based on an issue or a concern that EPA *had not previously discussed* with the registrants," and testified that "we must have measured dialogue after – during the process." Tr. 51:16-52:2 (emphasis added); RPHB at 2. The ALJ's suggestion that EPA could satisfy the dialogue requirement by engaging in discussions *after* reaching and issuing its cancellation determination, CID at 30, ignores this evidence and undermines the plain purpose of the dialogue requirement.

Second, the ALJ finds that the PAL "does not in any way explicitly require" that the dialogue be "measured" or "transparent," contending that "the term 'measured' comes *only* from Petitioners' self-generated e-mail communications with the Agency." CID at 30 (emphasis added). This is incorrect. The record shows that EPA did not object to or seek to correct Mr. Halder's bolded and underlined statement of Bayer's understanding of the type of dialogue required. RE 4 at 200036 (noting that the provisions require "a **measured** dialogue between the scientists") (emphasis in original). Ms. Lewis confirmed at the hearing that the dialogue must be "measured." Tr. 51:20-21; RPHB at 2.[12] The ALJ's suggestion that EPA could fulfill its obligations through discussion that was neither "measured" nor "transparent" shows a remarkable willingness to excuse the Agency from its obligations.

[12] *See also* Tr. 105:7-14 (Ms. Sanson, testifying that the dialogue requirement is informed by the email correspondence leading up to the PAL, and noting Ms. Lewis's reference to "measured dialogue"); *id.* 105:19-21 ("[W]e did expect that the science will be discussed and figured out in a fair manner.").

B. The Evidence Shows That EPA Did Not Engage in Good-Faith Dialogue on the Data and Its Conclusions.

The ALJ asserts that there is "no evidence of a lack of good faith" on the part of EPA. CID at 31. To the contrary, the record evidence, including specific testimony and correspondence presented by Registrants and cited in their Post-Hearing Brief, shows that EPA did not engage in good-faith dialogue on the data and its conclusions once it shifted its focus from extending the registrations to cancellation, and that the Agency affirmatively withheld critical positions and conclusions from Registrants to shield those from review and challenge until after a decision was reached. CID at 30-31; RPHB at 3-7.

Registrants provided testimony from Ms. Sanson and Mr. Johnson describing how the open, scientific discussion stopped once EPA shifted its focus and began pursuing cancellation based on a directive coming from a political level within the Agency, including the Assistant Administrator. RPHB at 4-5; *see, e.g.*, Tr. 189:4-10 (noting that the "good faith back and forth dialogue" typical of registration discussions with EPA "seemed to stop . . . almost like a light switch"). This testimony was corroborated by Ms. Lewis's acknowledgment that EPA's timing, withholding of information, and lack of transparency was "unfortunate" and her testimony confirming that the decision to cancel was "a very high level decision" coming from the Assistant Administrator, a political appointee. RPHB at 4; PBNX 116 at 17:1-23; Tr. 71:1-72:9, 91:16-92:2.

Even if one were to disregard this testimony describing the sudden shift away from transparent scientific dialogue – as the ALJ has done[13] – the undisputed facts show that EPA

[13] The ALJ repeatedly misstates the regulatory history in ways that downplay EPA's lack of transparency and suggest that Registrants had sufficient notice and were acting in bad faith to delay cancellation rather than advocating in good faith for continuation of the registrations based on the science. For example, the ALJ contends that after an EPA review of the water monitoring report issued in February 2015, "Petitioners knew their registrations were in jeopardy." CID at

affirmatively withheld critical information regarding the toxicity endpoints in discussions with Registrants held on the eve of a planned Agency cancellation decision:

- On December 15, 2015, EPA held a high level meeting attended by the Assistant Administrator and the CEOs of Bayer and Nichino to discuss EPA's evaluation of flubendiamide, at which Registrants were informed that EPA would reach a decision by December 18, 2015; after the meeting EPA asked the registrants to provide their "best, final mitigation proposal" as soon as possible for use in an internal briefing to the Assistant Administrator the next day. RPHB at 3; PBNX 116 at 14:1-22.
- At that meeting the *very next day*, EPA scientists briefed the Assistant Administrator on the Agency's scientific basis for cancellation using a superseded 0.28 ppb toxicological endpoint that was *70 times lower* than the 19.5 ppb endpoint that was the basis for the risk analyses, scientific review, and discussions between EPA and Bayer in the preceding months. RPHB at 3; PBNX 14.

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32. To the contrary, the record shows that in July and August 2015, *after* the February 2015 review, EPA presented its plan to extend the registrations for three more years to allow generation and review of additional data. PBNX 116 at 11:14-12:12; PBNX 11. The ALJ turns history on its head and paints Registrants in a false light by contending that "Petitioners did not want a few more *months* to submit a response to the toxicity end-points as determined by EPA or final determination [sic]. What Petitioners' wanted, but were not granted by EPA, . . . was another two to three *years* extended to their conditional registration justified based upon the need to undertake even more testing and in the meantime, to sell their pesticide." CID at 32 n.38 (emphasis in original). In fact, it was *EPA* that proposed in August 2015 that the registrations be extended for three more years to allow the generation and review of additional data it requested. PBNX 116 at 11:14-12:12; PBNX 11.

The ALJ contends that "Petitioners, by September 2015, must have suspected the flubendiamide registration was in doubt," as "demonstrated in Nichino's decision to stop making the pesticide." CID at 18. The ALJ cites testimony from Mr. Johnson to suggest that Nichino "became aware" in September 2015 that conversations with EPA were difficult – yet the actual testimony states that Nichino placed the order in September for the 2016 season precisely because at that time, "there were a lot of very positive developments, emails back and forth with EPA discussing the 3-year extension, talking about the different studies that were being agreed to . . . and at that point, we felt that it looked like the registration would continue, and so we made the decision to make some product in September." Tr. 174:2-14.

Perhaps most striking, in the June 1, 2016 uncorrected Initial Decision, the ALJ relied on an inaccurate quote from the rough, uncorrected transcript to suggest that Registrants were "still a little bit concerned, based upon the actual use of the product," but "[n]evertheless . . . believe they are entitled to an unconditional registration." June 1, 2016 Initial Decision (ALJ Dkt. #36) at 17 n.26. The actual testimony was not an admission of risk, but a confirmation that "we're still below levels of concern, based on actual use of the product" as opposed to EPA's theoretical modeling. Tr. 124:18-19. The ALJ corrected the misquote in response to Registrants' Motion to Correct (ALJ Dkt. #37), but did not change the disparaging comment that Registrants "nevertheless" sought unconditional registration. CID at 1 n.1, 17 n.27.

- In months of discussion with Registrants, including at the December 15 meeting itself, EPA "never told Bayer that it was changing the endpoint or even that EPA was reevaluating the endpoint." PBNX 14.

These undisputed facts show that EPA made an affirmative choice to thwart open scientific dialogue, and are clear evidence of "a lack of good faith." By withholding the new endpoint determination and scheduling the meetings in this way, EPA's scientists and regulatory personnel ensured (i) that Registrants were not aware of and could not challenge the sudden reversion to a drastically lower and scientifically unsound toxicological endpoint in the December 15 meeting with the Assistant Administrator, (ii) that the "best, final mitigation proposal" EPA asked Registrants to provide would not reflect or pass the new lower endpoint, and (iii) that EPA's scientists could brief the Assistant Administrator and obtain approval for cancellation based on the new endpoint before Registrants had a chance to review and challenge EPA's positions. EPA provided no alternative explanation for its actions and never responded to Bayer's December 16, 2015 email to the Assistant Administrator about the Agency's lack of transparency. PBNX 14.

Finally, EPA's lack of transparency and good faith cannot be cured by the Agency's decision to hold one last meeting on January 6, 2016. The PAL requires EPA to engage in dialogue on the data *and* its conclusions. PBNX 8 at PBN0019. Not only did EPA refuse to engage in an open discussion at that meeting,[14] EPA presented new analysis, conclusions, and modeling in the January 29, 2016 Decision Memorandum and supporting documents that were not discussed with Registrants and could not have been because they were issued *on the same day* as the cancellation demand. RPHB at 6-7. Moreover, the Decision Memorandum provides no explanation for EPA's decision to adopt the lower endpoint, and does not even explicitly acknowledge that it had done so. *Id.* EPA's failure to mention, let alone justify, its last-minute

[14] *See* Tr. 179:18-180:1.

substitution of a lower endpoint shows that the Agency continues to obscure its positions and conclusions to avoid challenge and thwart scientific dialogue.

C. Registrants Did Not Fail to Object to EPA's Refusal to Engage in the Required Scientific Dialogue.

Relying on the requirement under 40 C.F.R. § 164.22(a) that objections to a notice of intent to cancel "shall clearly and concisely set forth" objections, the basis for them, and "relevant allegations of fact," the ALJ incorrectly held that Registrants failed to object to EPA's lack of transparency in their Objections, and that such arguments are "untimely." To the contrary, the Objections include extensive, detailed allegations objecting to EPA's lack of transparency and refusal to engage in the open, good-faith scientific dialogue required under the PAL.

Registrants alleged 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 (emphasis added). Registrants alleged that "[a]ll subsequent analyses and discussions between the registrants and EPA" after EPA's July 2011 review of the spiked sediment study "were based on a foundation that the level of concern . . . was at the 19.5 or 22 ppb level" until December 2015, when EPA suddenly disclosed that it had reverted to the 0.28 ppb endpoint. *Id.* ¶¶ 111-112. The Objections describe the December 15 and 16 meetings and the change in endpoint, including allegations that EPA scientists "stopped using the directly relevant toxicity endpoint" and "briefed the EPA Assistant Administrator" on December 16 "based . . . on a different endpoint that appeared to be designed to ensure, after the fact, that the registrants' 'final' mitigation proposal would not be sufficient." *Id.* ¶¶ 87-92. The Objections describe and attach the December 16, 2015 email to the Assistant Administrator objecting to EPA's lack of disclosure and describe EPA's subsequent admissions that "the timing

of its change was 'unfortunate'" and EPA's attempts to explain the Agency's "activities . . . that had not been visible to the registrants." *Id.* ¶¶ 93, 96.

Finally, in a section titled "The Sudden Switch to the Lower Endpoint Undermined Transparency and Precluded Appropriate Review," Registrants objected to EPA's proposed cancellation because of EPA's lack of transparency and "maneuvering" that "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.[15] These allegations put EPA on notice that Registrants objected to EPA's refusal to engage in the required scientific dialogue, and Registrants' subsequent arguments on these issues were neither "new" nor "untimely."

III. THE ALJ'S EXCLUSION OF SUBSTANTIVE EVIDENCE ON FLUBENDIAMIDE'S RISKS AND BENEFITS AS "IRRELEVANT" TO THE HEARING WAS WRONG AND PREJUDICIAL.

Having failed to ground its cancellation and existing stocks determinations in sound and defensible science, EPA has attempted at every stage of this proceeding to avoid scientific scrutiny of those decisions. Only days before the evidentiary hearing was to commence, EPA sought and the ALJ granted an order precluding Registrants from presenting their expert and fact testimony and supporting documentary evidence demonstrating that: (1) EPA did not engage in the measured scientific dialogue mandated by the conditions of flubendiamide's registration, (2)

[15] *See also* PBNX 120 at 27:1-28:9 (Dr. Moore, who has more than 25 years' experience conducting risk assessments, including for EPA and Environment Canada, describing as "striking" and "troubling" EPA's lack of transparency in not discussing the critical endpoint or explaining "how and why" it was selected) (excluded as irrelevant).

EPA's risk-based cancellation of flubendiamide was based upon flawed modeling and ignored the real-world monitoring data EPA required Registrants to generate, and was based on an unsound toxicity endpoint, (3) flubendiamide's benefits to agriculture and the environment far outweigh any alleged risk, and (4) prohibiting the sale or distribution of existing stocks of flubendiamide would be highly disruptive and harmful to agriculture. Offer of Proof at 1-17.

This evidence was excluded based on a legally unsound determination that it was irrelevant to the resolution of the disputes permitted in a FIFRA § 6(e) hearing, and EPA's baseless claim that such a hearing could not possibly accommodate "a full and fair hearing on risk-benefit issues." MTL at 5. This evidence goes to the heart of Registrants' challenge to EPA's cancellation and existing stocks determinations and could have been presented without any delay to the already highly streamlined § 6(e) cancellation process.[16] The prejudice resulting from its exclusion from the hearing can only be undone by reopening the evidentiary hearing to admit all of Registrants' excluded written testimony and exhibits.[17]

As reflected in Registrants' Offer of Proof, had Registrants been permitted to introduce their risk-benefit testimony and evidence, they would have established that:

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[16] Less than one of the four days set aside for the hearing was used.

[17] Registrants' testimony and excluded exhibits were provided in the April 22, 2016 Prehearing Exchange (ALJ Dkt. #22) and can be admitted without convening a hearing. Because EPA represented that it would not seek to contest Registrants' risk-benefit evidence or introduce its own evidence on these subjects *even if* the ALJ deemed Registrants' evidence admissible, there is no need to provide EPA additional hearing time to introduce its own evidence or cross-examine Registrants' witnesses regarding flubendiamide's risks and benefits. *See* MTL at 3-4 ("If the Presiding Officer and Environmental Appeals Board do not agree with Respondent that it is consistent with FIFRA that registrants should not benefit from unlawfully refusing to comply with conditions of their registrations, *EPA will not make any further arguments with respect to the sale and distribution of existing stocks*.") (emphasis added); *id.* at 4 ("Respondent will not be contesting in this proceeding any factual issues with respect to whether flubendiamide causes unreasonable adverse effects on the environment."); *id.* at 6 ("Respondent will *neither raise nor contest* in this proceeding scientific or economic issues related to whether flubendiamide causes unreasonable adverse effects on the environment.") (emphasis added).

- EPA's conclusion that flubendiamide and its degradate des-iodo persist and accumulate to toxic levels in the environment was made based upon faulty theoretical modeling and has been disproven by the real-world monitoring studies that EPA required Registrants to conduct. *See* PBNX 119 at 10:3-16:12, 24:3-32:22; PBNX 120 at 10:10-15, 30:3-31:3; Tr. 124:2-19.
- EPA's conclusion based on theoretical modeling that flubendiamide and its degradate would accumulate in freshwater bodies to levels toxic to benthic organisms was the result of EPA's sudden, unwarranted substitution of a toxicity endpoint 70 times lower than the directly relevant and scientifically defensible endpoint that had been used for prior analyses. *See* PBNX 116 at 15:10-16:23; PBNX 119 at 30:13-32:8; PBNX 120 at 14:4-28:9.
- EPA failed to provide defensible explanations for its decisions to ignore real-world monitoring data and substitute a new toxicity endpoint, evidencing the Agency's intent to cancel flubendiamide no matter how flawed the scientific reasoning. *See* PBNX 116 at 15:10-16:23; PBNX 119 at 10:3-16:12, 24:3-32:22; PBNX 120 at 10:10-15, 14:4-28:9, 30:3-31:3.
- EPA's Decision Memorandum downplayed or outright ignored flubendiamide's many demonstrated benefits to growers, the agricultural economy, and the environment. Those benefits include: a good human health and safety profile, highly selective (targeted) efficacy in controlling caterpillar pests, low toxicity to beneficial insects including honeybees and other pollinators, non-systemic activity that minimizes the potential for resistance development, rainfastness and good residual activity that minimize the need for multiple applications, and cost-effectiveness. These attributes make flubendiamide a critical tool for growers practicing IPM to optimize pest control while minimizing pesticide impacts on the environment and the development of insect resistance. *See* PBNX 117 at 4:21-13:7; PBNX 121 at 7:21-15:3; PBNX 122 at 5:18-15:20.
- EPA's Decision Memorandum downplayed or outright ignored the extent to which flubendiamide's cancellation would lead growers to substitute IPM-disruptive compounds with comparatively poor human safety profiles, broad toxicity to beneficial insects such as pollinators, and greater potential for the development of insect resistance. *See* PBNX 121 at 16:6-17:2; PBNX 122 at 16:1-21:10.
- If, beginning in July, flubendiamide may no longer be purchased, growers will lose access to one of the most effective tools for managing caterpillar pests at the time when crops are most vulnerable to those pests. *See* PBNX 117 at 13:9-14:18; PBNX 121 at 17:5-22:8; PBNX 122 at 21:11-23:11.

FIFRA § 6(e) gives Registrants the right to request a hearing to contest EPA's cancellation and existing stocks determinations. The above excluded evidence is relevant to Registrants' challenge to the lawfulness of the "voluntary" cancellation provisions, EPA's compliance with them, and the soundness of EPA's determination to prohibit all sale and

distribution of existing stocks of flubendiamide. The evidence therefore should properly have been admitted. EPA argued, and the ALJ agreed, that because EPA had not grounded its decision to prohibit sale or distribution of existing stocks in a risk-benefit analysis,[18] Registrants should not be able to present evidence demonstrating that such an analysis weighs in favor of a more permissive determination. The fact that EPA unlawfully failed to justify its existing stocks determination based upon a risk-benefit analysis is grounds to reject EPA's determination, not to exclude Registrants' evidence. In granting EPA's Motion to Limit, the ALJ has instead enabled EPA to proceed with risk-based cancellation and existing stocks determinations, without ever actually having to defend the merits of those decisions.

EPA's protestations that a FIFRA § 6(e) hearing could not accommodate "a full and fair hearing on risk-benefit issues" – which the ALJ accepted without question – were demonstrably false at the time EPA made them, and were only further undermined at the hearing. EPA claimed, and the ALJ agreed, that there was not sufficient time in the 97 days set aside for the § 6(e) process for the parties to introduce and the ALJ to weigh the alleged risks of flubendiamide against its benefits. The ALJ reached this conclusion even though EPA had already completed its purported risk-benefit analysis in the January 29, 2016 Decision Memorandum, and Registrants had, in the time available, marshalled their own testimony and evidence demonstrating that EPA's analysis was unsound.

By the time the ALJ issued its exclusionary order, Registrants had already undertaken all the work to prepare and submit written direct testimony for three fact and four expert witnesses and prepared 57 exhibits, much of which addressed the alleged risks and many proven benefits of flubendiamide. In that same time span, EPA prepared direct testimony for a single witness, not

[18] EPA MTL at 3 ("EPA has made no determination in regard to the risks posed by existing stocks held by the registrants, distributors, and retailers.").

because it was incapable of doing more, but because it wanted to avoid any scrutiny of the scientific merits of the Agency's decision-making. EPA claimed there was not enough time in the four hearing days for Registrants to present risk-benefit testimony and for EPA to cross-examine their witnesses. MTL at 5. Registrants explained that four days would be more than sufficient, because the direct testimony was submitted in writing and the hearing was reserved primarily for cross-examination and redirect. MTL Opp. (ALJ Dkt. #25) at 11-12. Registrants were proven correct when the hearing proceeded without any risk-benefit testimony and concluded after little more than half of the first of four days set aside by the ALJ in its Scheduling Order. The schedule could easily have accommodated a streamlined but fair hearing on flubendiamide's risks and benefits in this context. In the supposed interest of preventing an overly long and drawn-out hearing,[19] the ALJ so curtailed Registrants' presentation of their case that the actual hearing ended in the midafternoon of the same day it began.

While EPA's stated concerns were proven to be overblown, every prediction that Registrants made regarding the prejudice that would result from exclusion of this evidence has come to pass. Of greatest concern to this appeal, Registrants predicted that it would be impossible for the ALJ to resolve Registrants' challenges to EPA's cancellation and existing stocks determinations without weighing in on the scientific soundness of EPA's decision-making, and they were proven right when the Initial Decision relied upon faulty Agency scientific findings that Registrants were never permitted to contest. MTL Opp. at 5-6.

For example, in the Initial Decision, the ALJ faulted Registrants for allegedly failing to substantiate their claims with evidence that EPA politics, not actual evidence of risk, "was the motive behind EPA's actions," without ever acknowledging the MTL Order's role in precluding

[19] MTL Order at 10 (holding that "the need to more tightly control evidence admitted at hearing is particularly significant in this case due to the extremely limited time-frame").

Registrants from introducing this very evidence. CID at 31. Even more seriously, the ALJ then backtracked on her commitment not to entertain arguments regarding the merits of EPA's scientific decision-making, by simply accepting the Agency's highly questionable scientific conclusions as established fact. *See, e.g.*, *id.* at 31 ("[T]here is much evidence that ecological risk to benthic invertebrates, derived from the pesticide and its des-iodo persistence in water, sediment, and pore water, drove the finding of unreasonable adverse effects triggering the voluntary cancellation.").

The ALJ's rulings on the lawfulness of EPA's "voluntary" cancellation provisions and proposed cancellation of flubendiamide are explicitly supported by repeated affirmations of EPA's conclusions that flubendiamide accumulates to toxic levels in aquatic environments, which is the heart of the scientific dispute between the Registrants and EPA. For example, the ALJ recites risk determinations and concludes that EPA "could have denied the Petitioners' registration applications [at the outset] based on these concerns." CID at 11. Throughout the Initial Decision, the ALJ uncritically recites in substantive detail EPA's analysis and conclusions with respect to flubendiamide's risks, contrary to the MTL Order excluding these issues as "irrelevant."[20] The Initial Decision even includes a footnote criticizing Registrants for seeking continued registration and sale of flubendiamide "after the submission of their water monitoring study in December 2014 (which evidenced pesticide persistence and accumulation)." *Id.* at 32

[20] *See, e.g.*, *id.* at 10 & n.21 (reciting EPA's initial toxicity and accumulation determinations); *id.* at 17 (reciting EPA's evaluation of the groundwater monitoring results as supporting rather than refuting EPA's risk concerns); *id.* at 20 n.31 (describing a January 29, 2016 EFED Memorandum that purports to expand the scope of identified risk concerns to a broader class of aquatic invertebrates); *id.* at 31 (reciting EPA's conclusions from the January 29, 2016 Decision Memorandum that "[w]ith each successive flubendiamide application, more flubendiamide is transported to aquatic environments via runoff and spray drift where it accumulates and slowly degrades to des-iodo, which in turn accumulates, causing unreasonable adverse effects to aquatic environments.").

n.38. The ALJ does not recite or acknowledge the detailed testimony of Registrants' expert witnesses refuting each and every one of EPA's accumulation and toxicity findings (including the claim that the December 2014 monitoring study "evidenced pesticide persistence and accumulation"); instead, the ALJ excluded such evidence as irrelevant. It was clear error for the ALJ to cite and rely on EPA's risk conclusions throughout the Initial Decision while excluding as "irrelevant" evidence refuting those same conclusions.

The prejudice to Registrants was threefold: they were denied the ability to present any substantive risk-benefit evidence; EPA's substantive risk-benefit evidence was admitted and factored into the ALJ's Initial Decision; and the ALJ allowed this one-sided presentation of the risks and benefits to color her views of flubendiamide products and the outcome of this proceeding. EPA was not prepared to defend the science behind its decision-making, and the ALJ ensured that it would not have to do so. Only an order vacating the MTL Order and reopening the hearing to introduce Registrants' excluded written testimony and evidence can undo the prejudice caused by the ALJ's preliminary order. Absent such relief, Registrants will have been denied a fair opportunity to contest EPA's cancellation determination and existing stocks determination under the process guaranteed by Congress.

IV. EPA'S PUNITIVE EXISTING STOCKS DETERMINATION IS INCONSISTENT WITH FIFRA AND AN ABUSE OF DISCRETION.

The question before the EAB is whether EPA can craft and issue an existing stocks determination in such a way that it is shielded from challenge and judicial review. That cannot and should not be the case. Moreover, Registrants submit that where EPA departs from FIFRA's risk-benefit framework and its own existing stocks policy, refuses to consider any relevant information regarding the quantity of existing stocks and their importance to growers, and issues a purely punitive existing stocks determination, that decision is properly reviewable and should be

overturned as an abuse of agency discretion. EPA argued and the ALJ concluded in her Initial Decision that stakeholders may *never* challenge an EPA determination to prohibit sales of existing stocks of a cancelled product. MTL at 5; CID at 55. This holding would extinguish a critical procedural right guaranteed to registrants and other stakeholders by Congress. It is wrong as a matter of law and must be reversed.

The evidence presented at the hearing demonstrated that EPA should have conducted a risk-benefit analysis before determining whether to permit the sale of existing stocks of flubendiamide. Evidence improperly excluded from the hearing would have shown that the benefits to agriculture and the environment of permitting existing stocks to be sold and distributed outweigh any alleged risks. Registrants therefore request that the EAB enter a decision permitting existing stocks of flubendiamide to clear the chain of commerce, rather than requiring them to be returned to Registrants and disposed of in the environment with no beneficial use.

A. EPA's Discretionary Determination to Prohibit Any Distribution or Sale of Existing Stocks Is Subject to Review for Consistency with the Purposes of FIFRA.

The ability to contest EPA's existing stocks determination is one of the core rights provided to pesticide registrants by Congress under the § 6(e) hearing process,[21] yet EPA and the ALJ's Initial Decision would read this right out of existence. Here, Registrants have sought but been denied the ability to challenge whether EPA's determination to prohibit any sale or distribution of existing stocks by registrants, distributors, or other third parties is consistent with the purposes of FIFRA. In doing so, the ALJ adopted an extreme and unprecedented interpretation of FIFRA § 6(e), which would preclude not only the present challenge, but would deny all registrants of cancelled pesticides "*any* cause of action or remedies . . . where the

[21] FIFRA § 6(e)(2), 7 U.S.C. § 136d(e)(2) (giving registrants the right to request a hearing to challenge "whether the Administrator's determination with respect to the disposition of existing stocks is consistent with [FIFRA]").

Administrator has not made a determination to allow the continued distribution, sale, and use of existing stocks." CID at 35 (emphasis added). This holding is contrary to the purpose and plain language of FIFRA and must therefore be reversed.

FIFRA establishes two considerations to bound EPA's existing stocks determinations: (1) that they be consistent with the purposes of FIFRA; and (2) that they not cause unreasonable adverse effects on the environment. FIFRA § 6(e)(1), 7 U.S.C. § 136d(e)(1). EPA must take these considerations into account when determining *whether or not* to permit the continued sale, distribution, or use of existing stocks. Here, however, EPA erroneously argued and the ALJ accepted that EPA only exercises its discretionary authority when it elects to *permit* sale or distribution of existing stocks, and that EPA's decision to prohibit sale or distribution therefore need not be shown to be consistent with the purposes of FIFRA:

> In this case, the Administrator *has not* exercised her discretion *to permit* the continued distribution, sale and use of existing stocks of flubendiamide, except use of the product presently in the hands of end-users. As such, she need not make any "determination" that continued use and sale is consistent with FIFRA's purposes. Therefore, arguably my query ends here.

CID at 35. In doing so, the Initial Decision not only adopts an "if . . . then" formulation of the relevant statutory provision that is missing from the actual text,[22] but also adopts the logic-defying premise that an Agency determination to permit sale, distribution, or use is reviewable, while a determination not to do so is non-reviewable and *need not even conform to the law under which it was reached and given effect*. Registrants respectfully submit that if determining to permit the sale, distribution, or use of existing stocks is a reviewable discretionary act that must be made consistent with the purposes of FIFRA, then so too is determining to prohibit sale,

[22] Initial Decision at 35 ("The language of the statute indicates that *if* the Administrator desires to exercise her discretion to permit the continued sale or use of existing stocks, *then* she must make a 'determination that such sale or use is not inconsistent' with FIFRA's purposes.").

distribution, or use. Notably, when EPA published its NOIC, EPA admitted as much, stating that "the *disposition of existing stocks* of a cancelled pesticide is at EPA's discretion," drawing no distinction between its discretion to permit or prohibit sale, distribution, or use of existing stocks. PBNX 20 at PBN0104 (emphasis added). The FIFRA Registration Standard considers both risks *and* benefits, and decisions to prohibit sale, distribution, and use of existing stocks, like decisions to permit them, must be made consistent with FIFRA.

FIFRA also guarantees registrants the right to challenge existing stocks determinations in a § 6(e) hearing. FIFRA § 6(e)(2) provides that one of the matters for resolution at the hearing is "whether the Administrator's *determination* with respect to the disposition of existing stocks is consistent with [FIFRA]." 7 U.S.C. § 136d(e)(2) (emphasis added). The statute nowhere limits the scope of the ALJ's review to only those EPA existing stocks determinations permitting sale, distribution, or use of existing stocks, and the ALJ erred when she imposed that limitation.[23]

It is an established rule of statutory construction that "Congress cannot be presumed to do a futile thing," yet that is the very presumption the ALJ made in her Initial Decision when she determined that, despite the plain language of § 6(e), Registrants have no cause of action or remedies available to contest a prohibitive existing stocks determination.[24] Such prohibitive determinations are of course the only determinations that registrants, distributors, retailers, or growers would ever seek to challenge. The Initial Decision's unprecedented interpretation of § 6(e) would therefore effectively extinguish the ability of any registrant or other stakeholder in the chain of commerce to *ever* contest an existing stocks determination.

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[23] The ALJ recognized this in the Scheduling Order and even quoted this very language earlier in the Initial Decision (pp. 32-33).

[24] *See Halverson v. Slater*, 129 F.3d 180, 185 (D.C. Cir. 1997) (citing *Ramah Navajo Sch. Bd., Inc. v. Babbitt*, 87 F.3d 1338, 1344-45 n.6 (D.C. Cir. 1996) ("We will not . . . assume that Congress intended for that jurisdiction[al] [provision] to be meaningless.")).

This interpretation also conflicts with the ALJ's ruling in the Reckitt Benckiser cancellation proceeding, which held that only in a § 6(e) proceeding do registrants have the right to request a hearing on the merits of an existing stocks determination. *See supra* p. 16. Yet the ALJ has now ruled that EPA can issue an unreviewable decision to prohibit sale and distribution of existing stocks whenever registrants fail to comply with a condition of registration, providing a way for EPA to bar registrants from challenging existing stocks determinations in the only circumstances where that right is guaranteed. Had Congress intended to preclude any stakeholder from contesting EPA existing stocks determinations, as the ALJ has now proposed, it would have stated so in the statute. Instead, Congress made clear that *all* existing stocks determinations are properly reviewable for consistency with the purposes of FIFRA.

Even if the ALJ were correct that EPA decision-making is only subject to review when the Agency has determined to permit sale or use of existing stocks, here EPA *did* permit use of existing stocks by end-users.[25] The Initial Decision glosses over this crucial fact without comment.[26] In doing so, EPA subjected its existing stocks determination as a whole to review, even under EPA and the ALJ's exceedingly narrow reading of the scope of a § 6(e) hearing. There is no reason to permit EPA to cabin off the permissive aspects of its existing stocks determination while shielding the prohibitive aspects of its determination from review, as the Initial Decision proposes. If anything, EPA's decision to permit growers' use of existing stocks while simultaneously cutting off the supply of existing stocks to those same end-users raises more questions about the reasonableness and consistency of EPA's exercise of its authority.

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[25] *See* PBNX 20 at PBN0104.

[26] Initial Decision at 35 ("In this case, the Administrator *has not* exercised her discretion *to permit* the continued distribution, sale and use of existing stocks of flubendiamide, *except* use of the product presently in the hands of end-users.") (emphasis added).

B. EPA's Existing Stocks Determination Is Arbitrary, Capricious, and an Abuse of Discretion.

EPA's determination to prohibit any sales of existing stocks of flubendiamide, even by third-party distributors and retailers, is reviewable under the "arbitrary, capricious, abuse of discretion" standard generally applicable to administrative actions.[27] Under this standard, the reviewing court must determine whether the agency has "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). Here, the record reflects that EPA examined *no* data and rendered a punitive existing stocks determination[28] that is inconsistent with the statute and EPA's written policy.

1. EPA's Refusal to Conduct a Risk-Benefit Analysis in Reaching Its Existing Stocks Determination Is Inconsistent with FIFRA.

EPA's determination to prohibit any sale or distribution of existing stocks held by Registrants, distributors, or retailers is inconsistent with FIFRA and the Agency's own Existing Stocks Policy (PBNX 52, the "Policy"). 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. When a conditionally registered product is cancelled, the statute permits the continued sale and use of existing stocks of that product "if

[27] The ALJ's Initial Decision does not identify the operative standard of review.

[28] *See* RE 10 at 200106 (stating that the punitive purpose was "[a]mong the reasons we determined not to allow any further sale or distribution"). While EPA protests that its existing stocks determination was not punitive, that claim is undermined by the Agency's nearly simultaneous accusation that it must prohibit all existing stocks sales so that Registrants are not "reward[ed]" for "having deliberately reneged on a condition of registration." *See* Tr. 56:8-14; EPA's Post-Hearing Brief ("EPHB") (ALJ Dkt. #35) at 11.

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).

The Policy, which is intended to effectuate the purposes of FIFRA and ensure that EPA administers its existing stocks determinations in a consistent and reasoned manner, divides existing stocks determinations into two categories – those involving cancellations "where the Agency has identified particular risk concerns" and those "where the Agency does not have significant risk concerns." PBNX 52 at PBN1553-54. Under Section III.A.1 of the Policy, governing all "[c]ancellations where [EPA] has identified particular risk concerns," EPA is to conduct a "case-by-case determination," including "an analysis of the risks and benefits of the distribution, sale, and use of existing stocks." *Id.* at PBN1553. Here, EPA has requested cancellation as a result of risk concerns regarding flubendiamide,[29] yet relies on a portion of the Policy expressly applicable to cancellations of products where it has no significant risk concerns. Applying the wrong portion of its policy, EPA determined to prohibit any further sale or distribution of existing stocks without ever conducting the requisite analysis of the risks and benefits of permitting continued sale and use of the product.

EPA's unjustified departure from its own policy was an abuse of discretion.[30] Remarkably, neither EPA nor the ALJ's Initial Decision ever addressed this argument,[31] despite Registrants having raised it in *every* legal brief on this subject that they submitted.[32] The Initial

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[29] *See* PBNX 30 at PBN0852 ("[T]he continued use of flubendiamide . . . will result in unreasonable adverse effects to the environment.").

[30] *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)).

[31] Registrants' argument with respect to EPA's departure from its Policy is even omitted from the ALJ's recitation of Registrants' arguments. *See* CID at 33-34.

[32] *See* Objections ¶¶ 205-10; MTL Opp. at 6-7; RPHB at 8-9.

Decision itself cites an inapplicable portion of the Policy[33] and concludes that EPA has acted consistently with that Policy. The ALJ does so even though EPA admits in its Post-Hearing Brief to having departed from its own Policy. EPHB at 11 ("The Agency's existing stocks determination *differs from the Policy* in that it would also generally prohibit third party sale and distribution of cancelled flubendiamide products already in the chain of commerce."). The ALJ never even mentions EPA's important admission in the Initial Decision, even as she defends the Agency's conduct as consistent with its Policy. CID at 36-37.

EPA's failure to properly apply its own policy in reaching its existing stocks determination was an abuse of discretion. The ALJ's failure to address either Registrants' argument that EPA had departed from that policy or EPA's admission that it had is reversible error.

2. EPA's Refusal to Request or Consider Relevant Information Regarding Existing Stocks of Flubendiamide Was Arbitrary, Capricious, and an Abuse of Discretion.

EPA could easily have requested and obtained certain basic information about the existing stocks of flubendiamide from Registrants and other impacted stakeholders to guide its existing stocks determination. EPA declined to do so and instead justified its existing stocks determination on speculation regarding Registrants' motives for seeking this hearing. EPA's failure to consider, let alone provide a rational connection between, the facts regarding flubendiamide existing stocks and EPA's determination to prohibit all sale and distribution was arbitrary, capricious, and an abuse of discretion.

EPA claims to have based its existing stocks determination on a desire to prevent Registrants from being "rewarded" for their refusal to voluntarily cancel by selling more

[33] The portion of the policy cited in the Initial Decision applies to cancellations of conditional registrations "where the Agency does not have significant risk concerns." PBNX 52 at PBN1554.

flubendiamide while the § 6(e) hearing is pending, but never identified any factual basis for this concern. EPA could easily have addressed concerns that Registrants might flood the market during cancellation by promptly requesting information from each Registrant regarding the quantity of product they had manufactured or formulated for sale, the quantity available for sale, and the quantity already sold to distributors and retailers. EPA chose not to do so.[34] EPA instead simply assumed that Registrants declined to voluntarily cancel their registrations to delay cancellation so that they could continue to manufacture and sell flubendiamide.[35] Had EPA inquired, it would have learned, for example, that Nichino had placed its final production order for flubendiamide in September 2015, and that neither Bayer nor Nichino produced any more flubendiamide for sale in 2016 than they had for 2015. PBNX 117 at 15:1-19; PBNX 118 at 3:20-4:2; Tr. 173:16-22. EPA would further have learned that because Nichino's particular formulation is not registered in any other jurisdiction, all existing stocks would need to be disposed of in the environment *without any beneficial use*. Tr. 173:11-15, 174:15-175:1.

EPA further admits to ignoring the economic interests of the distributors and retailers who purchased flubendiamide for resale to growers and applicators.[36] Worse still, EPA ignored the economic interests of the growers who depend on flubendiamide, and who will lose their supply

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[34] *See, e.g.*, Tr. 52:15-53:13 (Ms. Lewis admitting that EPA did not ask Registrants for information regarding the amount of flubendiamide in their own possession or in the possession of end-users, retailers, or distributors).

[35] *See, e.g.*, PBNX 20 at PBN0104 ("[Registrants'] refusal to comply with the condition will likely delay the cancellation for a number of months, during which time they *may* . . . continue to produce, sell and distribute additional quantities [of flubendiamide]."); Tr. 56:13-14 (Ms. Lewis admitting that despite not having sought any information regarding Registrants' production and formulation schedules, "[t]he rationale [EPA] put in [the existing stocks determination] was we did not want to reward additional production").

[36] *See, e.g.*, Tr. 56:20-22 ("Q So, it had to do with the registrants but not with the impact on the retailers. A Right, it was a registrant bonus.").

of this important pesticide at the height of the caterpillar pest season.[37] Because EPA never provided an opportunity for these directly impacted stakeholders to weigh in on its existing stocks determination, the Agency could not and did not take into account the impacts of its punitive determination on those stakeholders.[38] Registrants submit that an existing stocks determination made with no consideration for the impacts on the agricultural economy is arbitrary, capricious, and an abuse of discretion.

3. EPA's Only Basis for Departing from Its Own Policy Is an Unfounded Allegation That Registrants Acted in Bad Faith.

EPA has asserted that Registrants sought this § 6(e) hearing in bad faith.[39] It did so even though it had previously recognized Registrants' right to contest EPA's cancellation decision by seeking a § 6(e) hearing. Further, EPA did so even though it admitted (and as was recognized by the ALJ)[40] that Registrants here challenge a unique and therefore unprecedented condition of registration that was enforced on the same day that EPA made its unreasonable adverse effects finding. PBNX 30 (Decision Memorandum (Jan. 29, 2016)); PBNX 17 (Demand Letter (Jan. 29, 2016)). Registrants requested the hearing because they have a good-faith dispute with EPA over the lawfulness of the "voluntary" cancellation provision and the manner in which it has been

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[37] *See* Offer of Proof at 14 (Dr. Herbert would have testified that EPA's existing stocks proposal "would be very disruptive to growers in Virginia, " and would force growers to "identify and obtain a substitute for flubendiamide in 'the height of caterpillar pest season,' just as the product is most likely to be needed the most."); *id.* at 17 (Dr. Palumbo would have testified that "[w]hen lepidopteran pest numbers hit their peak this fall, growers will no longer be able to have flubendiamide applied on fall lettuce crops.").

[38] *See, e.g.*, PBNX 26.

[39] EPHB at 11 (accusing Registrants of "having deliberately reneged on a condition of registration" to delay cancellation for months); Tr. 153-156 (in which EPA's counsel badgered the President of one of the Registrants by repeatedly calling into question his and his company's integrity).

[40] *See* CID at 11 n.23.

implemented by EPA.[41] EPA need not have agreed with Registrants' arguments to acknowledge that they were brought in good faith, yet the Agency set out to punish Registrants as if their sole motivation was to delay. Nor should the fact that the ALJ decided against Registrants (in decisions Registrants also have good-faith bases to contest) warrant the Initial Decision's retroactive finding that Registrants "are intentionally out of compliance,"[42] and that EPA was therefore justified in making an example of them.

It cannot be true that registrants and affected stakeholders forfeit the right to contest an existing stocks determination simply because EPA alleges they have not met a condition of registration, yet that is the only rationale EPA provided for departing from its own governing policy to make its punitive existing stocks determination. *Every* § 6(e) cancellation involves an allegation by EPA that a condition of registration has not been met, and if all EPA must do to shield its existing stocks determination from review is claim it was issued to deter noncompliance with conditions of registration, then no registrants or other harmed stakeholders could *ever* contest an existing stocks determination as being too restrictive. If the Initial Decision is permitted to stand, registrants will be forced to either forgo their right under FIFRA to a § 6(e) hearing or become a target for punishment for contesting a cancellation demand. It defies reason that Congress would have established the § 6(e) hearing process for the express purpose of contesting EPA's existing stocks determinations and simultaneously foreclosed its use by registrants.

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[41] Tr. 125-126 ("[A]nd that's when suddenly we found out that the science division of EPA, they're assessing us using decision endpoint that was driving those discussions and was suddenly lower, 70 times, although it was, 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.* 135 ("We did comply with conditions of registration, so we should be allowed to sell those products."); *id.* 151 ("[W]e did not feel that the condition of cancellation was triggered, because the scientific discussions . . . broke down and some of the most relevant points in terms of the degradates and their persistence, or potential persistence were being ignored.").

[42] CID at 36.

C. Fact and Expert Testimony and Evidence Excluded From the Hearing Show That the Risks and Benefits Weigh in Favor of Permitting Existing Stocks to Clear the Channels of Commerce.

The direct testimony and exhibits excluded by the ALJ, which are summarized in Registrants' Offer of Proof, together with the limited evidence regarding EPA's existing stocks determination that the ALJ did permit, establish that the risks and benefits weigh strongly in favor of permitting existing stocks to clear the channels of trade.

Had Registrants been permitted to present their scientific experts, they would have established that EPA's conclusions regarding the unreasonable risks of adverse effects posed by flubendiamide were unfounded, and that the sale of any remaining existing stocks posed little, if any, risk to the environment. Had Registrants been permitted to present expert and fact witness testimony and evidence regarding the agricultural benefits of flubendiamide, they would have established that flubendiamide is a highly specialized and irreplaceable tool for growers practicing IPM and IRM, and that it would be severely disruptive to cut off the sale, distribution, and supply of this compound at the height of the caterpillar pest season.

As was further established at the evidentiary hearing: (1) flubendiamide is "not [a] heavily produced" pesticide; (2) Nichino placed its final order in September of 2015 and Bayer in February of 2016 and neither produced more product for sale in 2016 than in 2015; and (3) any Nichino flubendiamide products not in the hands of end-users at the time of cancellation cannot be sold in other jurisdictions and will need to be disposed of in the environment without any beneficial use. PBNX 117 at 15:1-9; Tr. 55:9-10, 173:21-22, 174:19-175:1.

For these reasons, if flubendiamide is cancelled, existing stocks should be allowed to clear channels of trade.

CONCLUSION

For the reasons stated above, the EAB should reverse the ALJ's rulings, reopen the hearing to admit the evidence excluded by the ALJ, deny the proposed cancellation of the flubendiamide registrations, and require EPA to follow the cancellation process outlined under FIFRA §§ 6(b)&(d) if the Agency wishes to cancel the registrations based on its unreasonable adverse effects determination.

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STATEMENT OF COMPLIANCE WITH WORD LIMITATION

I hereby certify that this Appeal Brief, including all relevant portions, contains fewer than 14,000 words.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 13th day of June, 2016, a true and correct copy of the foregoing Appeal 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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