**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

**BEFORE THE ADMINISTRATOR**

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

**REPLY IN SUPPORT OF MOTION FOR ACCELERATED DECISION BY BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.**

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## INTRODUCTION

Having declared at the outset that "this is a simple case that can and should be easily resolved," Opposition ("Opp.") at 1, EPA struggles unsuccessfully through its 66-page brief to find a viable justification for its position. EPA contends it can require registrants to accept forced "voluntary" cancellation conditions and use those conditions to cancel registrations based on an untested unreasonable adverse effects determination, thereby bypassing required statutory process that the Agency finds burdensome to provide. At issue in this case is whether that approach is consistent with and lawful under the detailed, mandatory cancellation process defined in Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136d.

EPA is attempting to use the "voluntary" cancellation conditions it imposed on the flubendiamide registrations to cancel those registrations based on its January 29, 2016 determination that continued registration would cause unreasonable adverse effects in violation of the FIFRA standard. EPA claims that these conditions allow it to cancel the registrations using the streamlined and time-limited FIFRA § 6(e) cancellation process, without providing the process required under FIFRA § 6(b) for cancellation based on an adverse effects determination under the FIFRA Registration Standard. 7 U.S.C. § 136d(b)&(e). EPA's approach unlawfully bypasses independent scientific peer review by the Scientific Advisory Panel ("SAP") and review by the United States Department of Agriculture ("USDA") that are required before the Notice of Intent to Cancel is issued, and denies Bayer and Nichino (the "Registrants") the right to request a hearing on the merits of the determination in a full administrative hearing under § 6(b).

EPA's decision to proceed in this way raises a threshold legal issue regarding whether EPA's proposed cancellation action has been perfected and is properly before this Tribunal, and thus whether the hearing should proceed at all. EPA has not satisfied statutory prerequisites for a

cancellation action based on a determination that continued registration of flubendiamide will cause unreasonable adverse effects. EPA did not submit its January 29, 2016 cancellation determination for review by the SAP or the USDA as required under § 6(b), and has instead invoked the streamlined § 6(e) process which Congress determined is appropriate where a registrant has failed to satisfy a condition, but not where, as here, EPA seeks cancellation because of a substantive determination that the registration does not meet the Registration Standard. The ALJ has the authority and obligation to determine whether the proceeding is properly before this Tribunal. Contrary to EPA's self-serving claims that such considerations are beyond the scope of this hearing and the ALJ's authority, these are foundational jurisdictional issues that should be resolved before any additional imposition on the Office of the Administrative Law Judges for an expedited live hearing and that must be resolved in any event as a prerequisite to any initial decision or final order in this matter.

For the most part, EPA seeks to dodge the central question, by assuming without explanation that the forced "voluntary" cancellation conditions it imposed are valid exercises of its regulatory authority. EPA then relies on its authority to take certain actions in response to failures to comply with a condition of registration. EPA thus seeks to avoid explaining whether and on what grounds EPA has the authority to devise and impose conditions of registration that allow the Agency to bypass required cancellation process at will. Instead, EPA claims unlimited and unreviewable authority to impose any condition it wishes, and to cancel a registration under FIFRA § 6(e) for failure to meet any condition it devises.[1] EPA maintains that because it can

[1] Opp. at 10 (citing without qualification the authority under FIFRA § 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C), to impose "*such other conditions as the Administrator may prescribe*"); *id.* (citing EPA's authority under 40 C.F.R. § 152.115(c) to "establish, on a case-by-case basis, other conditions applicable to registrations to be issued under FIFRA sec. 3(c)(7)" and 40 C.F.R. §

impose any conditions it wants, the "voluntary" cancellation conditions it imposed must be lawful and warrant no further scrutiny.

EPA relies on the claim that its discretion is unlimited and unreviewable because in actuality it lacks a sufficient factual and legal justification for the specific conditions it required here. The Registrants' Motion for Accelerated Decision is properly focused on the specific conditions used by EPA in an attempt to cancel the flubendiamide registrations. To find EPA's actions unlawful, the ALJ need not define the precise limits of EPA's authority to impose "other" conditions not related to the submission of data under FIFRA § 3(c)(7)(C) in other circumstances. Instead, the question is simply whether EPA's forced "voluntary" cancellation scheme in this particular instance is a legitimate and lawful exercise of EPA's regulatory authority. Whatever the limits on EPA's authority to impose conditions of registration may be, they cannot encompass the authority to circumvent the specific statutory rights and procedures Congress chose to require. *See* Registrants' Motion for Accelerated Decision ("Mot.") at 48-50; *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011) (FIFRA § 6 "establishes a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration.") (emphasis in original).

EPA has provided no factual or legal justification for its forced "voluntary" cancellation conditions other than its stated desire to avoid the legal risks and burden of the cancellation process EPA required. Due process rights mean nothing if regulators are permitted the right to demand and obtain the ability to bypass them at will. Accordingly, the Registrants respectfully request that the Tribunal enter an order finding EPA's forced "voluntary" cancellation conditions unlawful because they are contrary to FIFRA § 6 and beyond the scope of EPA's authority to

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152.115(d) for the proposition that EPA can seek cancellation under FIFRA § 6(e) "[i]f *any condition* of the registration of the product is not satisfied.").

impose "other" conditions of registration, and requiring EPA to follow the required process under FIFRA § 6(b) if EPA wishes to cancel the flubendiamide registrations for failure to meet the Registration Standard.

## ARGUMENT

### I. EPA'S FORCED "VOLUNTARY" CANCELLATION CONDITIONS WERE NOT NECESSARY AND DO NOT SERVE A VALID REGULATORY PURPOSE.

#### A. EPA Has Not Shown That the "Voluntary" Cancellation Conditions Were Necessary to Support the Conditional Registration of Flubendiamide.

In its Opposition, EPA suggests that the forced "voluntary" cancellation conditions it required the Registrants to accept were necessary to support the Agency's determination that conditional registration of flubendiamide products was in the public interest and would not cause unreasonable conditional adverse effects.[2] Although EPA chooses not to recognize any limits on the type and scope of conditions it can impose under the catch-all "other conditions" language of FIFRA § 3(c)(7)(C), it follows that, at a minimum, any condition imposed must have some factual relevance to EPA's evaluation of whether the registration meets the FIFRA Registration Standard. If EPA could legitimately claim the right to impose conditions that bypass required process where it finds it desirable to do so – an authority EPA could not exert without gutting due process protections – a far greater showing would presumably be necessary.

EPA claims it needed an automatic cancellation option to ensure that "the registrations could be quickly terminated . . . thereby minimizing the long-term risks or damage to the aquatic environment," and that the "ability to quickly cancel the registration was an important factor in

[2] *See, e.g.*, Opp. at 3 ("[W]ithout the [forced "voluntary" cancellation] conditions the initial FIFRA finding of no unreasonable adverse effects is unsupported and the registration itself should be considered invalid.").

EPA's decision to grant the registration." Opp. at 25, 27.[3] The assertion that quick cancellation was necessary to protect the environment is the only basis offered for EPA's claim that the Agency would not have granted the conditional registrations without the forced "voluntary" cancellation conditions, as well as EPA's spurious arguments that the conditions are not severable and that the entire registrations must be found void *ab initio* if the forced "voluntary" cancellation conditions are found unlawful.

EPA's claim that the Agency needed the forced "voluntary" cancellation conditions to protect the environment and support a positive registration decision fails for the simple reason that there is already an available and required process under the statute allowing EPA to quickly halt use of a product if necessary to prevent harm to the environment pending completion of cancellation proceedings. Under FIFRA § 6(c), if EPA "determines that action is necessary to prevent *an imminent hazard during the time required for cancellation* . . . the Administrator may, by order, *suspend the registration of the pesticide immediately*." 7 U.S.C. § 136d(c). (emphasis added).

Notices of suspension can be issued at the same time as a notice of intent to cancel under § 6(b), and registrants have five days after the notice to request an expedited hearing on suspension. § 6(c)(1). If no hearing is requested, the suspension order goes into effect after five days and is unreviewable. § 6(c)(2). If a hearing is requested, it must commence within five days, recommended findings and conclusions are due within ten days after the close of evidence, and the final order must issue within seven days thereafter. *Id*. If even this expedited process is too slow to prevent harm, EPA can issue an emergency order effecting immediate suspension

[3] EPA claims that the 2008 Decision Memorandum makes clear that the ability to quickly cancel the registration "was an important factor in EPA's decision to grant the registration[s]," but the language EPA cites describing the voluntary cancellation conditions in fact contains no such indication. Opp. at 27 (citing Opp. Attachment C at 9).

even before the suspension hearing is held and up to 90 days before a notice of intent to cancel is issued. § 6(c)(3).

This statutory process eliminates EPA's professed justification of and purported need for the forced "voluntary" cancellation conditions. EPA determined in its January 29, 2016 Decision Memorandum that continued registration of flubendiamide "will result in unreasonable adverse effects to the environment." Mot. Exhibit 30 at 10. If EPA believed environmental harm would occur during the cancellation process and had the necessary factual basis to support that conclusion,[4] it could have issued a notice of suspension with the March 1, 2016 Notice of Intent to Cancel and obtained an order suspending the registrations and halting use within little more than 22 days. If that were not fast enough, the Agency could have issued an emergency order on January 29, 2016 immediately suspending use of the registrations and preventing any alleged ongoing harm even faster than called for under the unlawful forced "voluntary" cancellation conditions.

The Registrants have consistently pointed out that § 6(c) both provides the tools that EPA claims to need and establishes certain process restraints regarding how they can be exercised. Request for Hearing and Statement of Objections ¶¶ 61-63, 156-158, 212; Mot. at 19, 53, 67. EPA offers no response and completely ignores the existence and impact of § 6(c) in its Opposition. The Opposition brief cites almost every other subparagraph of § 6 and many other wholly irrelevant cancellation provisions, but does not identify § 6(c) as a relevant authority and mentions the Section only once in passing in a footnote. Opp. at iii & n.25. EPA may choose to pretend that suspension does not exist, and likely prefers the forced "voluntary" cancellation

[4] Although EPA's Opposition is rife with unsupported factual assertions about the unreasonable adverse effects that would be caused by continued registration of flubendiamide, EPA notably does not claim any imminent harm is occurring or would occur during the time needed to conduct a proper § 6(b) cancellation hearing.

process it invented to allow immediate cancellation on its say-so with no further justification or statutory process, but cannot justify its attempt to bypass the statutory process on the basis that it was needed to reach a positive registration determination or to protect the environment.

### B. EPA Cannot Impose Forced "Voluntary" Cancellation Conditions to Avoid a Cancellation Process It Finds Too Burdensome Or Risky.

In its Opposition, EPA argues that the merits of its determination that continuation of the flubendiamide registrations would cause unreasonable adverse risks are irrelevant. Opp. at 4 n.1, 14. Yet, at the same time EPA repeatedly asserts that its determination was correct, without providing the requisite cites to factual documents or declarations supporting its position and without responding in any way to the evidence cited and declarations provided by the Registrants to the contrary. *Id*. at 15, 56.

The Agency likewise repeatedly seeks to assure the Tribunal that it is not hesitant to defend the merits of its cancellation determination in a § 6(b) process.[5] Yet this assertion is belied by the lengths the Agency has gone to avoid that very process, including its refusal to issue the registrations without the forced "voluntary" cancellation conditions, the Agency's lack of transparency in its discussions with the Registrants leading up to the cancellation determination, and its insistence on forcing the cancellation determination through the § 6(e) process which the Agency claims precludes and does not provide time for any consideration of the merits of EPA's cancellation determination.

EPA's actual rationale for its efforts to cancel flubendiamide under FIFRA § 6(e) is buried 53 pages into the Opposition, and has nothing to do with protection of the environment. There, the Agency complains that "[a] FIFRA section 6(b) proceeding is slow and resource-

[5] *See, e.g.*, Opp. at 53-54; Motion to Limit Scope of Testimony at 4 ("Respondent is prepared to litigate the broader scientific and economic issues related to flubendiamide in an appropriate hearing.").

intensive compared to a FIFRA section 6(e) proceeding." Opp. at 53. In a letter EPA sent to the Center for Food Safety only four weeks ago, EPA was even less discrete regarding its motive:

> In light of this cancellation action, we do not intend to declare the registrations expired; declare an imminent hazard; or issue Stop Sale, Use or Removal orders. Without going into detail, I would note that those options 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.

Opp. Attachment A.

EPA's Opposition and this letter reflect the Agency's unwillingness to devote the time and resources necessary to defend its decision that flubendiamide no longer meets the Registration Standard. EPA is apparently further concerned that opening its decision-making up to review would present "legal risks." While EPA may *prefer* a quicker and less burdensome process that shields its decision-making from any legal or scientific scrutiny, Congress took that decision out of EPA's hands. EPA's convenience does not trump statutory rights provided to registrants and other stakeholders, nor should it.

### C. EPA's Denial of the Cancellation Process Cannot Be Justified as a Legitimate Exercise of Regulatory Flexibility or Discretion.

Congress has spoken in creating specific cancellation procedures under FIFRA §§ 6(b)-(e) and determining when they apply. Mot. at 16-20, 46-47. Although it may dislike the statutory process it is required to follow, EPA cannot invent and impose its own process of automatic or forced "voluntary" cancellation. Whatever the scope of EPA's authority under FIFRA § 3(c)(7)(C) may be to impose "such other conditions as the Administrator may prescribe," it cannot include the authority to circumvent at will the specific rights and procedures Congress chose to require. Mot. at 48.

EPA argues that there is a "variety of grounds for cancelling a pesticide product" and that EPA has "discretion to choose which to exercise when there appear to be alternative grounds for

cancellation." Opp. at 49-50. EPA lists eight different statutory provisions allowing cancellation under FIFRA for different grounds, including failure to comply with data compensation obligations, § 3(c)(1)(F)(iii), 7 U.S.C. § 136a(c)(1)(F)(iii); failure to provide notices or submit required data in connection with reregistration, §§ 4(d)(5) & (e)(3)(A), 7 U.S.C. §§ 136a-1(d)(5) & (e)(3)(A); and failure to pay required maintenance fees, § 4(i)(1)(H), 7 U.S.C. § 136a-1(i)(1)(H). The list also includes the two provisions at issue here, cancellation based on a determination by EPA that continued registration will cause unreasonable adverse effects on the environment under § 6(b) and cancellation based on the registrant's failure to satisfy conditions of registration under § 6(e). *Id.* at 50. As described by EPA, in some cases Congress modified the cancellation process required based on the grounds for cancellation, such as allowing cancellation by order and without hearing for failure to pay maintenance fees, and providing for a streamlined and limited hearing process for cancellation under § 6(e) where a registrant fails to meet a condition of registration. *Id.* at 49-50.

This litany of cancellation provisions does not support EPA's position. Rather, it confirms that Congress acted deliberately in determining what process would apply in a given cancellation situation, and that the process provided in each instance depends on the *grounds* for cancellation. While EPA may have discretion to choose which cancellation provision to invoke if more than one ground for cancellation exists, EPA does not have and cannot be granted the discretion to devise a mechanism that allows it to cancel a pesticide based on grounds addressed in one provision using the process defined in a different provision. EPA cannot force registrants to accept registration "conditions" whose sole purpose is to convert a potential future determination by EPA that a product will cause unreasonable adverse effects, which is grounds for cancellation under § 6(b), into grounds for cancellation under § 6(e) with its more limited

cancellation rights.

EPA made similar arguments about regulatory discretion in its failed effort to defend and justify a different scheme employed by the Agency to avoid required cancellation process. EPA previously claimed discretion to take action against a product it determined did not meet the regulatory standard by deeming the product "misbranded" as of a certain date, making the product illegal to sell. *Reckitt Benckiser*, 762 F. Supp. 2d at 39. The District Court for the District of Columbia concluded that EPA could not creatively interpret FIFRA to allow it to bring a misbranding action in lieu of cancellation where doing so would allow EPA to "bypass[] cancellation proceedings" and "effect[ively] cancel[] the registrations without following the regulatory procedures provided in Section 6." *Id.* at 43. Doing so would "render[] Section 6 superfluous" and "allow[] EPA to avoid the rigorous cancellation process Congress provided for in the statute." *Id.*

Likewise, EPA cannot invoke regulatory discretion and interpret FIFRA to allow it to impose forced "voluntary" cancellation conditions that give EPA the right to choose to cancel a product for failure to meet the Registration Standard without providing the specific, rigorous process required under § 6(b) for cancellation based on those grounds.

## II. EPA'S OWN EXHIBITS CONFIRM THAT IT WAS EPA THAT PROPOSED THE VOLUNTARY CANCELLATION CONDITIONS, NOT THE REGISTRANTS AS EPA SUGGESTS.

In its Opposition, EPA mischaracterizes the correspondence between EPA and the Registrants regarding the conditions of registration to suggest that the Registrants are challenging conditions that they proposed themselves. EPA asserts that after EPA "proposed that the registration automatically expire in July 2013 unless EPA, at its sole discretion, extended the registration," the Registrants "objected to the language concerning automatic cancellation" and eventually "proposed using the FIFRA section 6(f) voluntary cancellation process" and offered

language "for EPA's consideration" that "is almost identical to the final language incorporated in the final PAL as paragraphs 6(d) and 8(d)." Opposition at 29-30.

The emails between EPA and the Registrants show the opposite to be true. EPA initially proposed an even more Draconian "voluntary" cancellation provision, Bayer requested that it be removed entirely, and the Agency rejected Bayer's request and itself proposed conditions requiring "voluntary" cancellation within one week at EPA's demand.

The actual chronology is as follows:

- July 17, 2008: C. Rodia (EPA) emails C. Halder (Bayer) a draft PAL with language requiring Bayer to submit a request for "voluntary" cancellation within 60 days of registration, to be effective as of July 2013 unless Bayer submits required data and EPA has not issued a written determination that it is "unable to make a determination that further registration of flubendiamide will not result in unreasonable adverse effects on the environment." Opp. Attachment D at unnumbered pp. 5-6 (Section 6).

- July 23, 2008: D. Larochelle (Bayer) emails C. Rodia (EPA) a counterproposal which *eliminates* the proposed "voluntary" cancellation condition in Section 6 and would require *EPA* to cancel the registration. *Id.* at unnumbered pp. 9-10.

- July 29, 2008: C. Rodia (EPA) emails D. Larochelle (Bayer) a revised draft PAL which requires that if EPA "has not [sic] determined in writing on or before September 1, 2013, that, after review of the data, the Agency is unable to make a determination that further registration of the flubendiamide technical product will not result in unreasonable adverse effects," Bayer and Nichino must submit irrevocable voluntary cancellation requests "within one (1) week of this finding." Id. at unnumbered p. 14 (Sections 5(c) and 7(c)).

- July 30, 2008: C. Halder (Bayer) emails L. Rossi (EPA) with proposed revisions to the voluntary cancellation provisions, noting that the voluntary cancellation conditions are a "sore point," and acknowledging that EPA is insisting on a "fast death" provision to allow cancellation "without any due process from us." The email includes proposed revisions to Sections 5(c) and 7(c) because Bayer found the previous language "not . . .understandable" and to require EPA to make an affirmative determination of unreasonable adverse effects to trigger the required "voluntary" cancellation. *Id.* at unnumbered p. 17. It also emphasized that the Registrants are basing their response on the assumption that there will be a "measured dialogue between the scientists" *Id.* (emphasis in original).

Rather than absolving EPA of its role in forcing these unlawful conditions upon Registrants, the correspondence confirms that it was EPA that first proposed and then insisted on the "voluntary" cancellation conditions. The email also confirms that Bayer accepted the "fast death" provisions

for cancellation "without any due process" not because it agreed with those conditions, but because it understood EPA would not issue the registrations without them and was confident the science would prove the safety of its product (as it has) and trusted that the Agency would follow the science (which it has not).

## III. EPA'S RELIANCE ON THE *WOODSTREAM* DECISION IS MISPLACED.

Throughout the Opposition, EPA claims that the *Woodstream* decision vindicates its position that EPA can use conditions of registration to cancel registrations "for risk-based reasons, and without a formal hearing." Opp. at 20 (citing *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174 (D.D.C. 2012)). EPA's reliance on *Woodstream* as the primary legal support for its position is misplaced for several reasons.

First, the facts of *Woodstream* are quite different. In that case, EPA granted a routine request by Woodstream to amend existing registrations for five rodenticide products to update package size and net contents information. *Woodstream*, 845 F. Supp. 2d at 178. At the time of the request, three of the five registrations already included a condition of registration requiring Woodstream to comply with conditions specified in EPA's final Rodenticide Risk Mitigation Decision "on the same time schedule" as similar rodenticides. *Id.* In granting the amendments in November 2008, EPA imposed new conditions requiring compliance with the Risk Mitigation Decision for all five products by a date certain (June 4, 2011), and stating that, absent compliance, the registrations would "expire" on that date. *Id.*

That situation is quite different from the facts presented here. The *Woodstream* expiration date was fixed and based on a substantive determination by EPA in the Risk Mitigation Decision that the products did not meet the Registration Standard without required risk mitigation measures, but should continue for a time to allow for development of compliant products. *Id.* at 177. Woodstream refused to comply with the conditions requiring adoption of

the mitigation measures and thus faced cancellation along with similar products covered by the Risk Mitigation Decision. *Id.* at 178. Moreover, Woodstream had a choice whether to accept the amended registrations with the new conditions (including the automatic expiration provision) or retain its existing registrations without those provisions.

By contrast, EPA granted Bayer and Nichino new conditional registrations for flubendiamide products based on a determination that registration was in the public interest and would not cause unreasonable adverse effects, and imposed conditions requiring the Registrants to generate additional data on the persistence and accumulation issue, but refused to issue the new registrations without the cancellation conditions the Agency wanted so that it could demand "voluntary" cancellation in the future if EPA reached a decision based on the not-yet-generated data that the products would cause unreasonable adverse effects. While the automatic cancellation provisions imposed in *Woodstream* were based on an existing substantive, risk-based determination by EPA, the forced "voluntary" cancellation provisions at issue here had no such basis. On their face, their sole purpose was to give EPA the option to convert a potential future unreasonable adverse effects determination by the Agency (which falls under the express terms of § 6(b)) into a "failure" by the Registrants to satisfy purported "conditions of registration" that the Agency would use to pursue cancellation under § 6(e). The "voluntary" cancellation conditions at issue here are, if anything, a more egregious attempt by EPA to circumvent required process.

In addition, Woodstream was confronted with a different "choice" than the Registrants were here. Woodstream could have chosen to comply with the mitigation conditions imposed in the Risk Mitigation Decision, could have refused the amendment and retained its existing registrations without the automatic expiration condition, or could have pursued an administrative

or legal challenge to the expiration it knew was pending in three years. By contrast, the Registrants faced a choice between accepting the forced "voluntary" cancellation conditions EPA required or receiving no registrations at all. Moreover, the Registrants fulfilled all conditions of registration that were in their control and had every reason to believe that EPA would consider the data to be generated and submitted by the Registrants, and would follow the science and extend the registrations or remove the conditions. Thus, the Registrants had no reason or justification for filing a preemptive challenge to the forced "voluntary" cancellation provisions. Even if they had done so out of an abundance of caution, they would surely have faced arguments from EPA that such a challenge was not ripe absent any final agency action invoking and relying on the "voluntary" cancellation provisions and without first exhausting administrative remedies (as the Registrants have done by requesting this hearing).

The *Woodstream* decision is also wrong on the merits. The opinion focuses largely on the question of whether EPA can impose any non-data conditions of registration at all, an issue which the Registrants do not contest. *Woodstream*, 845 F. Supp. 2d at 179-182. Having resolved that issue, the decision never squarely addresses why EPA could exercise its authority to issue "other" conditions of registration (in that case, the automatic expiration conditions) to bypass required cancellation process. The decision never explains why grafting an automatic cancellation provision onto a routine, non-substantive registration amendment was not an unlawful attempt to "bypass[] cancellation proceedings" and "effect[ively] cancel[] the registrations without following the regulatory procedures provided in Section 6." *Reckitt Benckiser*, 762 F. Supp. 2d at 43 (quoting *Reckitt Benckiser*, 613 F.3d at 1136).

Instead, the *Woodstream* court relied on the premise that Woodstream *could have* filed "a new request for an amended registration removing the conditions" and, in so doing, could have

obtained a hearing on EPA's denial of *that* request under FIFRA § 3(c)(6). *Woodstream*, 845 F. Supp. 2d at 182. The decision wrongly requires Woodstream to have filed a straw-man application to vindicate cancellation rights it already held, and wrongly assumes that EPA would have then afforded Woodstream the required process. In fact, the underlying briefs make clear that Woodstream asked EPA *twice* to amend its registration to remove the expiration date and EPA simply did not respond.[6]

The Tribunal need not conclude the *Woodstream* decision was wrong in order to invalidate the quite different purported conditions of registration at issue here. Nonetheless, it is clear that EPA rests its legal theory on a flawed and incorrect decision.

## IV. REGISTRANTS' CHALLENGE IS TIMELY.

The Registrants timely exercised their statutory right to object to and request a hearing regarding EPA's Notice of Intent to Cancel ("NOIC"). EPA recognized Bayer's right to bring this challenge in the NOIC, which provides that "[u]nder FIFRA section 6(e), affected registrants and other adversely affected persons must request a hearing within 30 days from the date that the affected registrant received EPA's Notice of Intent to Cancel." Mot. Exhibit 20 at 11,558. The Registrants received the NOIC on March 1, 2016 and filed their Request for Hearing and Statement of Objections on March 31, 2016. Accordingly, the Registrants' claims were timely filed before the only deadline applicable to this proceeding. That EPA now argues that Bayer's timely exercise of its statutory right to an administrative challenge of EPA's cancellation decision is somehow barred by a plainly inapplicable statute of limitations demonstrates the lengths the Agency will go to attempt to shield its decision-making from review.

[6] *See* Plaintiff's Mot. for Summary Judgment at 11 (ECF No. 11) and Defendant's Opp. to Mot. for Summary Judgment at 13 (ECF No. 12), *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174 (D.D.C. 2012) (No. 1:11-cv-867).

As EPA acknowledges, there is no statute of limitations under FIFRA governing the Registrants' challenge. Despite EPA's claims to the contrary, it does not make sense to apply 28 U.S.C. § 2401(a), the statute of limitations for civil actions against the United States, to bar an administrative challenge that is expressly authorized under FIFRA. *Impro Products, Inc. v. Block*, the lone case cited by EPA, bears no substantive or procedural similarity to this proceeding. 722 F.2d 845 (D.C. Cir. 1983). *Impro Products* involved a civil action brought against the United States Department of Agriculture in federal district court under the Administrative Procedure Act. The court found that the plaintiff had failed to bring its challenge to the Department's final agency action within the six-year statute of limitations applicable to the civil action. Here, the final agency action that the Registrants challenge is EPA's March 1, 2016 NOIC, and the Registrants have properly and timely brought their challenge under the administrative process mandated by FIFRA by filing a request for hearing within 30 days.

## V. THE RELIEF THE REGISTRANTS SEEK PRESERVES, RATHER THAN UPSETS, THE EXISTING FIFRA FRAMEWORK.

Because EPA cannot defend the lawfulness of the voluntary cancellation decision (and goes so far as to tell the ALJ to not even consider whether it is lawful), [7] the Agency argues instead that a failure to rubber stamp its cancellation decision will result in a parade of horribles for registrants, growers,[8] and the environment. The supposedly dire ramifications that EPA warns will flow from the ALJ's granting of this narrow, product-specific challenge have no basis

[7] Opp. at 3 ("[T]he focus in this case should not be on whether the conditions were lawful.").

[8] EPA's claim to be acting in the best interest of growers and registrants is undercut by the *amicus curiae* motions filed by a collection of over 30 grower organizations and CropLife America (the national trade association that represents the manufacturers, formulators and distributors of pesticides) *opposing* EPA's cancellation decision and use of the § 6(e) process in this instance.

in fact. In reality, a ruling in the Registrants' favor will simply require EPA to follow the procedural process that FIFRA demands and nothing more.

EPA first argues that were the ALJ to find the voluntary cancellation decision unlawful, the entire flubendiamide registrations must be invalidated. Opp. at 3. EPA offers no legal support for this proposition other than its own unsubstantiated assurances that it must be so. The unlawful provisions are entirely procedural and can be removed without affecting or jeopardizing EPA's substantive determination of whether flubendiamide presents an "unreasonable risk of adverse effects."[9]

EPA next threatens that if EPA is not permitted to enforce mandatory "voluntary" cancellation conditions, it will be forced to curtail its use of conditional registrations to the detriment of registrants, growers, and the environment. Opp. at 3. Here, EPA alleges as definitive what its sole declarant admitted to be mere speculation.[10] The reality is that EPA has the specific statutory authority to grant conditional registrations, granted them before it invented its mandatory "voluntary" cancellation conditions, and should continue to grant conditional registrations after those specific conditions are held to be unlawful. The Registration Standard, and not the § 6(e) process, is what ensures that the environment is protected against the risk of unreasonable adverse effects.

### A. The Voluntary Cancellation Provisions Can Be Found Unlawful Without Invalidating the Flubendiamide Registrations in Their Entirety.

EPA presents the ALJ with a false choice, submitting that the voluntary cancellation provisions must either be upheld or the registrations invalidated. Opp. at 37. EPA's argument

[9] As discussed above, EPA's claim that the ability "to quickly cancel" the registrations using the forced "voluntary" cancellation provision is needed to protect the environment from ongoing harm requires ignoring that the § 6(c) suspension process exists.

[10] Opp. Attachment B ¶ 27.

that the ALJ cannot strike the voluntary cancellation provisions without invalidating the registrations is premised on two flawed propositions: (1) that the registrations would be invalid because the Agency "has never made a determination that flubendiamide products would be eligible for registration under terms and conditions that do not include the cancellation conditions"; and (2) that no administrative record exists to support a registration without the cancellation conditions, because the Registrants have not requested an amendment or new registration without the cancellation conditions. Opp. at 37-38. EPA tellingly cannot and does not cite any legal authority (or even any of its own guidance) for either of these propositions. In fact, the only consequence of striking the voluntary cancellation provisions would be to require EPA to pursue cancellation (if it still believes cancellation to be necessary) under § 6(b) rather than § 6(e), which EPA claims it is prepared to do. *See* Motion to Limit Scope of Testimony at 4 ("Respondent is prepared to litigate the broader scientific and economic issues related to flubendiamide in an appropriate hearing.").

EPA's misleading statements regarding the absence of any registration determination without the "voluntary" cancellation provisions have no bearing on whether the Agency must conduct any cancellation based on alleged unreasonable adverse effects on the environment consistent with the process due under FIFRA § 6(b). Because the unlawful provisions are procedural, serve no valid regulatory purpose, and were unnecessary given the existence of § 6(c), it was irrelevant to EPA's 2008 finding that registration of flubendiamide was in the public interest (made months before the registrations were granted) and would not pose unreasonable adverse effects on the environment.

In the unlikely event EPA has a factual basis to argue that the registration, with the voluntary cancellation provisions removed, no longer satisfies the Registration Standard, then the

Agency can make the requisite unreasonable adverse effects finding and initiate cancellation under FIFRA § 6(b). Indeed, *any* registration, whether conditional or unconditional, may be cancelled upon an EPA finding that the product no longer satisfies the FIFRA Registration Standard. And if EPA is truly concerned that the continued registration of flubendiamide presents immediate concerns that rise to the level of an imminent hazard, then the Agency is free to pursue suspension under FIFRA § 6(c) while that cancellation process is ongoing.

EPA's attempt to recast the recent Ninth Circuit decision rejecting EPA's request for vacatur of the Enlist Duo registrations as anything but a rejection of the Agency's attempt to bypass FIFRA cancellation procedures falls flat. EPA asked the court to vacate a registration without even the superficial nod to FIFRA § 6 it has provided in this proceeding. As here, the registrant objected and argued that EPA must not be allowed to "short-circuit" the statutory cancellation process. Mot. at 50 & Exhibit 53. The court denied EPA's request and remanded the matter for litigation before the Agency. Mot. Exhibit 54. It is hardly "conjecture" to reason that the court's rebuke of EPA's unlawful request and its ruling, consistent with the registrant's argument, confirm that registrations cannot be "vacated" without following FIFRA's defined administrative process.

Even less persuasive is EPA's argument that it is the Registrants that are attempting to "short-circuit" the FIFRA process. EPA suggests that the Registrants are requesting a new registration outside the bounds of the FIFRA process. This is incorrect. The Registrants merely ask that the Tribunal require EPA to follow the process outlined by FIFRA § 6(b) based on the Agency's determination that continued registration of flubendiamide would cause unreasonable adverse effects on the environment. To cast the Registrants' request that EPA follow the

appropriate § 6(b) cancellation process as an attempt to "short-circuit" FIFRA is a stretch by any measure.

### B. The End of an Unlawful Condition Does Not Mean the End of Conditional Registrations.

A ruling in the Registrants' favor would not, as EPA claims, render the Agency "unable to rely on registrants' compliance with the terms and conditions of registration." Opp. at 3. The Agency would continue to be able to enforce all *lawful* conditions of registrations,[11] including, for example, the remainder of the conditions in the flubendiamide registrations, all of which are valid. Had the Registrants, for example, failed to submit a monitoring study required by a certain deadline as a condition of registration, the Registrants would not have grounds to challenge EPA's initiation of cancellation proceedings under § 6(e).

Nor would a ruling in the Registrants' favor require the Agency to "reconsider whether its current practice of approving conditional registrations is adequate to prevent unreasonable adverse effects." Opp. at 3. This Agency claim is particularly disingenuous, given how often in its Opposition EPA insists that it has not relied upon a finding of unreasonable adverse effects to initiate cancellation. *Id.* at 42, 52-53, 56. EPA's claim is further undermined by a passage from EPA's only declaration, in which Susan Lewis acknowledges that she "cannot predict what the

[11] EPA claims that enhanced adverse incident reporting agreed to by Bayer Healthcare LLC and other registrants as a condition of continuing certain companion animal registrations is somehow analogous to the purely procedural voluntary cancellation condition that EPA imposed upon the flubendiamide Registrants. Opp. at 35-36. EPA neglects to mention that FIFRA expressly requires pesticide registrants to submit adverse effects information, and that EPA's regulations specifically identify the types of information and permit EPA to require reporting of other information "if the registrant has been informed by EPA that such additional information has the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product." See FIFRA § 6(a)(2); 40 C.F.R. § 159.195. The companion animal product registrants accepted EPA's enhanced adverse incident reporting because it is a lawful condition, consistent with the statute and relevant to EPA determining whether a product continues to meet the Registration Standard. In contrast, FIFRA does not permit EPA to force the flubendiamide Registrants to waive their statutory procedural rights to contest an EPA determination that a product no longer meets the Registration Standard.

Agency's reaction would be if [EPA] were precluded from including such conditions in future registrations." Opp. Attachment C ¶ 27. Ms. Lewis candidly offers only the vaguest speculation that without the ability to include undefined "special conditions . . . the Agency *might* have to reject applications that, as with flubendiamide, it was comfortable granting for limited periods of time." *Id.* (emphasis added). The Tribunal need not take seriously an argument so speculative that EPA's only supporting witness would not endorse it.

## VI. EPA'S EFFORT TO EXPLAIN ITS CONTRADICTORY STATEMENTS ON THE NATURE AND SCOPE OF SECTIONS 6(c) AND 6(e) FALLS SHORT.

In the most recent FIFRA cancellation proceeding conducted by this Tribunal before this one, EPA acknowledged the fundamental difference between § 6(b) and § 6(e). EPA explained that the "provisions governing risk-based cancellations" are contained in § 6(b) and pesticides "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." Mot. at 51 (quoting Exhibit 55 at 4 n.2 & 5). EPA further explained that, by contrast, "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*." *Id.* (quoting Exhibit 55 at 4 n.2) (emphasis by EPA).

In this proceeding, EPA ignores the statutory distinction it previously recognized by seeking cancellation based on its January 29, 2016 determination that "the registrations did not meet the FIFRA standard for registration" – a "risk-based cancellation" based on "a problem with the pesticide product itself" – under § 6(e) rather than § 6(b). Mot. Exhibit 20 at 11,559. Confronted with its contradictory positions, EPA contends that its prior brief simply summarized the "distinction between FIFRA section 6(b) and 6(e) *adjudications*" and did not make any representations about the nature and applicability of § 6(b) and § 6(e). Opp. at 57-58.

This is not correct. First of all, in a portion of the prior brief EPA chooses not revisit, it described §§ 6(b) & (c) as "the provisions *governing risk-based cancellations.*" Mot. Exhibit 55 at 4 n.2 (emphasis added). Thus, according to its own prior representations to the Tribunal, EPA's current cancellation efforts are "governed" by § 6(b). Furthermore, EPA was not simply parroting statutory language describing the scope of hearings under § 6(b) and § 6(e), but was pointing out that the scope of hearings under each provision was different precisely because of the contrasting types of cancellation proceedings that can be brought under each.

More specifically, EPA was responding to CropLife America's contention that existing stocks provisions must be considered within the scope of § 6(b) hearings because "it would be 'ironic' for Congress to have established a broader scope for cancellation hearings pursuant to FIFRA section 6(e) and suspension hearings pursuant to FIFRA section 3(c)(2)(B) than it did for section 6(b) cancellation hearings." Mot. Exhibit 55 at 4. EPA responded that the "Congressional choice" to define the scope of the hearings in this manner was "eminently reasonable" because § 6(e) "is about the *registrant's* failure to meet its obligations, and not about a problem with *the pesticide product itself*," while § 6(b) "govern[s] risk-based cancellations." *Id.* at 4 & n.2. EPA now denies any such distinction and attempts to thwart "Congressional choice" by claiming the right to bring a "risk-based" cancellation action under § 6(e) rather than § 6(b) so that it can shield its risk-based cancellation determination from review under the streamlined § 6(e) hearing process. EPA's prior position, though inconvenient for the Agency in this proceeding, was correct.

## CONCLUSION

Accordingly, the Registrants request that the ALJ issue an accelerated decision denying EPA's proposed cancellation of the flubendiamide registrations, finding that the forced "voluntary" cancellation condition approach is unlawful and contrary to FIFRA, and ordering

EPA to follow the FIFRA § 6(b) cancellation process if it wishes to cancel the flubendiamide registrations for failure to meet the Registration Standard.

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Respectfully Submitted,

Kathryn E. Szmuszkovicz
David A. Barker
Daniel A. Eisenberg
BEVERIDGE & DIAMOND, P.C.
1350 I Street, N.W. Suite 700
Washington, D.C. 20005
Telephone: (202) 789-6000
Email: kes@bdlaw.com
dab@bdlaw.com
dae@bdlaw.com

*Counsel for Bayer CropScience LP*

Kenneth D. Morris, Esq. L.L.C.
Law Offices
1320 Vale Dr.,
West Chester, PA 19382
Telephone: (484) 607-8203
Email: kdm@kenmorrislaw.com

*Counsel for Nichino America, Inc.*

## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 21th day of April, 2016, a true and correct copy of the foregoing Reply In Support Of Motion For Accelerated Decision By Bayer CropScience LP And Nichino America, Inc. was filed electronically using the EPA OALJ e-filing system; and served in the following manner to the below addressees:

**Electronically Using EPA OALJ e-filing system:**

Sybil Anderson, Headquarters Hearing Clerk
Office of Administrative Law Judges
U.S. Environmental Protection Agency
Ronald Reagan Building, Room M1200
1300 Pennsylvania Avenue, N.W.
Washington, DC 20004
202-564-6261
Anderson.sybil@epa.gov

**By Email:**

Michael B. Wright, Staff Attorney
Ryan Yaeger, Staff Attorney
Office of Administrative Law Judges
USEPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 1900R
Washington, DC 20460
Wright.michaelb@Epa.gov
Yaeger.ryan@Epa.gov

Ariadne Goerke
Robert G. Perlis
Scott Garrison
Michele Knorr
Pesticides and Toxic Substances Law Office
Office of General Counsel (Mail Code 2333A)
U.S. Environmental Protection Agency
WJC North 7318B
1200 Pennsylvania, Avenue, N.W.
Washington, DC 20460
goerke.ariadne@epa.gov
Perlis.Robert@epa.gov
garrison.scott@epa.gov
knorr.michele@epa.gov

*Counsel For Respondent*

Katherine M. Fowler
Sarah B. Mangelsdorf
One South Memorial Drive, 12th Floor
Saint Louis, MO 63102
kfowler@foxgalvin.com
smangelsdorf@foxgalvin.com

*Counsel for Amicus Curiae Growers*

Kirsten L. Nathanson
Warren U. Lehrenbaum
Jared B. Fish
Preetha Chakrabarti
CROWEL &MORING LLP
1001 Pennsylvania Ave., N.W.
Washington, DC 20004
knathanson@crowell.com
wlehrenbaum@crowell.com
jfish@crowell.com
pchakrabarti@crowell.com

*Counsel for Amicus Curiae CropLife America*

Stephanie Parent
Hannah Connor
Center for Biological Diversity
PO Box 11374
Portland, OR 97221
sparent@biologicaldiversity.org
hconnor@biologicaldiversity.org

*Counsel for Amicus Curiae Center for Biological Diversity*

David A. Barker