UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Bayer CropScience LP, and	)	**Docket No. FIFRA-HQ-2016-0001**
Nichino America, Inc.,	)	
	)	
Petitioners.	)	

ORDER ON PETITIONERS' MOTION FOR ACCELERATED DECISION

I. PROCEDURAL HISTORY

On March 31, 2016, Bayer CropScience LP and Nichino America, Inc. ("Petitioners") initiated this action by the filing a Request for Hearing and Statement of Objections ("Hearing Request"). The Hearing Request contests the Notice of Intent to Cancel Pesticide Registrations ("NOIC") issued on February 29, 2016 by the Environmental Protection Agency ("EPA" or "the Agency"). Flubendiamide; Notice of Intent To Cancel Pesticide Registrations ("NOIC"), 81 Fed. Reg. 11558 (Mar. 4, 2016). The NOIC states that EPA intends to cancel four of Petitioners' conditional pesticide registrations for flubendiamide "owing to the registrants' failure to comply with a required condition of their registrations." NOIC, 81 Fed. Reg. at 11558. Specifically, EPA asserts that "the registrants' failure to . . . submit[ ] requests for *voluntary cancellation* makes the flubendiamide products identified . . . subject to [involuntary] cancellation" under Section 6(e) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), codified at 7 U.S.C. § 136d(e). *Id*. at 11560 (emphasis added). The NOIC also contains EPA's determination regarding existing stocks of flubendiamide products. The Agency states that it intends to prohibit the use of existing stocks of the flubendiamide technical registration and to prohibit the sale and distribution of end use registrations. *Id*.

On April 4, 2016, an Order Scheduling Hearing and Prehearing Procedures ("Prehearing Order") was issued. The Prehearing Order established an extremely expedited schedule for this matter, consistent with both FIFRA Section 6(e)(2)'s mandate that "a hearing shall be held and a determination made within seventy-five (75) days after receipt of a request for such a hearing," and with the Rules of Practice Governing Hearings, under the Federal Insecticide, Fungicide, and Rodenticide Act, Arising from Refusals to Register, Cancellations of Registrations, Changes of Classifications, Suspensions of Registrations and Other Hearings Called Pursuant to Section 6 of the Act ("Rules of Practice"). 40 C.F.R. Part 164. Perhaps most significant in this regard is Section 164.40(d), which provides that "the Administrative Law Judge shall have power to take actions and decisions in conformity with statute or in the interests of justice." 40 C.F.R. § 164.40(d).

On April 7, 2016, a collection of agricultural groups calling themselves the "Growers"[1] filed a Motion for Leave to File Amicus Curiae Brief, along with their proposed Brief and 33 supporting exhibits ("Growers' Brief"). The Growers' Brief supports the Petitioners' objections to the NOIC. Growers' Br. at 2. The Agency did not oppose the motion, which was granted April 8, 2016.

CropLife America filed a Motion to File an Amicus Curiae Brief and Memorandum ("CropLife Motion") in support of Petitioners' objections to the NOIC on April 11, 2016. Croplife describes itself as "the national not-for-profit trade association representing the companies that develop, manufacture, formulate and distribute crop protection chemicals and plant science solutions for agriculture and pest management." Croplife Mot. at 1. CropLife's Motion was granted the day it was filed.[2]

On April 15, 2016, the Center for Biological Diversity ("CBD") filed a combined Motion for Leave to File an Amicus Curiae Brief and Memorandum ("CBD Motion") in support of the Agency's cancellation of the conditional registrations. The CBD describes itself as a "non-profit organization with 990,000 members and supporters committed to the preservation, protection, and restoration of native species and the ecosystems upon which they depend through science, policy, and environmental law." CBD Mot. at 1. CBD's Motion was granted without objection on April 18, 2016.

On April 11, 2016, Petitioners filed a Motion for Accelerated Decision ("Motion").[3]

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[1] The Growers include the American Soybean Association, Agricultural Council of California, Agricultural Retailers Association, Almond Hullers & Processors Association, American Peanut Council, American Pistachio Growers, California Alfalfa and Forage Association, California Cherry Board, California Cotton Ginners and Growers Association, California Farm Bureau Federation, California Fresh Fruit Association, California League of Food Processors, California Pear Advisory Board, California Specialty Crops Council, California Tomato Growers Association, California Tomato Research Institute, Inc., California Walnut Commission, Delta Council, Florida Fertilizer & Agrichemical Association, Florida Fruit & Vegetable Association, Grower- Shipper Association of Central California, Minnesota Agri-Growth Council, National Corn Growers Association, National Cotton Council, National Potato Council, National Sorghum Producers, Northwest Horticultural Council, Oregonians for Food & Shelter, Pacific Northwest Vegetable Association, South Dakota Corn Growers Association, Tobacco Growers Association of North Carolina, Inc., US Apple Association, Washington Asparagus Commission, Washington Blueberry Commission, Washington Friends of Farms & Forests, Western Agricultural Processors Association, and Western Growers Association.

[2] The Agency indicated it did not oppose any amicus briefs filed before April 15, 2016.

[3] In support of the 66 page Motion, Petitioners submitted 55 numbered exhibits. Those exhibits are cited in this Order as "Petitioners' exhibit __" or "PX __." However, neither the whole group of exhibits, nor the individual exhibits themselves, were Bates-stamped. Further, some of the exhibits do not contain individually numbered pages. In such cases, citation to the exhibit number only is provided.

EPA, the Respondent here, filed its Opposition to the Motion ("Opposition") on April 18, 2016.[4] On April 21, 2016, Petitioners filed their Reply to the Opposition ("Reply").[5]

II. RELEVANT STATUTORY AND REGULATORY PROVISIONS

FIFRA was first enacted in 1947 and has been periodically amended thereafter. 7 U.S.C. §§ 136–136y. FIFRA requires that all pesticides[6] used in the United States be registered with the EPA Administrator,[7] who may regulate their distribution and sale "[t]o the extent necessary to prevent unreasonable adverse effects on the environment."[8] 7 U.S.C. § 136a(a) ("Except as provided by this subchapter, no person in any State may distribute or sell to any person[9] any pesticide that is not registered under this subchapter."). "A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used." *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010).

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[4] EPA submitted five additional lettered exhibits (A-E) with their Opposition. Those exhibits are cited as "Agency exhibit __" or "AX __."

[5] Because this proceeding is governed by a 75-day statutory time limitthat must be shared between this Tribunal and the Environmental Appeals Board, this Order is being issued on an expedited basis less than two business days after the Petitioners filed their Reply.

[6] FIFRA defines "pesticide" as, among other things, "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." 7 U.S.C. § 136(u).

[7] "The term 'Administrator' means the Administrator of the Environmental Protection Agency." 7 U.S.C. § 136(b).

[8] "The term 'environment' includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these." 7 U.S.C. § 136(j). FIFRA further defines the term "unreasonable adverse effects on the environment" as:

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

7 U.S.C. § 136(bb).

To obtain registration, an applicant is required to submit to EPA an extensive application, including scientific data establishing the health and safety properties and potential effects of a pesticide. 7 U.S.C. § 136a(c)(1), (c)(2); 40 C.F.R. Part 158 ("Data Requirements for Pesticides"); 40 C.F.R. § 158.1 ("This part describes the minimum data and information EPA typically requires to support an application for pesticide registration;" and that "EPA requires in order to make regulatory judgments under FIFRA secs. 3, 4, and 5 about the risks and benefits of pesticide products."). EPA has developed standard guidelines for conducting the required tests and studies used to generate the requisite data. *See* Test Guidelines for Pesticides and Toxic Substances, accessible at https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances. EPA works with applicants and conditional registrants[10] to review and approve any departure from standard guideline protocols, and to develop, review, and approve protocols as needed for additional studies. Hr'g Req. ¶ 37. Notice of pending pesticide applications are required to be published by EPA in the Federal Register to allow for comment by any other federal agency or interested person. 7 U.S.C. § 136a(c)(4).

FIFRA mandates that

> The Administrator *shall* register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d) —
>
> > (A) its composition is such as to warrant the proposed claims for it;
> > (B) its labeling and other material required to be submitted comply with the requirements of this Act;
> > (C) it will perform its intended function without unreasonable adverse effects on the environment; and
> > (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. § 136a(c)(5) (emphasis added). Once registered under this section, a pesticide continues to be registered indefinitely, although its registration is subject to review every 15 years and can be cancelled if it is found to no longer meet the standards for registration. 7 U.S.C. § 136a(g)(1)(A). On the other hand,

> [i]f the Administrator determines that the requirements . . . for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period . . . , the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor.

[10] "The term 'registrant' means a person who has registered any pesticide pursuant to the provisions of [FIFRA]." 7 U.S.C. § 136(y).

> The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6.

7 U.S.C. § 136a(c)(6).

The remedies available to a pesticide applicant denied registration are set forth in FIFRA section 6(b) and include the right to a lengthy and complex administrative hearing process to consider the soundness of the Administrator's determination. 7 U.S.C. § 136d(b). That determination must, *inter alia*, "take[] into account the impact of the action proposed . . . on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy" and notify and consider comments from the public, the Secretaries of Agriculture and Health and Human Services, and the Scientific Advisory Panel, etc., as appropriate." *Id*. The administrative law judge adjudicating the proceeding is also authorized to issue subpoenas for testimony and documents from "any person" and may refer relevant questions of scientific fact to a Committee of the National Academy of Sciences. 7 U.S.C. § 136d(d). After completing the hearing and evaluating the data and reports submitted, the Administrator is required, within 90 days, to issue an order revoking the denial or denying the registration and "setting forth detailed findings of fact" based upon the "substantial evidence of record." *Id.* Judicial review of final orders from this administrative review process is available to applicants denied registration. 7 U.S.C. §§ 136d(h), 136n.

In lieu of unconditionally granting or denying a pesticide application, FIFRA also permits EPA to grant a "conditional registration" under three "special circumstances," one of which is relevant here:

> The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data *and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe.* A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

7 U.S.C. § 136a(c)(7)(C) (emphasis added).

Furthermore, FIFRA section 6(e) sets forth the circumstances for EPA's issuance of a notice of intent to cancel a conditional registration, and specifies distinct procedures applicable thereto:

> (1) The Administrator shall issue a notice of intent to cancel a registration issued under section 136a(c)(7) of this title if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment.
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> (2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section. *The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing*.

7 U.S.C. § 136d(e) (emphasis added). The Agency's regulations further provide, in pertinent part, that EPA "may establish, on a case-by-case basis, other conditions applicable to registrations to be issued under FIFRA sec. 3(c)(7)," and that "[i]f any condition of the registration of the product is not satisfied, or if the Agency determines that the registrant has failed to initiate or pursue appropriate action towards fulfillment of any condition, the Agency will issue a notice of intent to cancel under FIFRA sec. 6(e)." 40 C.F.R. § 152.115(c), (d).

A final order of the Administrator cancelling a conditional registration under FIFRA section 6(e) is subject to the same review by the federal courts as a denial or cancellation of an unconditional registration under Section 6(b). 7 U.S.C. § 136d(h).

III. **FACTUAL BACKGROUND**

On May 2, 2007, EPA published notice of its receipt of Petitioners' application to "register pesticide products containing new active ingredients not included in any previously

registered products."[11] Pesticide Products; Registration Applications, 72 Fed. Reg. 24299, 24299 (May 2, 2007). Those products were three pesticides containing flubendiamide: Flubendiamide Technical (for formulation into end-use products), SYNAPSE (insecticide for controlling lepidopterous insect pests on vegetables), and BELT (insecticide for controlling lepidopterous insect pests on pome and stone fruit, nut trees).[12] Pesticide Products; Registration Applications, 72 Fed. Reg. at 24300.

EPA undertook its statutory obligation to "review the data" to determine whether the application met the standards for conditional registration and under what conditions it would grant the conditional registration Petitioners requested. *See* 7 U.S.C. § 136a(c)(3), (c)(7)(C). Establishing conditions for the registration was not a unilateral act on the part of the Agency. Rather, it involved an extended back and forth negotiation on terms and language between the Agency and Petitioners to reach what Petitioners described as a "legal agreement." *See* AX D (*e.g.*, email dated July 23, 2008, with Petitioners' "counter proposal to EPA's draft preliminary acceptance letter for Flubendiamide" and email dated July 30, 2008, from Petitioners' representative stating "Given that this [draft preliminary acceptance letter] is a legal agreement . . . "). EPA's main point of concern in registering flubendiamide, which had been the subject of an Environmental Fate and Effects risk assessment, was that the pesticide and its des-iodo degradate "will accumulate to concentrations in aquatic environments that will pose risk to freshwater benthic invertebrates." *Id.* It was noted that "[t]he available mesocosm data does not provide evidence to refute these conclusions. No degradation pathway was identified for des-iodo. As such, Bayer will commit to generate and submit the following data (studies) on the des-iode degradate to determine if Agency assumption of chemical stability are appropriate . . . ". *Id.* EPA and Bayer negotiated an initial five-year period to generate the data. *Id.*

Further, Petitioners negotiated and agreed to the following additional conditions as part of the conditional registration:

> 5. Nichino America Inc. (Nichino) . . . understands and agrees that the time-limited registration of the flubendiamide technical product shall be cancelled if the Agency determines that the continued use of flubendiamide will result in unreasonable adverse effects on the environment.
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> 6. The EPA and Nichino . . . agree on the following data review guidelines and timelines related to the conditions of registration under section 3(c)(5) of FIFRA for the flubendiamide technical product, as well as Nichino's . . . generation of, and the EPA's subsequent review of such additional data during the term of the time-limited registration, as follows:
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> [. . .]

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[11] According to EPA, the Petitioners' application was filed on April 6, 2006. EPA Opp'n at 13. According to Petitioners, "[f]lubendiamide is the first pesticide in its class of chemistry, known as phthalic acid diamides, to be registered by EPA under FIFRA." Hr'g Req. ¶ 12.

[12] Lepidopterous insect pests are caterpillars. Hr'g Req. ¶ 12.

(c) *By September 1, 2013*, the EPA shall either: (1) Approve the registration of the flubendiamide technical product unconditionally, notwithstanding any restrictions that are deemed necessary; or (2) The EPA and Nichino will mutually agree on a path forward, revising or providing additional data under a conditional registration; or (3) The Agency will accept the voluntary cancellation of the time-limited registration of the flubendiamide technical product.

(d) *If, after EPA's review of the data as set forth in 6(b) above, the Agency makes a determination that further registration of the flubendiamide technical product will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, Nichino will submit a request for voluntary cancellation of the flubendiamide technical product registration*. That request shall include a statement that Nichino recognizes and agrees that the cancellation request is irrevocable.

[. . .]

7. Bayer understands and agrees that the time-limited registration of the flubendiamide end-use products shall be cancelled if the Agency determines that the continued use of flubendiamide will result in unreasonable adverse effects on the environment. In addition, this regulatory action will establish permanent tolerances in primary crops for residues of flubendiamide.

8. The EPA and Bayer . . . agree on the following data review guidelines and timelines related to the conditions of registration under section 3(c)(5) of FIFRA for the flubendiamide end-use products, as well as Bayer's . . . generation of, and the EPA's subsequent review of such additional data during the term of the time-limited registration, as follows:

[. . .]

(c) *By September 1, 2013*, the EPA shall either: (1) Approve the registration of the flubendiamide end-use products unconditionally, notwithstanding any restrictions that are deemed necessary; or (2) The EPA and Bayer will mutually agree on a path forward, revising or providing additional data under a conditional registration; or (3) The Agency will accept the voluntary cancellation of the time-limited registration of the flubendiamide end-use products.

(d) *If, after EPA's review of the data as set forth in 8(b) above, the Agency makes a determination that further registration of the flubendiamide end-use products will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September*

> *1, 2013, Bayer will submit a request for voluntary cancellation of the flubendiamide end-use product registrations.* That request shall include a statement that Bayer recognizes and agrees that the cancellation request is irrevocable.
>
> [. . .]
>
> The "Notice of Registration" will be issued under separate cover when you have agreed in writing to the conditions stated within this letter.
>
> [. . .]
>
> Nichino and Bayer should recognize that if EPA issues any technical and/or end-use product registration pursuant to the requirements of section 3(c)(7)(C) of FIFRA, such registration will contain any conditions that are a necessary component of EPA's findings that the statutory requirements for issuing a registration are met. Any such registration will provide that Nichino's or Bayer's release for shipment of any product pursuant to any such registration signals Nichino's or Bayer's acceptance of all of those conditions. *If either Nichino or Bayer does not agree with any of the conditions of registration, they should consider any such registration to be null and void. If either Nichino or Bayer notifies EPA that it is unwilling to accept any of those conditions, EPA will commence the appropriate denial process under section 3(c)(6) of FIFRA.*

PX 8 (emphasis added).

On July 31, 2008, EPA issued and Petitioners counter-signed the final negotiated Preliminary Acceptance Letter ("PAL"). EPA agreed that Petitioners application for conditional registration of the flubendiamide products would be accepted under FIFRA Section 3(c)(7)(C), for a period of five years, *provided* the Petitioners agreed to certain conditions. PAL at 1. It is particularly significant here to note that during the parties' negotiation, Petitioners recognized the significance of the provision required them to submit within one week a request for "voluntary cancellation" of the registrations if after reviewing the data the Agency determined that further registration of flubendiamide products would result in unreasonable adverse effects on the environment. Petitioners' representative expressly stated:

> My take is that the Agency would like to avoid having to go through Section 6 cancellation proceedings. We understand this, so have little problem with fitting in the 'fast death' approach, i.e. voluntary cancellation within a week of the decision. From our side, we expect that a fair cancellation demand can only occur after . . . all the submitted data have been reviewed alongside all voluntary data submitted by Bayer, plus following a **measured** dialogue between the scientists.

AX D (email dated July 30, 2008, from Clive Halder to Lois Rossi). Further, Petitioners offered essentially the exact language for the provisions that appear in the parties' final PAL. *Id.*; PX 8.

On August 1, 2008, EPA issued registration statements for flubendiamide products: NNI-0001 Technical (Flubendiamide), EPA Reg. No. 71711-26; NNI-0001 480 SC (BELT SC Insecticide), EPA Reg. No. 264-1025. PX 7. Each registration statement declared the product was "conditionally registered in accordance with FIFRA section (3)(c)(7)." *Id*. at 1. Each also specified that "[y]our release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA." *Id*. at 2.

Thereafter, Petitioners released for shipment, *i.e.*, began actively selling flubendiamide products, indicating their acceptance of the terms of the conditional registration. Further, they began to generate data required by EPA in support of the applications and to communicate with EPA about study protocols, conduct, and reports, and the interpretation of the study results. Based on this data, EPA over time approved the expansion of flubendiamide's conditional registrations for use on more than 200 crops. Hr'g Req. ¶¶ 74, 75.

In correspondence dated July 18, 2013, EPA extended the registration expiration date for all flubendiamide products two additional years, "out to August 31, 2015," to allow Petitioners "sufficient time to complete the 3-year monitoring program required by the original conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008." PX 10.

On August 26, 2015, EPA again extended the registrations to December 10, 2015, to "provide time for [the registrants] and the EPA to discuss whether potential additional data requirements and label amendments are necessary to address areas of uncertainty" related to EPA's ecological risk assessment. Hr'g Req. ¶ 80; PX 12. *See also* PX 11. In its letter, EPA stated that "[a]s of July 31, 2012, [the registrants] ha[ve] submitted all data required by the original conditions of registration for flubendiamide." PX 12.

On December 8, 2015, EPA extended the December 10th expiration date to December 18, 2015, "to provide additional time for BCS [Bayer CropScience] and EPA to discuss areas of uncertainties." PX 13. The "uncertainties" being referred to related to the appropriate benthic organism ecotoxicity endpoint and whether flubendiamide met that endpoint. PX 14. This brief extension allowed time for a high-level meeting held December 15, 2015, between the Assistant Administrator responsible for all pesticides and the CEOs of both Bayer and Nichino. Hr'g Req. ¶ 86. According to Petitioners,

> [a]t the December 15 meeting, the Assistant Administrator described his view of flubendiamide, repeatedly using precautionary language and contending that flubendiamide should be cancelled based on its persistence alone. He stated the view that, absent any action by EPA beforehand, the registrations would expire on December 18, 2015. He stated that EPA would consider whether to take action, and would inform the registrants of its decision by the end of the day on December 18, 2015.

Id. ¶ 87. The registrants complained of practical difficulties with that timing, and requested that

EPA extend the December 18, 2015 deadline to ensure an orderly process. *Id.* ¶ 88. They also asked that EPA advise the registrants promptly when a decision had been made and that the Agency leave at least a small amount of time before the deadline. *Id*. "EPA committed to respond [regarding] the extension, and suggested that the registrants submit the best, final mitigation proposal they could develop as promptly as possible in light of an internal briefing of the EPA Assistant Administrator the following day." *Id.* "The registrants convened their experts and prepared and submitted a further mitigation proposal later the same day." *Id*.

On December 18, 2015, EPA granted Petitioners' request for an additional brief extension, until January 15, 2016, "to accommodate the necessary time for discussions regarding the registrations." PX 15. This extension was followed with another issued January 14, 2016, extending the registrations until January 29, 2016, "to accommodate the necessary time needed for EPA to consider BCS' label proposal." PX 16.

EPA did not favor Petitioners' proposals resolving the uncertainties concerning, *inter alia*, the toxic nature of the primary degradate des-iodo to invertebrates of aquatic systems. PX 17. Consequently, on January 29, 2016, EPA sent a letter to Respondents requesting that they voluntarily withdraw registration of their flubendiamide products. *Id*. The letter stated, in relevant part, the following:

> The Agency has made a determination that the continued use of the currently registered flubendiamide products will result in unreasonable adverse effects on the environment. . . . [Bayer]/[Nichino] understood and agreed by signing the PAL that if, after review of the referenced conditional data, EPA makes a determination of unreasonable adverse effects on the environment, that [Bayer]/[Nichino] would within one (1) week of notification of this finding submit a request for voluntary cancellation of all the flubendiamide registrations. We are hereby notifying you that we have made such a finding and under the terms of the time-limited/conditional registration, you are obligated to submit an appropriate request for voluntary cancellation to EPA by or before Friday, February 5, 2016. This request for voluntary cancellation must include a statement that [Bayer]/[Nichino] recognizes and agrees that the cancellation request is irrevocable. Failure to submit a timely voluntary cancellation request will result in the Agency initiating cancellation of all currently registered flubendiamide products under section 6(e) of FIFRA.

Id.

In response, Petitioners notified EPA by letter dated February 5, 2016, that they "decline EPA's request to voluntarily cancel all flubendiamide registrations." PX 18.

As a result, on February 29, 2016, EPA issued a formal notice of intent to cancel Petitioners' flubendiamide pesticide registrations. Flubendiamide; Notice of Intent To Cancel Pesticide Registrations, 81 Fed. Reg. 11558 (March 4, 2016); PX 20. The Notice states that EPA

intends to cancel four pesticide registrations[13] containing flubendiamide "owing to the registrants' failure to comply with a required condition of their registrations." NOIC, 81 Fed. Reg. at 11558. It asserts that under Section 6(e) of FIFRA, codified at 7 U.S.C. § 136d(e), "the registrants' failure to . . . submit[] requests for voluntary cancellation makes the flubendiamide products identified . . . subject to cancellation." *Id.* at 11560.

The NOIC also contains EPA's determination regarding existing stocks[14] of flubendiamide products. The Agency states that it intends to prohibit the use of existing stocks of the flubendiamide technical registration and to prohibit the sale and distribution of the end use registrations. *Id.* The Agency explains that this choice is in accordance with its June 26, 1991 policy statement regarding disposition of existing stocks, which provides as follows:

> On the other hand, if a registrant of a conditional registration fails to comply with a specific condition identified at the time the registration was issued, the Agency does not believe it is generally appropriate to allow any sale and use of existing stocks if the registration is cancelled. Accordingly, the Agency does not anticipate allowing a registrant to sell or distribute existing stocks of cancelled products that were conditionally registered if the registrant fails to demonstrate compliance with any specific requirements set forth in the conditional registration.

Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29362, 29366–67 (June 26, 1991).

The Agency reaches a different conclusion with regard to existing stocks of flubendiamide products currently held by end users. The NOIC indicates those products should be allowed to continue in use because the quantity currently possessed by end users is small, and "the costs and risks associated with collecting them for disposal would be high compared to those associated with the use of the cancelled product in accordance with its labeling." NOIC, 81 Fed. Reg. at 11560. The Agency also notes that open containers may pose additional risk of spillage during transport, that disposal costs for open containers may be high due to testing requirements, and that notification and enforcement of end-use prohibition would impose

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[13] EPA Reg. No. 264-1025 - BELT SC Insecticide; EPA Reg. No. 71711-26 - FLUBENDIAMIDE Technical; EPA Reg. No. 71711-32 - VETICA Insecticide; and EPA Reg. No. 71711-33 - TOURISMO Insecticide.

[14] FIFRA does not define "existing stocks," but, in this case, the Agency defined "existing stocks" as "those products that were 'released for shipment' prior to the effective date of cancellation." NOIC, 81 Fed. Reg. at 11560. Courts have accepted Agency-provided definitions focusing on whether a particular item has been "released for shipment" prior to the date its registration is cancelled. *See Ciba-Geigy Corp. v. United States EPA*, 801 F.2d 430, 433 (D.C. Cir. 1986) (Existing stocks are those that are "sold, distributed, shipped, or released for shipment" before registration cancellation is effective.); *NRDC v. United States EPA*, 2010 U.S. Dist. LEXIS 10631, *11 n.7 (S.D.N.Y. Feb. 8, 2010) ("[E]xisting stocks of a pesticide are stocks which have been packaged, labeled, and released for shipment prior to the effective date of the regulatory action, such as a cancellation.") (internal quotation marks omitted).

significant costs on state and federal authorities. *Id.* The NOIC does, however, state that the Agency might "amend its position . . . if the quantity of those products in the hands of end users increases prior to cancellation." *Id*.

IV. ARGUMENTS ON ACCELERATED DECISION

A. Petitioners' Arguments

As indicated above, Petitioners filed a Motion for Accelerated Decision ("Motion") on April 11, 2016, arguing that this proceeding is unlawful and that the Agency's NOIC must be rescinded.

Petitioners' main argument is that this proceeding, a hearing on cancellation of conditional registrations under FIFRA Section 6(e), 7 U.S.C. § 136d(e), is the wrong procedure for canceling its registrations. Mot. at 46–48. Rather, they assert that cancellation of their conditional registrations requires the full process provided by FIFRA Section 6(b), 7 U.S.C. § 136d(b). *Id.* at 47.

In support of this conclusion, Petitioners characterize the "voluntary cancellation" condition as "unlawful." *Id.* at 48. They argue this condition was "designed," "devised and imposed" by EPA "to create a mechanism by which EPA could seek to short circuit the statutory process and claim the right to cancel a product it believes no longer meets the Registration Standard without any outside review of its reasoning or any substantive cancellation process." *Id.*

> 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 must fall well short of granting itself the authority to preclude the specific cancellation rights and procedures Congress chose to require and cut others – in addition to registrants – out of the process. Otherwise, EPA could by pass the cancellation and suspension requirements in FIFRA § 6 at will, rendering them meaningless.

Id. (citing *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) for the cardinal principle of statutory construction that a statute should be read as a whole so as to be construed to make no provision superfluous, void, or insignificant).

Petitioners cite *Reckitt Benckiser*, 613 F.3d 1131, 1136 (D.C. Cir. 2010), where the court rejected another recent attempt by EPA to "by-pass[] cancellation proceedings" for a pesticide it believed did not comply with the registration standard. *Id.* at 49.[15] In that case, instead of initiating cancellation proceedings, EPA attempted to use a "misbranding scheme," making distribution after a certain date unlawful. *Id.* Petitioners state the court found "[t]he statute was

[15] In further support for this position, Petitioners cite *NRDC v. EPA*, No. 14-73353, Dkt. #128 (9th Cir. Jan. 25, 2016) (order remanding registrations) in which the Court denied EPA's motion for vacatur of certain contested pesticide registrations where the registrant argued the motion was an attempt to short-circuit the statutory cancellation process. Mot. at 50.

'not ambiguous' and EPA's creative 'interpretation' was entitled to no deference." *Id.* "The same result applies here," Petitioners claim, based upon the "plain language of FIFRA's cancellation provisions" and "Congress' intent for establishing robust due process rights for existing registrations." *Id.*

Further, the Agency's position in this proceeding contradicts its own description of the differing functions of cancellations under Section 6(b) and 6(e), Petitioners' argue. *Id.* at 50–51. They point to a filing by the Agency in another FIFRA case in which the Agency argued that "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.* at 51 (citing EPA's Conditional Opposition to CropLife America's Motion to File an Amicus Curiae Brief at 4–5 & n.2, Dkt. #24, *In re Reckitt Benckiser*, EPA FIFRA Dkt. 661 (May 6, 2013)). Petitioners' contend that because it is "indisputable" that the Agency's request for voluntary cancellation of its registrations here was "due to its risk concerns and for the failure to meet the Registration Standard," (citing PX 20 [NOIC] at 11,559), the "risk-based" cancellation proceedings of Section 6(b) must apply. *Id.* at 51–52. They characterize any position taken by EPA otherwise as "implicitly disavow[ing] its earlier representations," "turn[ing] that distinction on its head," and being "flatly inconsistent" "when it suit[s] its purpose." *Id.*

The unlawfulness of the "voluntary" cancellation provision, Petitioners' suggest, also arises out of the fact that it was "forced" upon them. *Id.* at 52. They cite the NOIC for the recognition by EPA that if they had not accepted the condition of "voluntary" cancellation, their conditional registrations would not have been approved in 2008. *Id.* at 52-53 (citing PX 20 [NOIC] at 11,559). "EPA cannot be permitted to avoid its obligations by presenting powerless entities the Hobson's choice of either accepting conditions designed to bypass the cancellation process or receiving no registration at all." *Id.* at 52. Petitioners also argue that they were "confident the science would prove the safety of [their] product (as it has) and trusted that the Agency would follow the science (which it has not)." Pet'rs' Reply in Supp. of Mot. for Accelerated Decision ("Reply") at 12.

Further, "[t]he 'voluntary' cancellation provision serves no regulatory purpose," they suggest. Mot. at 53. In granting the conditional registrations, Petitioners' note, EPA found the registration in the public interest and that it posed no unreasonable adverse effect on the environment. *Id.* If they had "refused to generate the data required," EPA could cancel the registrations under section 6(e), or if EPA determined the pesticides did not meet the registration standard, they could cancel under section 6(b). *Id.* Thus, the only purpose the voluntary cancellation provision serves is to "allow EPA to evade statutory obligations and deny registrants and other affected parties' due process." *Id.* "Allowing EPA to proceed in this fashion would render the provisions in § 6 meaningless and would deny the cancellation due process protections Congress chose to provide." *Id.*[16]

The "voluntary" cancellation provision additionally "circumvents" the procedural requirements for pre-cancellation interagency and peer review, which assures the interests of the

[16] Petitioners note that EPA has authority to suspend registrations and quickly remove products posing an imminent hazard from the market under FIFRA § 6(c). Mot. at 53.

stakeholders in the agricultural community are fully considered and that a "robust and transparent record" is available. Mot. at 54. Petitioners say that because EPA avoided that process here, the record lacks an independent scientific review of EPA's scientific conclusions in support of the cancellation, which is relevant to whether this process was wrongly invoked and the existing stocks determination. *Id.* They claim that by "demanding that registrants accept the 'voluntary' cancellation condition, the Agency is not only holding registrations that should issue under FIFRA hostage to its demand for powerless entities to waive their due process rights, it is also effectively asking pesticide companies to waive the rights of other important stakeholders," which the companies have no authority to do and which is contrary to Congressional intent. *Id.* at 55 (citing FIFRA §§ 6(b), 25(d), *Envtl. Def. Fund, Inc. v. Costle*, 631 F.2d 922, 936–37 (D.C. Cir. 1980) (noting the Congressional objective in amending FIFRA in 1972 was to "broaden the category of hearing requestors" beyond registrants.).

Petitioners devote the remaining significant portion of their Motion to arguing that they have complied with what they characterize as the "lawful conditions" of their registration and that flubendiamide meets the registration standard. Mot. at 55–65. As determination of the Motion does not turn on these issues, those arguments are not set forth in detail here. *Id.* at 1 (describing this as a "threshold motion" on process), Reply at 2 ("these are foundational jurisdictional issues"), Mot. at 3 ("The ALJ need not reach the merits of EPA's proposed cancellation or determine whether flubendiamide meets the FIFRA registration standard to grant this motion and deny the proposed cancellation."), Mot. at 67 (noting that Petitioners "do not here seek a finding . . . that flubendiamide meets the Registration standard," only that the "forced 'voluntary' cancellation condition approach is unlawful").

The Reply Petitioners filed in support of their Motion largely reiterates the initial points made, and otherwise responds to the Agency arguments.

B. Respondent's Arguments

The Agency filed its Opposition to the Motion on April 18, 2016. EPA argues that (1) Petitioners waived their right to challenge the legality of the condition when it accepted the registrations, (2) the condition is a legal and appropriate exercise of the Agency's authority under FIFRA, (3) even if the condition were deemed illegal the only remedy would be the invalidation of the registrations, (4) this Section 6(e) proceeding is, at minimum, an available option the Agency could choose, and (5) Petitioners' Motion falls outside the limited scope of this Section 6(e) hearing.

EPA proposes two threshold bases upon which it argues the Motion should be denied. First, it suggests that "Petitioners waived or reduced their due process rights from a fuller FIFRA section 6(b) hearing to the more limited FIFRA sections 6(e) and 6(f) rights to get their products to market quicker." Opposition at 61 n. 27. The Agency argues that because "Petitioners voluntarily with knowledge and intelligence agreed to the limited hearing rights afforded in FIFRA sections 6(e) and 6(f)," their waiver of any additional due process rights they may have possessed is consistent with case law allowing such waiver. *Id.* (citing *D. H. Overmyer Co. v. Frick Co.*, 405 U.S. 174, 185–86 (U.S. 1972)).

Second, the Agency briefly argues that Petitioners' challenge to the legality of the "voluntary withdrawal" condition should be barred by the statute of limitations. Opp'n at 65. "While there is no statute of limitations included in the pesticide registration process, it makes sense to apply the six year general statute of limitations for civil actions against the United States." *Id*. (citing 28 U.S.C. § 2401(a) ("[E]very civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues."). In the Agency's view, "the statute of limitations begins to run" when a registration is issued, as thereafter "the Agency is responsible for no immediate formal, additional review procedures." *Id*. (citing *Impro Products, Inc. v. Block,* 722 F.2d 845, 850–51 (D.C. Cir. 1983)). Failing that, "the statute of limitations could begin to run upon the release for shipment of the relevant products." *Id*. EPA argues that in either case, "if the Registrants had an issue with any of the agreed-upon conditions in the pesticide registrations, they should have filed an action within six years of sometime in August of 2008." *Id*.

The Agency's Opposition further argues that that challenged conditions are, in fact, lawful. The Agency's position is that "the cancellation conditions are lawful, were accepted by the Registrants, and remain material elements of the flubendiamide registrations." *Id*. at 16–17. EPA points to one of the few cases that have addressed the lawfulness of registration conditions, *Woodstream Corp. v. Jackson,* 845 F. Supp. 2d 174 (D.D.C. 2012) *(Woodstream II),* and argues that the district court there "upheld EPA's authority to include appropriate, non-data-related, conditions on pesticide registrations, including expiration dates." *Id*. at 17. The Agency also highlights "discussions between Registrants and EPA [that] demonstrate that" not only were the Registrants "well aware of the cancellation provisions, [they] were materially engaged in shaping those provisions, and ultimately acceded to the cancellation provisions [that were] included in the PAL." *Id.* at 31. Therefore, while it does not believe the merits regarding the legality of the conditions at issue should even be considered in this proceeding, EPA contends that those conditions would withstand judicial scrutiny as examples of the lawful exercise of its authority to regulate pesticides under FIFRA.

The reason EPA argues that "the focus in this case should not be on whether the conditions were lawful" is that, in its view, "without the conditions the initial FIFRA finding of no unreasonable adverse effects is unsupported and the registration itself should be considered invalid." *Id*. at 3. The Agency points to the language of the PAL and registration documents as proof that it "clearly . . . relied upon the mutually agreed-upon conditions in the registration in order to grant the registration." *Id*. at 27. It suggests that the only remedy this Tribunal could offer Bayer, if it were to hold the conditions unlawful, would be to simply declare the registrations void *ab initio*. *Id*. at 40.

In seeking other relief, the Agency contends Petitioners are "in effect, asking this Tribunal to rewrite the terms and conditions of their registrations," which would exceed its authority. *Id*. at 37. "Under no circumstances," the Agency declares, "is it appropriate to provide Registrants with registrations that EPA's appropriate pesticide personnel have never determined, ***and never even been asked to determine***, meet the standard for registration under FIFRA." *Id*. at 41. Rather, in the event "one or more terms or conditions of a pesticide registration were found inappropriate or unlawful, EPA maintains that the appropriate remedy would be to invalidate the entire registration and remand the decision to EPA" to conduct a new

registration proceeding. *Id*. at 37.

The Opposition also argues this Section 6(e) proceeding is the correct—or failing that, at least a permissible—procedure for cancellation of these registrations. The Agency emphasizes that it clearly and unambiguously "announced its intent to cancel on account of the Registrants' failure to comply with terms of their conditional registrations . . . [and not] on account of unreasonable adverse effects." *Id*. at 52. Therefore, even if "evidence might exist that would support a decision to pursue cancellation of Registrants' flubendiamide products pursuant to FIFRA section 6(b), it is unquestionably true that those products were registered under FIFRA section 3(c)(7)[.]" *Id*. at 53. As it is similarly uncontested "that Registrants failed to satisfy certain conditions of those registrations," the Agency asserts they "are therefore subject to cancellation pursuant to FIFRA section 6(e)." *Id*. Moreover, EPA believes "[i]t would be a misuse of public resources to pursue a [slower and more resource-intensive] section 6(b) proceeding when the conditions for a section 6(e) cancellation have been met." *Id*.

The Agency further stresses that Petitioners were fully capable of forcing the Section 6(b) hearing they now seek, and simply chose not to do so:

> [T]he Registrants could have obtained a hearing equivalent to a FIFRA section 6(b) proceeding by refusing to accept the conditional registration and insisting upon a FIFRA section 3(c)(6) denial hearing. In the almost eight years since, Registrants have also failed to request amendments removing the conditions, and failed to apply for new, unconditional registrations, which also offer paths to the equivalent hearings. So the Registrants have had ample opportunities to obtain the hearing they claim to seek; to the extent that EPA's commencement of a cancellation proceeding under FIFRA section 6(e) forecloses some of these opportunities, it is simply a matter of Respondents having let their time run out.

Id. at 45.

Finally, the Opposition argues that the Motion falls outside the narrow scope of this Section 6(e) hearing. "This limited proceeding under section 6(e) of FIFRA, with a statutorily imposed time-limit for decision . . . is manifestly not the appropriate forum for Registrants to raise the science issues dotted throughout their Motion and their Request for Hearing and Statement of Objections." *Id*. at 34. The statutory "limitation on the scope of a FIFRA section 6(e) proceeding effectively precludes the scientific, economic and other fact-finding that might be encountered in a FIFRA section 6(b) hearing, and therefore precludes the detailed consideration of EPA's unreasonable adverse effects determination[.]" *Id*. at 54–55. It would be "simply impractical to conduct the evidentiary hearing mandated by FIFRA section 6(b)—not to mention SAP review—within the 75-day limit mandated by FIFRA section 6(e)(2)." *Id.* at 55. Moreover, EPA asserts the Motion's request that I "determine that the condition at issue in this proceeding is inappropriate or unlawful . . . take[s] this Tribunal outside the scope of FIFRA section 6(e), [and] those arguments [therefore] could, and should, be dismissed summarily." *Id*. at 62.

C. Amici Arguments

In their Amicus Brief, the Growers state that they "rely on administrative agencies to provide a fair process prior to cancelling a pesticide because it is critical to their operations that they have choice and availability of safe and effective pesticides." Growers' Br. at 17. They suggest the proper process is the "detailed, multi-step" one set forth in FIFRA § 6(b) involving a "comprehensive evaluation of risk, benefits, and possible risk-mitigation options," stakeholder and interagency input, and independent scientific analysis. *Id.* at 17–18. Here, the "unlawful" process being used will "bypass[] all of these established regulatory procedures" and "effectively silence[] growers from having any input in a decision which directly impacts them." *Id.* at 19.

The Growers' suggest that in amending FIFRA in 1972, Congress intended to ensure their economic interest was considered before any pesticide was withdrawn from the market. *Id.* at 19 (citing *McGill v. Environmental Protection Agency*, 593 F.2d 631, 634 (5th Cir. 1979)). They express strong concern that this action under FIFRA §6(e), the first of its kind "in more than 20 years," is part of EPA's "continued efforts to circumvent statutory procedures in order to summarily cancel pesticides, rendering stakeholders impotent." *Id.* at 19, 21. They cite a series of cases related to pesticide cancellation, including *Ciba-Geigy Corp. v. United States EPA*, 801 F.2d 430 (U.S. App. D.C. 1986) (EPA sought to deny hearing on cancellation of pesticide by claiming entitlement to effectuate cancellation via procedures governing "misbranded" pesticides); *In the Matter of American Food Security Coalition*, 1993 EPA ALJ LEXIS 46 (holding that the "conclusion seems inescapable" that sole purpose of EPA's actions was to "oust [growers] from the hearing and make the cancellation of the contested issues final"); *Crop Life America v. EPA*, 329 F.3d 876, 882 (U.S. App. D.C. 2003) (holding that EPA's action was unlawful because it constituted a binding regulation that was issued without the notice of proposed rulemaking and period for public comment mandated by FIFRA); *Reckitt Benckiser, Inc. v. EPA*, 762 F. Supp. 2d 34 (U.S. App. D.C. 2011) (EPA sought to effectuate cancellation of a pesticide via a misbranding enforcement action rather than the appropriate process established under Section 6 of FIFRA); and *Natural Res. Def. Council v. EPA*, No. 14-73353 (9th Cir. Dec. 7, 2015) (order denying EPA's motion for voluntary vacature of pesticide registration). *Id.* at 19–21.

Further, the Growers argue "EPA's unlawful demand for voluntary cancellation effectively shields EPA's determination from review and challenge," by independent, transparent, scientific review and oversight authorities who assure against "arbitrary or ill-considered regulation" and safeguard their interest in choice of pesticide availability. *Id*. at 21-22. They also make very extensive arguments, not relevant here, regarding the benefits, safety, effectiveness, cost, etc. of flubendiamide. *Id.* at 23–46. In conclusion, they request an order denying EPA's request for cancellation under FIFRA § 6(e), and that EPA be ordered to proceed under FIFRA § 6(b). *Id.* at 46.

CropLife, in its amicus brief, argues that it is unlawful for EPA to here use the FIFRA §6(e) "abridged" and "truncated" process, offering three reasons in support thereof:

> First, the plain text of FIFRA makes clear that Section 6(b), not Section 6(e), provides the exclusive means of canceling a registration due to a finding of "unreasonable adverse effects." Second, EPA's approach runs afoul of the canon of statutory construction that specific language in one provision of a statute trumps general language or silence in another. And, third, EPA's approach fails to account for Congress' use of the same language in both Section 3(c)(7)(C) and Section 6(b), which indicates an intent that the two provisions be read together rather than as siloed statutory concepts."

CropLife's Amicus Br. at 11–12.

In further support for its proposition, CropLife cites legislative history, "particularly leading to the 1975 amendments," for the proposition that it was "Congress' intent that Section 6(b) serve as the mechanism to cancel a registration based on 'unreasonable adverse effects' on the environment," because that process took into account the interest of various agricultural stakeholders. *Id.* at 16 (citing, *inter alia*, H. R. Rep. No. 94-497 to Accompany H.R. 8841(Sept. 19, 1975), at 36-37 (". . . under section 6(b) the Administrator must include among those factors to be taken into account [before cancellation] the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy . . . ."), S. Rep. No. 94-452, at 8 (1975) (noting the bill's provisions for "advance notification of the Secretary of Agriculture of proposed cancellations and changes in classification and of regulations, are in response to the often-stated concern that EPA has not adequately considered the impact of its actions' on agriculture.")). Similarly, Courts and agency decisions indicate a "robust" cancellation process is required, and have "highlighted the impropriety of circumventing Section 6(b)," CropLife claims. *Id*. at 18 (citing *McGill v. E.P.A.*, 593 F.2d 631, 635 (5th Cir. 1979); *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d at 42).

Finally, CropLife argues that Congress did not intend for Section 6(e) proceedings to be used to force voluntary cancellations based upon unilateral unreasonable adverse effects determinations by the Agency. *Id*. at 20. Rather, "Congress created the abbreviated cancellation process of Section 6(e), to address situations in which a registrant was not making adequate progress toward fulfilling its data generation requirements or when a registrant failed entirely to generate the required data within the time allotted as part of the condition of registration." *Id.* at 20–21 (citing 123 Cong. Rec. S13, 090-92 (1978) (Debate re Senate Passage of S. 1678 as Amended, July 29, 1977)).[17] CropLife continues:

[17] With regard to conditional registrations, CropLife quotes from this Report to the effect that "[t]he Agency does change its data requirements. What provides an appropriate basis on which to reach scientific conclusions about toxicity today, the scientist may wish to augment tomorrow." CropLife Amicus Br. at 21 (quoting 123 Cong. Rec. S13,090-92 (1978) (Debate re Senate Passage of S. 1678, as amended, July 29, 1977)). This language is pertinent here to the extent that Petitioners allege that EPA unlawfully changed its data requirements for registration, specifically the toxic endpoint, seven years after the conditional registration was granted, leading to the cancellation.

> There is no indication that Congress intended to allow EPA unbridled discretion to use the conditional registration provisions of FIFRA Section 3(c)(7)(C) to impose a 'condition of registration' that purports to require 'voluntary' cancellation of a registration upon EPA's unilateral determination that a pesticide product no longer satisfies the FIFRA registration standard.

Id. at 23. As such, CropLife urges that EPA be required to follow FIFRA 6(b) proceedings with regard to Petitioners. *Id.* at 24.

Unlike the Growers and CropLife, the Amicus Brief filed by the Center for Biodiversity ("CBD") supports the Agency's decision to cancel the Petitioners' registrations. CBD Br. at 1. It asserts Petitioners arguments against the use of the section 6(e) are in error, making three points. First, CBD contends, Petitioners rely on the proposition that "a conditionally-granted registration is functionally equivalent to its unconditional counterpart" and so is entitled to the same privileges as they relate to registration and cancellation. *Id*. at 10. Second, Petitioners are attempting to refute "in a post hoc fashion, the legality and applicability of the conditions of [their] registrations" which they agreed to and are anticipated by statutory language, CBD claims. *Id*. at 10, 14–16. Third, Petitioners allege that the cancellation of a conditionally registered pesticide is entitled to the same scope of review as a fully registered pesticide, CBD argues. *Id.* at 10–11.

CBD notes Petitioners have only conditional registrations, because they were "unable to fulfill the criteria necessary for immediate registration" when they originally applied. *Id.* at 13. They could have withdrawn their application and reformulated to meet FIFRA registration criteria, CBD states, but instead opted to accept the qualified, conditional registration aware that if the listed conditions were not complied with their registrations were immediately subject to review and cancellation under Section 6(e). *Id.* As such, their claims of significant "property rights" relating to registration and cancellation attaching to a full registration are erroneous, CBD states. *Id.* at 12. In support, CBD advises that all of the property rights cases cited by Petitioners in their Motion "rel[y] upon fact situations in which the registrant had a full and final registration." *Id*.

Further, CBD argues Petitioners have benefited from accepting the conditional registration by selling their products, which they would not have done had EPA opted to reject their original deficient application. *Id*. at 15. In exchange, they were required to provide EPA with evidence that their products met or exceeded registration requirements that (indefinite use) would not cause unreasonable adverse effects on the environment, CBD observes. *Id*. Petitioners "were unable to do so" so by the conditions agreed to, CBD concludes, so they were required to expeditiously request voluntary cancellation. *Id*. CBD also notes that Petitioners complied with the voluntary cancellation provision—which it now asserts is unlawful—in regard to a fifth flubendiamide registration for SYNAPSE. *Id.* (citing Hr'g Req. Ex. 21).[18]

[18] CBD also includes in its Brief arguments regarding the sale of existing stocks not relevant to the Motion, here. CBD Amicus Br. at 18–20.

V. STANDARDS FOR ACCELERATED DECISION

Petitioners cite as authority for their Motion 40 C.F.R. § 164.91(a)(7). Mot. at 1, 45. That Rule provides as follows:

> The Administrative Law Judge, in his discretion, may at any time render an accelerated decision in favor of *Respondent* as to all or any portion of the proceeding, including dismissal without further hearing or upon such limited additional evidence such as affidavits as he may receive, under any of the following conditions:
>
> > (7) Theat [sic] there is no genuine issue of any material fact and that the *respondent* is entitled to judgment as a matter of law.

40 C.F.R. § 164.91(a)(7) (emphasis added).

Under the Rules of Practice, the "Respondent" is defined as "the Assistant Administrator of the Office of Prevention, Pesticides, and Toxic Substances." 40 C.F.R. § 164.2(s). As defined by procedural rules, the Motion was filed by the "Petitioners," i.e., the "person[s] adversely affected by a notice of the Administrator who requests a public hearing," and/or "registrants."[19] 40 C.F.R. §§ 164.2(o), 164.2(r).

However, this Tribunal has the power to take actions in conformity with statute or in the interests of justice. 40 C.F.R. § 164.40(d). Further, this Tribunal is obliged to rule upon all motions prior to the entry of an accelerated or initial decision. 40 C.F.R. § 164.60(c). Consequently, I find Petitioners are authorized to file for accelerated decision in this proceeding.

VI. ANALYSIS

The crux of Petitioners' argument is that, because EPA has determined flubendiamide products cause unreasonable adverse effects to aquatic environments, the only cancellation procedure available to the Administrator is under FIFRA Section 6(b), 7 U.S.C. § 136d(b). They contend the voluntary cancellation condition of their registrations, which requires them to voluntarily request cancellation of the pesticides within one week of being notified by EPA that the pesticides generally causes unreasonable adverse effects on the environment, is "unlawful because" it violates the text and structure of FIFRA. Thus, they are entitled to a judgment as a matter of law and an order dismissing this proceeding under Section 6(e), 7 U.S.C. § 136d(e). Mot. at 1–4.

I disagree. FIFRA's text, structure, and legislative history and federal court opinions allow for this Section 6(e) proceeding.

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[19] "The term *Person* includes any individual, partnership, association, corporation, and any organized group of persons, whether incorporated or not." 40 C.F.R. § 164.2(n).

It is undisputed that Petitioners neither applied for nor received a general registration for their flubendiamide pesticide products under FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5). Mot. at 20; PX 7. Rather, they applied for and received in 2008 "conditional registrations" for their flubendiamide products under FIFRA Section 3(c)(7)(C) based upon the "special circumstance" of their pesticide containing a new active ingredient. 7 U.S.C. § 136a(c)(7)(C) ("Notwithstanding the provisions of paragraph (5) . . . . The Administrator may conditionally register a pesticide containing an active ingredient not currently contained in any currently registered pesticide.") Mot at 20; PX 7. FIFRA Section 3(c)(7)(C), the statutory provision authorizing the *granting* of conditional registrations under such circumstances, was enacted in 1978, and concomitant therewith, Congress revised FIFRA Section 6(e) to explicitly set forth a procedure for *cancelling* the newly authorized conditional registrations. 7 U.S.C. § 136d(e). Petitioners have cited nothing in those two statutory provisions themselves, nor in the legislative history of the 1978 amendments, suggesting there was any intent to require EPA to employ a cancellation process other than that explicitly set forth under Section 6(e). In particular, Petitioners have cited nothing in the statute or legislative history to suggest that EPA is obliged to use the pre-existing general registration cancellation process under FIFRA Section 6(b) for cancelling general registrations, to cancel conditional registrations.

In fact, the legislative history of the addition of the conditional registration provisions suggests the opposite. *See* H.R. Rep. No. 95-343, at 10–11 (1977) ("We strongly believe that the Agency should be required to cancel the registration if the conditions are not met within the appropriate time interval, and that any hearing on such cancellation should be confined to whether or not the conditions were met and how existing stocks should be handled. *Public resources should not be devoted to long, drawn-out cancellation procedures for these types of registrations.*") (emphasis added); S.Rep. No. 95-334, at 10-11 (1977) (it was agreed "that the Administrator could cancel conditional registrations with only limited notice," and also "that the Administrator in implementing this provision should take necessary steps to assure that conditional registrations are granted only in circumstances in which the risk of unreasonable adverse effect would be minimal").

Finding no support in the particularly applicable statutory provisions for conditional registrations themselves or the legislative history relevant thereto, Petitioners support their claim by referring instead to the general registration cancellation procedures of Section 6(b), 7 U.S.C. § 136d(b). Specifically, they argue that section must be applied here because it allows for cancellation of general registrations if the Administrator, as she allegedly did here, determines that a pesticide "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." 7 U.S.C. § 136d(b); Mot. at 47. However, Petitioners offer no authoritative support for that proposition either. While Section 6(b) does allow for cancellation on various grounds, such as non-submission of required materials or when found to cause unreasonable adverse effects on the environment, it makes no mention of conditional registrations. 7 U.S.C. § 136d(b). Further, if it could be the basis for cancellation of conditional registrations due to non-submission of required materials, e.g., the data required by a conditional registration, then Section 6(e) would be rendered superfluous, and violate a cardinal rule of statutory construction. *Marx v. Gen. Revenue Corp.*, 133 S. Ct. 1166, 1168 (2013) ("The canon of statutory construction against surplusage is strongest when an interpretation would render superfluous another part of the same statutory

scheme."); *Greenpeace, Inc. v. Waste Technologies Indus.*, 9 F.3d 1174, 1179 (6th Cir. 1993) ("We must interpret the statute as a whole, making every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless, or superfluous."); *see also Lake Cumberland Trust, Inc. v. U.S. E.P.A.*, 954 F.2d 1218, 1222 (6th Cir. 1992); *Boise Cascade Corp. v. U.S. E.P.A.*, 942 F.2d 1427, 1432 (9th Cir. 1991)), *modified* (Apr. 10, 1992); 2A Sutherland Stat. Const. § 46.05 (5th ed. 1992).

The few cases that Petitioners cite to support their claim that EPA is required to go through a Section 6(b) proceeding to cancel pesticide registrations are all clearly distinguishable from the facts of this case because they involve general registrations, not conditional registrations. Mot. at 47–49. *See, e.g.*, *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011) (full registration could not be effectively cancelled by misbranding action); *Reckitt Benckiser, Inc. v. EPA*, 613 F. 3d 1131 (D.D.C. 2010) (same).

Moreover, the application of an extended cancellation process for conditional registrations makes no sense in the FIFRA scheme. Full registrations for pesticides cancelled under Section 6(b) are entitled to an extended process because EPA previously determined their use, on an *indefinite basis*, would not cause unreasonable adverse effects on the environment. *Reckitt Benckiser Inc.*, 613 F.3d at 1134 (D.C. Cir. 2010) ("A pesticide product remains registered until EPA or the registrant cancels it pursuant to Section 6, 7 U.S.C. § 136d."). Conditional registrations, on the other hand, are granted explicitly because the Administrator *cannot* make such a determination. She lacks all the necessary information to do so, and it will take some period of time for the applicant to acquire data for a determination on its indefinite use. But based upon the limited data she has, the Administrator can determine "that use of the pesticide *during such period* [to gather the missing data] will not cause any unreasonable adverse effect on the environment."[20] 7 U.S.C. § 136a(3)(C); *Woodstream Corp. v. Jackson*, 2011 U.S. Dist. LEXIS 151994, *2–3 (D.D.C. June 3, 2011) (Preliminary Injunction Order, Judge Boasberg) (*Woodstream I*) ("Products may be conditionally registered in certain circumstances. Where EPA does not yet have all of the required information to issue a registration under § 136a(c)(5), it may still do so, but only after a finding that the pesticide will not create or significantly increase a risk of unreasonable adverse effects on the environment."); *Woodstream Corp. v. Jackson*, 2011 U.S. Dist. LEXIS 151994 *12–13 (D.D.C. 2012) (Summary Judgement Order, Judge Rothstein) (*Woodstream II*) ("There is no dispute that FIFRA explicitly allows for a conditional registration when test data is unavailable."). The alternative to conditional

[20] At the time Petitioners submitted their application for registration, neither they nor the Administrator had sufficient information to warrant a full registration, necessitating additional conditions of a traditional, data-gathering nature. *See, e.g.*, PX 8 ("The Agency believes that the efficacy of vegetative buffers for flubendiamide use is uncertain. Open literature and Bayer-conducted studies on compounds with similar characteristics to flubendiamide provide information that permits an estimation of the impact of such buffers on the risk picture. A confirmatory small-scale run-off/vegetative buffer strip study with flubendiamide would allow the Agency to quantitatively consider the impact of such buffer strips on risk reduction in critical use areas. . . . The Agency will make use of the results of the small-scale run-off/vegetative buffer strip study in refining the aquatic exposure and risk assessment.").

registration is for the Administrator to deny registration based upon the applicant failing to prove its pesticide meets the standard and/or for the applicant to wait until it had absolutely all of the necessary data for a full registration. As such, a "conditional registration" is not equivalent to a full registration; it is a stop-gap status that gives the registrant time to gather data to prove it is entitled to general registration. This situation is analogous to obtaining a learner's permit to obtain the requisite skill to demonstrate competence on the practical driving skills test in order to obtain a driver's license. As such, conditional registrations are not entitled to the same lengthy procedures for cancellation under Section 6(b). *See Woodstream II*, 845 F. Supp. 2d 174, 177 ("Cancellations of conditioned registrations fall under Section 6(e)."); *Woodstream I*, 2011 U.S. Dist. LEXIS 151994 (same).

Perhaps recognizing the weakness of its statutory arguments, Petitioners come from another angle to attack the use of the Section 6(e) process here, arguing that the "forced" voluntary cancellation condition in their conditional registrations is "unlawful." Mot. at 52. However, statutory and regulatory language undermines their argument, and the case law Petitioners cite in support of their Motion is inapposite to their position. Specifically, FIFRA section 3(c)(7) states the Administrator can register a pesticide with a new ingredient "on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this Act, *and on such other conditions as the Administrator may prescribe*." 7 U.S.C. § 136a(3)(c)(7) (emphasis added). The term "other conditions" in the statute is in no way limited. Moreover, the regulations promulgated to implement the Act also allow for "other conditions" to be applied on a case-by-case basis, suggesting flexibility to meet the needs of the Agency and circumstance. 40 C.F.R. 152.115(c) ("The Agency may establish, on a case-by-case basis, other conditions applicable to registrations to be issued under FIFRA sec. 3(c)(7)."). The courts have upheld the Administrator's authority to impose a wide range of conditions, including those that effectively limit cancellation proceedings for conditional registrations. *Woodstream I*, 2011 U.S. Dist. LEXIS 151994; *Woodstream II*, 845 F. Supp. 2d 174.

In the *Woodstream* cases, which Petitioners claim are flawed and distinguishable from this case,[21] the holders of conditional pesticide registrations challenged whether EPA could place conditions unrelated to test data on such registrations, such as expiration dates. In response to

[21] Petitioners argue that the Woodstream cases are "quite different," because the "expiration date was fixed and based on a substantive determination by EPA in the Risk Mitigation Decision," and "Woodstream refused to comply with the conditions." Reply at 12. They also argue the *Woodstream II* decision was wrong because "[t]he 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.'" *Id.* at 14. (quoting *Reckitt Benckiser*, 762 F. Supp. 2d at 43 (internal quotations omitted)). The court, in *Woodstream II*, found that "EPA's decision is entitled to deference, and was not arbitrary or capricious." 845 F. Supp. 2d at 184. The fact that Petitioners here frame their argument similarly to *Reckitt Benckiser* does not make *Woodstream II* incorrect or distinguishable from the facts presented in this proceeding. Moreover, as explained in this Order, the plain language of the statute entitles Petitioners to a cancellation proceeding only under FIFRA Section 6(e).

the claim that Congress "clearly intended" to limit EPA's authority to apply conditions related only to the submission of test data, the court in *Woodstream I* stated:

> [S]uch a reading of the statute is not obvious at all. First, the plain language does not restrict EPA's authority in this fashion. Although this is the only condition mentioned, the language does not expressly bar others. The legislative history, moreover, suggests that when Congress created the current registration process in the 1978 amendments, including the conditional registration process, it favored practicality over the "more stringent requirements." S. REP. NO. 95-334 at 4. Congress was concerned with the logjam of registration applications and the "lack of middle ground" in the registration process. Id. A middle ground between registration and denial would, of course, be conditional registration.
>
> The structure of the statute likewise does not lead to Plaintiff's conclusion. Plaintiff suggests that if EPA is allowed to place conditional expiration dates on registrations, it will make Section 6 cancellation procedures superfluous. [] This argument is unpersuasive because a registrant may challenge any conditions on its registration through the Section 6 procedure. *See* 7 U.S.C. § 136a(c)(6). While EPA's interpretation may shift the burden to the registrant to initiate the proceedings, it does not make these proceedings superfluous or deny a registrant an opportunity to challenge EPA's decision. The structure of the statute thus does not evidence Congress's intent to limit EPA's authority to place conditions on registrations.
>
> [. . .]
>
> Having considered the plain language, legislative history, and structure of FIFRA, the Court cannot say that the statute unambiguously forbids EPA from placing non-test-data conditions on registrations. . . .

Woodstream I, 2011 U.S. Dist. LEXIS 151994 *13–14. *See also, Woodstream II*, 845 F. Supp. 2d 180, 181 ("The plain language of the statute does not restrict EPA's authority as to the type of conditions that may be placed on registrations. . . . There is nothing to suggest that Congress intended to limit conditions on registrations to test data.").

Further, in response to the claim that the placement of an expiration date is not appropriate because it constitutes an "end run" around Section 6(b)'s cancellation procedures," the court found that –

> Such an argument, however, neglects Plaintiff's other options. At the hearing, EPA explained (and Plaintiff conceded) that Woodstream had at least three options in the face of EPA's imposition of the conditions: (1) it could have withdrawn its request for an amendment; (2) it could have accepted the conditions and submitted a new amended registration seeking to remove those restrictions; or (3) it could have sought judicial review in a district court of the conditions imposed on the amended registrations.
>
> Plaintiff's first option was to withdraw its request for an amendment. This action would have only affected its bromethalin registrations, as those were not previously

> subject to the RMD or an expiration date. Had Plaintiff chosen this route, it could have continued to sell its bromethalin products under the terms of its prior registration until EPA initiated Section 6 cancellation proceedings. At the hearing, Plaintiff said this option was unacceptable because the amendments were commercially valuable to the company. While that may be a business decision for Woodstream to make, it does not negate withdrawal as a valid option.
>
> If Woodstream genuinely needed the commercial benefits of the amended registrations, it had an option to take advantage of those benefits while still challenging the conditions. Under its second option, Plaintiff could have accepted the conditions but immediately filed a new request for an amended registration removing the conditions. EPA presumably would have denied such a request, thereby entitling Woodstream to a denial hearing under § 3(c)(6). As that section makes clear, the denial hearing procedures mirror those of a Section 6 cancellation proceeding. Id. Woodstream thus could have forced EPA into a denial proceeding while continuing to sell under the amended registrations.
>
> Plaintiff's third option was to seek judicial review of the conditions EPA imposed. See 7 U.S.C. § 136n. Plaintiff finally chose this option, but only after waiting for almost three years. It could have instituted such a challenge in 2008. Having bypassed its first two options and postponed its third, Plaintiff cannot now claim that EPA's procedures robbed it of alternatives. Plaintiff, nevertheless, argues that its position is supported by the decision in Reckitt Benckiser, 762 F. Supp. 2d 34, 2011 WL 263730 at *16, where another court in this District found that Section 6 is the exclusive means for EPA to remove a product with a valid registration from the market. Reckitt Benckiser involved a situation different from this case. There the plaintiff had a valid registration that EPA was attempting to cancel without following Section 6. Id. at 7. Here, on the contrary, the registrations themselves carry their own expiration dates. They are not valid pending EPA action; indeed, they are invalid as of June 4, 2011.

Woodstream I, 2011 U.S. Dist. LEXIS 151994, *17–19. *See also Woodstream II*,

> Woodstream claims that EPA abused its discretion by conditioning its registrations on complying with the RMD [Risk Mitigation Decision] or facing the expiration of its registrations on June 4, 2011, because the conditions allow EPA to 'bypass' the cancellation procedures under Section 6, 'without affording Woodstream the important procedural protections . . . provided by FIFRA § 6(b).' [] However, what Woodstream fails to recognize it that there were other avenues available to it by which it may have received an administrative hearing. For example, Woodstream could have accepted the conditions, but immediately filed a new request for an amended registration removing the conditions. If the EPA denied the request, as it presumably would, Woodstream would be entitled to the same remedies available under Section 6 in the case of a cancellation, including an opportunity for a full administrative hearing.

845 F. Supp. 2d at 182–83.

Petitioners' challenge here regarding the "voluntary cancellation" provision is very much the same as that made by the plaintiffs in the *Woodstream* cases regarding the expiration date and rejected by *two* judges of the D.C. District Court. Moreover, Petitioners here too had options. Specifically, when presented with the final Preliminary Acceptance Letter in July 31, 2008, providing that their pesticides would be conditionally registered with a voluntary cancellation provision, they could have withdrawn their applications for registration, accepted the conditions and submitted a new amended registration seeking to remove those restrictions, sought judicial review of the conditions imposed (7 U.S.C. § 136n), or refused to accept the conditions and allowed EPA to deny the registration.[22] Had Petitioners' registrations been denied, then they would have then been entitled to a Section 6(b) hearing. 7 U.S.C. § 136a(c)(6); PX 8. However, Petitioners chose *none* of those other options. Like the *Woodstream* Plaintiffs, they made a business decision, likely for excellent economic reasons, and accepted the conditions and put their products on the market under conditional registrations. Thus, Petitioners' characterization that EPA "forced" them into accepting the condition or gave them a "Hobson's choice," is unpersuasive.[23]

Moreover, the record in this case indicates that Petitioners played an active part in drafting the conditions in the PAL containing the voluntary cancellation provisions and were well aware of their significance. E-mail exchanges between Petitioners and EPA evidence that the parties negotiated the conditional terms and language in the PAL, with Petitioners offering up the language regarding the voluntary cancellation, which appears in the final draft, and describing that document as a "legal agreement." *See*, AX D; PX 8. Further, Petitioners recognized the significance of the "voluntary cancellation" provision. Specifically, Petitioners' representative noted in regard thereto that - "My take is that the Agency would like to avoid having to go through Section 6 cancellation proceedings. We understand this, so have little problem with fitting in the 'fast death' approach, i.e. voluntary cancellation within a week of the decision." AX D (email dated July 30, 2008 from Clive Halder to Lois Rossi.). Petitioners' argument that they were not the first to propose the voluntary cancellation provision is of no moment, because the correspondence reflects that the Petitioners' advanced the proposal reflecting the best deal it could reach with the EPA. Reply at 10–12; AX D. Contrary to

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[22] The PAL explicitly specifies that "[i]f either Nichino or Bayer does not agree with any of the conditions of registration, they should consider any such registration to be null and void." PX 8 at 4. The letter goes on to state that "[i]f either Nichino or Bayer notifies EPA that it is unwilling to accept any of those conditions, EPA will commence the appropriate denial process under section 3(c)(6) of FIFRA." *Id*.

[23] If disappointed by the cancellation action here, Petitioners are still entitled to refile for registration and if denied, appeal that denial under Section 6(b), which would provide them and the Amici (CropLife and the Growers), with the full review they claim to desire. During that proceeding, however, they would not be entitled to sell their products while that action was pending, as they are presently.

Petitioners' assertion that the voluntary cancellation provision serves no regulatory purpose (Reply at 4–10), the e-mail exchanges demonstrate that Petitioners recognized EPA was concerned with the ability to quickly cancel the conditional registrations in an orderly fashion should the Petitioners fail to mollify EPA's concerns about the risks of Petitioners' untested products on the environment. Thus, it appears, the purpose of the voluntary cancellation was to quickly stop the sale and distribution of Petitioners' pesticide products—a regulatory obligation Petitioners' do not dispute. As such, this Tribunal sees no reason to allow Petitioners out of the 2008 legal agreement they knowingly made for a "fast death" cancellation arrangement. This is especially true because Petitioners only sought to challenge the voluntary cancellation arrangement as "unlawful" *seven years* after entering into it and only when EPA sought to trigger the cancellation and make Petitioners live up to their end of the bargain.[24] In the interim, Petitioners financially benefited from the conditional registration, which allowed them to sell their products while pursuing data to remove the "uncertainty" as to their adverse effects on the environment.

In sum, this is properly a Section 6(e) proceeding. This Tribunal's authority in a 6(e) proceeding is very limited, as is its time for acting. The "only matter" for resolution here[25] is whether Petitioners "initiated and pursued appropriate action to comply with the condition," 7 U.S.C. § 136d(e)(2). Petitioners also do not dispute that "voluntary withdrawal" was a condition of their conditional registration and that they did not comply with that condition.

Accordingly, the Motion for Accelerated Decision by Bayer CropScience and Nichino America, Inc., is **DENIED**.

SO ORDERED.

Susan L. Biro
Chief Administrative Law Judge

Dated: April 25, 2016
Washington, D.C.

[24] Voluntary Cancellation of registrations is a known and statutorily authorized process, and Petitioners have used it in connection with other products. *See* 7 U.S.C. §136d(f); Flubendiamide; Notice of Receipt of request to Voluntarily Cancel a Pesticide Product Registration, 69 Fed. Reg. 21344 (Apr. 11, 2016).

[25] The statute also directs me to examine whether the Agency's determination regarding existing stocks is consistent with FIFRA, but that question is not at issue in this order.

In the Matter of Bayer CropScience LP and Nichino America, Inc., Petitioners.
Docket No. FIFRA-HQ-2016-0001

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Order on Petitioners' Motion for Accelerated Decision**, dated April 25, 2016, and issued by Chief Administrative Law Judge Susan L. Biro, was served on this 25th day of April 2016 in the following manner to the addressees listed below:

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