UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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

INITIAL DECISION

I. PROCEDURAL HISTORY

On March 31, 2016, Bayer CropScience LP and Nichino America, Inc. ("Petitioners") initiated this action by filing a Request for Hearing and Statement of Objections ("Hearing Request"). The Hearing Request contests a Notice of Intent to Cancel Pesticide Registrations ("NOIC") issued February 29, 2016, by the Environmental Protection Agency ("EPA," "the Agency," or "Respondent"). 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"), 7 U.S.C. § 136d(e). *Id*. at 11560. The NOIC also contains EPA's determination regarding existing stocks of flubendiamide products. The Agency states that it intends to prohibit use of the flubendiamide technical registration product used to manufacture other pesticide products, prohibit further distribution and sale of end use registration products, but allow the use of products held by end-users. *Id*.

On April 4, 2016, I issued an Order Scheduling Hearing and Prehearing Procedures ("Prehearing Order"). The Prehearing Order established an 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,"[1] and with the Rules of Practice Governing Hearings, under the Federal Insecticide, Fungicide, and

[1] The parties here agreed to an extension of the 75-day statutory period by 22 days. Joint Stipulation of the Parties for an Extension of Time (April 4, 2016). *See also* 40 C.F.R. § 164.40(d) ("[T]he Administrative Law Judge shall have power to take actions and decisions in conformity with statute or in the interests of justice.").

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.

On April 7, 2016, a collection of agricultural groups calling themselves the "Growers"[2] 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") also 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.

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.

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[2] 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. Grower's Brief at 1. Flubendiamide products are sold nationwide, with their primary use running across the south and up the west coast. Growers use them on a wide range of crops throughout the year, including fall and winter vegetables, tree fruits, nuts, soybeans, cotton, and alfalfa. PBNX 117 at PBN1621.

On April 11, 2016, Petitioners filed a Motion for Accelerated Decision challenging the Agency bringing this cancellation action under FIFRA Section 6(e), rather than Section 6(b). By Order dated April 25, 2016, that motion was denied. This Tribunal found that the Agency was permitted to bring this matter under FIFRA Section 6(e) and that as such, the only issues to resolve were whether Petitioners "initiated and pursued appropriate action to comply" with the voluntary cancellation provision of their conditional flubendiamide registration and whether the Agency's determination regarding existing stocks of the pesticide was consistent with FIFRA. Order on Petitioner's Motion for Accelerated Decision at 29 (April 25, 2016).

Furthermore, the Agency on April 18, 2016, moved to exclude at hearing any testimony related to whether flubendiamide causes unreasonable adverse effects on the environment. The Agency contended such evidence was irrelevant to this Section 6(e) proceeding and therefore inadmissible at hearing. That Motion was granted over the Petitioners' opposition. Order on Respondent's Motion to Limit Scope of Testimony at 10 (May 3, 2016). On May 9, 2016, Petitioners filed a Notice of Objection to the Order on Accelerated Decision and the Order on Respondent's Motion to Limit Scope of Testimony to preserve issues raised in those Orders for appeal.

The hearing in this matter was held May 10, 2016, in Washington, D.C. The following exhibits were admitted into the record upon Petitioners' request:[3] PBNX 7–36, 52, 116–118, 123, and 127–128. Three of these exhibits included the written direct testimony of Petitioners' witnesses: Charlotte Sanson (PBNX 116), Lee Hall (PBNX 117), and Jeffrey Johnson (PBNX 118).[4] Tr. at 194. I also admitted into evidence ten of Respondent's exhibits:[5] RE 1–10. One of these exhibits included the written direct testimony of Respondent's sole witness, Susan Lewis (RE 10).[6] Tr. at 194. At hearing, the parties were permitted to cross-examine the witnesses

[3] The Petitioners exhibit numbers and page numbers are prepended by the letters "PBNX" and "PBN," respectively. Citation to Petitioners' exhibits will be in the following format: "PBNX _ at PBN_."

[4] Ms. Sanson is Bayer's Director of Registrations and is responsible for all of Bayer's federal and state registrations of crop protection pesticide products, including all products that contain flubendiamide. PBNX 116 at PBN1593; Tr. 99. Mr. Hall is Bayer's Industry Relations Lead. In that position he works with stakeholders in various commodity, grower, and trade organizations. PBNX 117 at PBN1618. Mr. Johnson is the president of Nichino America, Inc. PBNX 118 at PBN1636; Tr. 141. He oversees studies required for registration of pesticides. Tr. 141. Some portions of these witnesses' direct written testimony was excluded, and not subject to cross examination, following this Tribunal's May 3, 2016 Order on Respondent's Motion to Limit Scope of Testimony.

[5] Citation to Respondent's exhibits will be in the following format: "RE _ at _."

[6] Ms. Lewis is the Director of the Registration Division in the Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention of the U.S. Environmental Protection Agency. RE 10 at 200094; Tr. 19.

based on their previously-submitted written direct testimony. The Tribunal and the parties received the transcript of the hearing on May 13, 2016.[7] The parties filed post-hearing briefs on May 19, 2016. In addition, on May 19, 2016, Petitioners filed a written offer of proof with respect to testimonial and documentary evidence excluded from the record under the Tribunal's May 3, 2016 Order. [8]

II. RELEVANT STATUTORY AND REGULATORY PROVISIONS

FIFRA was first enacted in 1947 and has been periodically amended since then. 7 U.S.C. §§ 136–136y. FIFRA requires that all pesticides[9] used in the United States be registered with the Administrator,[10] who may regulate their distribution and sale "[t]o the extent necessary to prevent unreasonable adverse effects on the environment."[11] 7 U.S.C. § 136a(a) ("Except as

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[7] On May 17, 2016, the parties' joint motion to correct errors in the hearing transcript was granted. The following day, the Tribunal and parties received a corrected transcript. Citation to the corrected transcript will be in the following form: "Tr. _."

[8] As a result of that Order, Petitioners' proposed exhibits PBNX 37–51, 80–115, and 119–122 were not admitted by agreement of the parties as well as the following testimony: Charlotte Sanson (PBNX 116 at PBN1601:3–9, PBN1604:18–19 [starting at "The levels of detection. . ."] PBN1605:1–16, PBN1614:17–22); Lee Hall (PBNX 117 at PBN1621:20–1622:3, PBN1623:1–PBN1630:7; and Jeffrey Johnson (PBNX 118 at PBN1638:21–1639:2 [starting with "Given the modeling . . ."]. In addition, certain testimony was treated as inadmissible as to the substantive merits of EPA's cancellation decision and flubendiamide's risks and benefits but admissible to provide context for the regulatory process, communications, and parties' actions prior to cancellation. This included part of Ms. Sanson's testimony (PBNX 116 at PBN1607–09) and part of Mr. Hall's testimony (PBNX 117 at PBN1622:4–21).

[9] 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).

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

[11] "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

provided by this subchapter, no person[12] in any State may distribute or sell to any person 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).

To obtain registration, an applicant must submit to EPA extensive information, 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 ("The purpose of this part is to specify the kinds of data and information 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 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[13] to review and approve any departure from standard guideline protocols and to develop, review, and approve protocols as needed for additional studies. EPA must publish notice of pending pesticide applications 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)—
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> (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.

> 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).

[12] The term "person" means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not. 7 U.S.C. § 136(s).

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

7 U.S.C. § 136a(c)(5). 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

The remedies available to a pesticide applicant denied registration are set forth in FIFRA Section 6 and include the right to notice of denial of registration, the right to an administrative hearing to consider the soundness of the Administrator's determination, and post-hearing judicial review. 7 U.S.C. §§ 136d(d), (f)(2), (h), 136n. The Administrative Law Judge adjudicating the proceeding is 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 either issue an order revoking the denial or an order denying the registration and "setting forth detailed findings of fact" based upon the "substantial evidence of record." *Id.*

In lieu of unconditionally granting or denying a pesticide application, EPA may grant a "conditional registration" under FIFRA in three "special circumstances." One of those circumstances 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.

Section 6(c), Federal Pesticide Act of 1978, Pub. L. No. 95-396, § 6(c), 92 Stat. 819, 825-26 (1978) (codified at 7 U.S.C. § 136a(c)(7)(C)) (emphasis added).

Section 6(e), enacted simultaneously with Section 6(c), sets forth the circumstances for EPA's issuance of a notice of intent to cancel a conditional registration, for which it specifies distinct procedures:

> (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 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).

The Rules of Practice provide with regard to Section 6 hearings that "the proponent of cancellation . . . has the burden of going forward to present an affirmative case for the cancellation . . . of the registration." 40 C.F.R. § 164.80(a). "On all issues arising in connection with the hearing, the ultimate burden of persuasion shall rest with the proponent of the registration." 40 C.F.R. § 164.80(b). The proponent of the registration may meet its burden by either rebutting the prima facie case for cancellation and the existing stocks determination or demonstrating by a preponderance of the evidence that 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 that the Administrator's determination with respect to the disposition of existing stocks is not consistent with FIFRA. *See In the Matter of Ciba-Geigy Corp.*, 3 E.A.D. 232, 237, 1990 EPA App. LEXIS 94, *11 (EAB July 12, 1990).

A final order of the Administrator cancelling a conditional registration under FIFRA Section 6(e) is subject to review by the federal courts. 7 U.S.C. §§ 136d(h), 136n(b).

III. FACTUAL BACKGROUND

Established in 1928 and based in Tokyo, Japan, Nihon Nohyaku., Ltd. ("Nihon") is a researcher and manufacturer of plant protection products. It has conducted insecticide research near Osaka, Japan since 1990. PBNX 118 at PBN1637. In 1998, Nihon invented flubendiamide, the first pesticide in its class of chemistry – phthalic acid diamides.[14] PBNX 117 at PBN1619; PBNX 118 at PBN1637; Tr. 178.

On April 6, 2006, Nichino America, Inc. ("Nichino"), a wholly owned subsidiary of Nihon, and Bayer CropScience LP ("Bayer")[15] jointly submitted an application to EPA to register Flubendiamide Technical[16] as a pesticide. Pesticide Products; Registration Applications, 72 Fed. Reg. 24299, 24300 (May 2, 2007); RE 10 at 200098. Bayer also submitted an application to register two end-use products containing Flubendiamide: SYNAPSE, an insecticide for controlling lepidopterous insect pests on vegetables, and BELT, an insecticide for controlling lepidopterous insect pests on pome and stone fruit, nut trees, grapes, corn, cotton, and tobacco. Pesticide Products; Registration Applications, 72 Fed. Reg. at 24300; RE 10 at 200098. The application materials Petitioners submitted included human toxicology, environmental, and non-target data and more than 200 studies following eight years of research and development.[17] PBNX 116 at PBN1594. EPA publically announced it had received Petitioners' applications for conditional registration of a pesticide containing new active ingredients in a notice published

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[14] Flubendiamide works on immature lepidoptera pests (certain worms, moths, and caterpillars) by activating the ryanodine receptor that regulates muscle and nerve activity. This modifies calcium levels in these cells, causing rapid cessation of feeding followed by death. PBNX 27; PBNX 21 at PBN0107.

[15] Bayer has a licensing, product development, and marketing agreement with Nihon and Nichino under which it serves as Nichino's regulatory agent for flubendiamide. Tr. 143. As regulatory agent, Bayer took the lead in discussions with the EPA and in generating data necessary to support flubendiamide registrations. PBNX 117 at PBN1619; PBNX 118 at PBN1638.

[16] Flubendiamide Technical consists of nearly pure flubendiamide and is used to manufacture end-use flubendiamide products. PBNX 117 at PBN1620; PBNX 116 at PBN1614.

[17] At hearing, Nichino touted that it and Nihon spent more than $65 million on the initial discovery, data, and development costs to bring flubendiamide to the U.S. market, and a total of $200 million globally. Tr. 145, 178. Bayer also indicated that it spent more than $60 million in data and development costs to obtain the initial flubendiamide registrations and to support the expansion and continuation of those registrations. PBNX 117 at PBN1620. The record is unclear however as to whether the amounts Bayer, Nihon, and Nichino claim to have spent are shared or overlap one another. Also unclear is the extent of the profits the companies have made from the registrations to date. Tr. 181–82.

May 2, 2007. Pesticide Products; Registration Applications, 72 Fed. Reg. 24299. *See also* RE 10 at 200098 ("Flubendiamide was a new active ingredient, not previously registered by EPA.").

EPA undertook its statutory obligation to "review the data" to determine whether the pesticides met the standards for registration under FIFRA. *See* 7 U.S.C. § 136a(c)(3), (c)(7)(C). Generally, "decision-making on registration applications centers on whether use of the product under the terms of the proposed registration will result in unreasonable adverse effects to man or the environment." RE 10 at 200095; PBNX 116 at PBN1595. This is a complicated determination that considers such factors as potential toxicity to humans, other mammals, birds, insects, aquatic life, and plants; the persistence and mobility of the pesticide; possible routes of exposure to the pesticide; the extent of pesticide that will remain on food; and economic or health benefits the pesticide might provide. RE 10 at 200095–96. EPA relies on all available data, scientific information, policies, and methodologies, as well as possible alternatives. RE 10 at 200096. Uncertainties about a pesticide's effects may not provide the Agency with sufficient scientific confidence to issue a registration. RE 10 at 200096–97. Further, before granting conditional registration, EPA is also required to find that registering the pesticide is in the public interest, which it did for flubendiamide on April 15, 2008.[18] PBNX 21; PBNX 116 at PBN1595.

Where the existing scientific data suggests the pesticide potentially creates a risk of unreasonable harm, the Agency may consider imposing terms and conditions upon the registration to mitigate those risks.[19] RE 10 at 200096. Such mitigation options include

> label requirements to utilize engineering controls or additional protective equipment; limiting the timing of applications; limiting the amount of pesticide that can be applied at a particular site; requiring the use of buffer zones between the application and sources of water or neighboring locations; restricting particular methods of application; restricting who can apply the pesticide; requiring specific training for applicators; prohibiting use on specific sites or crops; requiring changes in the formulation of a pesticide product; or limiting the overall amount of product that can be used, through limits on the quantity allowed to be produced.

RE 10 at 200097. Other conditions to clarify the extent of risk may include "requirements to generate additional studies, conduct monitoring, or submit additional information about incidents related to use of the pesticide." RE 10 at 200097. "Another possible risk mitigation measure is limiting the duration of the registration." RE 10 at 200097.

Establishing conditions for registration is not a unilateral act on the part of the Agency. As Ms. Lewis testified:

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[18] The public interest finding was based upon the registrant's representations and data showing the efficacy of the pesticide as equivalent to industry standards, the lack of cross resistance with current pesticides, and its potential use as a valuable tool in developing integrated pest management programs. PBNX 21.

[19] If that is not possible, applicants typically withdraw their applications. RE 10 at 200096.

> [W]e typically have discussions with the applicants on the need for the conditions or measures; what conditions or measures may be practicable or appropriate; and, where applicable, an applicant's preference where, as is often the case, a number of alternative options could address EPA's concerns. Our ultimate goal is to come up with conditions and mitigation measures that resolve our concerns and enable us to make the regulatory findings necessary to allow the product to become registered for use, while allowing applicants wide latitude in identifying the particular suite of conditions and mitigation measures that if incorporated into their licenses would enable us to make those necessary findings.

RE 10 at 200098.

Accordingly, after the filing of applications for the new flubendiamide-based pesticides, the Agency and Petitioners engaged in extensive back and forth negotiations on terms and language to reach what Petitioners described as a "legal agreement" that would govern their conditional registrations. *See* RE 4 (*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 [preliminary acceptance letter] is a legal agreement . . . "). EPA's main point of concern in regard to registering flubendiamide, which had been the subject of a lengthy EPA Environmental Fate and Effects Risk Assessment (PBNX 27), was that the available scientific data suggested the pesticide and its des-iodo degradate "will accumulate to concentrations in aquatic environments that will pose risk to freshwater benthic invertebrates." RE 1 at 200007;[20] RE 2 at 200011; RE 4 at 200032, –40, – 47, –52, –57, –63; PBNX 8 at PBN0018; PBNX 9 at PBN0030; PBNX 27 at PBN0453; Tr. 119–21 ("EPA had identified an area of uncertainty . . . [i]f it ends in water, what is the risk to these aquatic organisms," and noting Petitioners "weren't certain either."). As Ms. Lewis elaborated: "Flubendiamide is a very persistent compound, especially in aquatic systems. Flubendiamide itself is toxic to freshwater benthic invertebrates[.]" RE 10 at 200099; *see also* PBNX 33 (Bayer's Des-iodo Spiked Water Study dated May 21, 2008). It was further noted at the time that "[t]he available mesocosm data does not provide evidence to refute these conclusions. No degradation pathway was identified for des-iodo." RE 2 at 200011; RE 4 at 200032, –40, –47, –52, –57, –63; PBNX 8 at PBN0018; PBNX 9 at PBN0018; PBNX 27 at PBN0453–54.

[20] EPA's Decision Memorandum recommending the conditional registration of the new insecticide flubendiamide dated August 1, 2008, opined that based upon the available data "[f]lubendiamide is expected to be slightly to hardly mobile' and [d]es-iodo is expected to be moderately mobile." As such, they "have the potential to contaminate surface water through run-off due to their persistence in soil and also have the potential for groundwater contamination." RE 1 at 200006. Further, in terms of degradation over time, it was noted that the pesticides' "overall stability/persistence suggests they will accumulate in soils, water column and sediment with each successive application." RE 1 at 200006. However, [u]ncertainties in the model results make long term estimates of accumulation and risk unreliable." *Id*. at 200007.

The Agency could have denied the Petitioners' registration applications based on these concerns of a potential unreasonable risk, which likely would have precluded flubendiamide from ever reaching the market, but it was intrigued by the pesticide's positive aspects, *i.e.*, its "relatively low toxicity to humans and most other taxa." RE 10 at 200099. The Agency's Pesticide Fact Sheet indicates "there are no acute or chronic dietary exposure considerations that would preclude registration of flubendiamide for the requested uses" and that "post application exposure to flubendiamide does not pose a risk to occupational workers." PBNX 9 at PBN0025, –27; PBNX 116 at PBN1597–98; RE 1 at 200005. *Accord* PBNX 116 at PBN1597 (Sanson: "Flubendiamide has an excellent safety profile."); RE 7 at 200079, –81 (noting flubendiamide's excellent safety profile); PBNX 116 at PBN1597 (same).

As such, "EPA determined that it was appropriate under FIFRA to give a time-limited registration for flubendiamide with a requirement that vegetation buffers[21] be used, during which time the registrants would be required to generate data to try and resolve the uncertainty over whether flubendiamide caused unreasonable adverse effects." RE 10 at 200099; *see also* RE 2 at 200011; RE 4 at 200032, –40, –47, –52, –57, –63; PBNX 8 at PBN0018 ("Bayer will commit to generate and submit the following data (studies) on the des-iode degradate to determine if Agency assumptions of chemical stability are appropriate . . . ."). The studies conducted would measure the effectiveness of the buffers at reducing runoff of flubendiamide and its degradate, des-iodo. PBNX 8; PBNX 116 at PBN1596. The Agency viewed a time limit on the registration as necessary to combat "the persistence of flubendiamide and its potential toxicity in water" and the associated harm caused by long term use. RE 10 at 200100; *see also* Tr. 82–83 ("[H]aving a date certain and irrevocable voluntary cancellation request was very important to know that if we reached an unreasonable adverse effects [determination] after reviewing the data, that we knew that this could be withdrawn.").

Initially, EPA proposed a plan it has used for other applications – that registration "automatically expire in July 2013 unless EPA, at its sole discretion, extended the registration." RE 10 at 200102. Petitioners generally objected to automatic cancellation, so discussions shifted to the idea that "if after review of the new studies and discussions with the Registrants, EPA concluded that the products still did not meet the registration criteria for an unconditional registration, the Registrants would be required to submit a request for voluntary cancellation within one week of EPA informing them of a finding of unreasonable adverse effects."[22] RE 10 at 200102. EPA and Bayer negotiated an initial five-year period to generate the data. RE 2 at 200012; RE 10 at 200100; PBNX 116 at PBN1595–96, 1602. Further, Petitioners negotiated and agreed to the following additional conditions as part of the conditional registration:

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[21] Vegetation buffers are narrow, permanent strips of dense perennial vegetation established parallel to the contours of and perpendicular to the dominant slope of a field for the purposes of slowing water runoff, enhancing water infiltration, and minimizing the risk of any potential pollutants from leaving the field and reaching surface waters. *See e.g.*, 40 C.F.R. § 412.4.

[22] All the hearing witnesses testified that this provision appears to be unique, something negotiated by Bayer and included just in these particular registrations, and not a provision generally included in conditional registrations issued by the Agency. Tr. 90, 105, 145–46.

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.

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:

[. . .]

(b) The EPA shall complete its review of the entire required data set and will consider any additional data and supporting information voluntarily submitted by Nichino (or some other person who consents to Nichino's reliance on the data) by January 31, 2013. *EPA scientists and Bayer scientists, as agents for Nichino, shall engage in dialogue about the data and the Agency's conclusions.*

(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:

[. . .]

(b) The EPA shall complete its review of the entire required data set and will consider any additional data and supporting information voluntarily submitted by Bayer (or some other person who consents to Bayer's reliance on the data) by January 31, 2013. EPA scientists and Bayer scientists shall engage in dialogue about the data and the Agency's conclusions.

(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.*

PBNX 8 at PBN0018–20 (emphasis added); *see also* RE 10 at 200101 ("One condition of the flubendiamide registrations required that if the Agency makes a determination that further registration of the flubendiamide technical and end-use products would result in unreasonable adverse effects on the environment, within one week of this finding, the Registrants must submit a voluntary cancellation . . . ."). Thus, the Agency found "the ability to quickly cancel the registration . . . an important factor in [its] decision to grant the registration" and "relied upon the mutually agreed-upon conditions in the registration in order to grant the registration." RE 10 at 200100; PBNX 128 at PBN1911; Tr. 77.

On July 31, 2008, EPA issued and Petitioners signed the final negotiated Preliminary Acceptance Letter ("PAL"), the legal agreement which "memorialized the conditions that had been negotiated between EPA and the Registrants" and was incorporated by reference into each of the flubendiamide registrations. PBNX 8; RE 10 at 200101; PBNX 116 at PBN1595–96.

It is particularly significant that during the parties' negotiation, Petitioners recognized the importance of the unique PAL provisions (identified as paragraphs 8(d) & 6(d)) that required them to submit within one week a request for "voluntary cancellation" of the registrations if after reviewing the data submitted the Agency determined that further registration of flubendiamide products would result in unreasonable adverse effects on the environment. Petitioners' representative expressly stated:

> Basically, there is only one remaining 'sore point,' . . . it appears to allow EPA to demand cancellation without any due process from us. 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.

RE 4 at 200036 (email dated July 30, 2008, from Clive Halder of Bayer to the EPA's Lois Rossi); *see also* RE 10 at 200100 ("The applicants were well aware of EPA's concerns."); RE 10 at 200102-103. Further, Petitioners offered language that is nearly identical to the provisions that appear in the PAL. RE 4 at 200036; PBNX 8. Petitioners' representative described the language as "hopefully address[ing] our collective needs . . .":

> 5(c) If after review of the data, as set forth in 5(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, Nichino will submit a request for voluntary cancellation of the registration of the flubendiamide technical product. That request shall include a statement that Nichino recognizes and

> agrees that the cancellation request is irrevocable.
>
> 7(c) If after review of the data, as set forth in 7(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, Bayer will submit a request for voluntary cancellation of the registration of the flubendiamide end-use products. That request shall include a statement that Bayer recognizes and agrees that the cancellation request is irrevocable.

RE 10 at 200103 (quoting RE 4 at 200036). "Taken together, the discussions between Registrants and EPA demonstrate that the Registrants were well aware of the cancellation provisions, were materially engaged in shaping those provisions, and ultimately acceded to the cancellation provisions included in the PAL," Ms. Lewis observed.[23] RE 10 at 200103. "This exchange not only shows the Registrants involvement in the discussions, it also demonstrates their willing acceptance of the conditions, and negates their notion that they were coerced or threatened into acceptance." RE 10 at 200103. Further, she adds, she is not aware of any objections Petitioners had until late 2015, when it became apparent EPA would invoke the voluntary cancellation provision. RE 10 at 200103–104.

Petitioners characterize their agreement with the Agency somewhat differently. Ms. Sanson testified that

> EPA refused to issue the registrations unless the applicants 'concur[red]' that if in the future EPA made an affirmative finding that 'further registration of the flubendiamide . . . products will result in unreasonable adverse effects on the environment,' the companies would immediately, within seven days, request 'voluntary' cancellation of the registrations. EPA threatened that, absent this provision, it would not grant the registrations, even though it already had determined months earlier that the registrations were in the public interest.

PBNX 116 at PBN1599 (quoting PBNX 8 at PBN0019). This was the first such provision Ms. Sanson had seen that would allow the EPA "to make an unreasonable adverse effects finding based on an evaluation that no one could comment or challenge." PBNX 116 at PBN1599. She also believed Petitioners had no choice but to concur with this provision because they already "had invested years of effort and many millions of dollars to demonstrate the safety profile and efficacy of" flubendiamide. PBNX 116 at PBN1600. Still, Bayer intended to honor the provision because it expected EPA would rely on "real world data" and because Bayer "had no choice . . . or it would have had to forfeit registrations it believed could and should properly be issued under the FIFRA standard, and to lose a very promising product in which it had invested years of work and many millions of dollars." PBNX 116 at PBN1600. Ms. Sanson further

[23] Bayer is, in essence, as much of an expert in pesticide registrations as EPA, in that Mr. Hall testified the company holds "more than 250" such registrations. Tr. 136–37. He suggested this instance was the first where the company's registration was involuntarily cancelled. Tr. 138.

proclaimed that Bayer would have pursued voluntary cancellation if it believed that science showed flubendiamide's risks outweighed its benefits. PBNX 116 at PBN1600. Bayer mitigates risk by revising application methods or amounts, removing uses from the label, or cancelling products, she added. PBNX 116 at PBN1600–01.

On August 1, 2008, based upon the executed PAL, EPA issued registration statements for flubendiamide products: NNI-0001 Technical (Flubendiamide), EPA Reg. No. 71711-26, and NNI-0001 480 SC (BELT SC Insecticide), EPA Reg. No. 264-1025. PBNX 7; RE 1; RE 3 at 200014, 200016; RE 9; RE 10 at 200101; PBNX 116 at PBN1595-96. Each registration statement declared the product was "conditionally registered in accordance with FIFRA section (3)(c)(7)." PBNX 7 at PBN0001, -0005; RE 3 at 200014, 200016. 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 [PAL] 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." PBNX 7 at PBN0002, -0006; RE 3 at 200014, 200016.

Thereafter, Petitioners released for shipment, *i.e.*, began actively selling, flubendiamide products,[24] indicating their acceptance of the terms of the conditional registration. Further, they began to generate EPA-required data in support of the applications and to communicate with EPA about study protocols, conduct, and reports, and the interpretation of the study results. Hr'g Req. ¶¶ 74, 75; PBNX 10, 12, 13, 15, 16; PBNX 116 at PBN1601. On March 4, 2009, EPA issued registration statements for flubendiamide products: NNI-0871 SC (Vetica™ Insecticide), EPA Reg. No. 71711-32, and NNI-0772 SC (Tourismo™ Insecticide), EPA Reg. No. 71711-33. RE 3 at 200018, 200019A. These products were also conditionally registered under FIFRA section 3(c)(7) and subject to the same conditions in the July 31, 2008 preliminary acceptance letter.[25] RE 3 at 200018–19, 200019A–19B. In addition, over time, EPA approved the expansion of flubendiamide's conditional registrations for use on more than 200 crops. Hr'g Req. ¶¶ 74, 75; PBNX 116 at PBN1601–02; PBNX 117 at PBN1619; PBNX 118 at PBN1637.

Under the PAL, to clarify the pesticide's risks to benthic invertebrates, the Petitioners were required to first conduct a Small-Scale Run-Off/Vegetative Buffer Strip Study, and if there

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[24] Bayer sells flubendiamide products under the brand name Belt. Nichino sells flubendiamide products under the brand names Vetica™ and Tourismo™. PBNX 117 at PBN1620; PBNX 118 at PBN1638.

[25] The registration statements for Vetica™ and Tourismo™ 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 + buprofezin, dated March 4, 2009. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA." RE 3 at 200019, 200019B. Ms. Lewis testified "[t]hat date of March 4, 2009 was in error. There was no unique acceptance letter for this newer thing. It should have referenced the July 31, 2008 [PAL]. It is my understanding that there is no March 4, 2009 [PAL]." Tr. at 85. This statement was not disputed by Petitioners.

were "still risk concerns," to then conduct a farm pond water Monitoring Program. PBNX 8, PBN0017; RE 5 at 200066; Tr. 121–22. Bayer submitted the vegetative buffer strip study on August 3, 2010. RE 5 at 200066. EPA found "a major modeling error" in the study and indicated that the results "would be insufficient to preclude ecological risk concerns," even if the modeling error was corrected. RE 5 at 200066. As a result, the farm pond monitoring program requirement was "triggered." RE 5 at 200066; Tr. 115, 123. In correspondence dated July 18, 2013, at Petitioners' request, 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." PBNX 10; RE 10 at 200104; PBNX 116 at PBN1602.

Bayer conducted the pond water monitoring study over three years at two farm ponds and submitted the results on December 22, 2014. RE 5 at 200066; Tr. 123. The EPA's Fate and Environmental Effects Division (EFED) provided its review of the monitoring study on February 20, 2015 concluding that "both flubendiamide and des-iodo were accumulating in all of the farm ponds' overlying water, sediment, and pore water; therefore, the VFSs [vegetative field strips] were ineffective at preventing flubendiamide and des-iodo from accumulating in aquatic systems downstream of the fields to which flubendiamide had been applied." RE 5 at 200066–67; PBNX 35 (noting pond water monitoring study data "indicate flubendiamide slowly converts to its des-iodo degrade, which does not breakdown. EFED modeling [] predicts that flubendiamide and its degradate (des-iodo) will accumulate in aquatic systems eventually exceeding Agency levels of concern."). As a result, the parties began discussing the future of the conditional registrations.

In May and June 2015, Petitioners submitted to EPA documents in support of the continued registration of flubendiamide that included more than 300 pages summarizing the pesticide's aquatic risk assessment and purported human health, environmental, safety, and pest management benefits across fifteen representative crops. PBNX 22, 24; PBNX 117 at PBN1622. In these submissions, Petitioners attempted to counter EFED's conclusion of "clear evidence of accumulation" using the standard modeling methodology, with "higher tier monitoring data" showing limited, if any accumulation.[26] PBNX 24 at PBN0438. They further noted their agreement with EPA that the duration of the 3½ year field study conducted was "insufficient to quantify the longer term accumulation potential under real world conditions." Petitioners suggested it would take "two to three more years to fully confirm the accumulation profile by EFED is not occurring," and sought to maintain their registrations while conducting the further studies. PBNX 24 at PBN0438.

In July 2015, EPA responded in writing with its assessment of Petitioners' aquatic risks evaluation and benefits submissions. PBNX 23, 25, 36; PBNX 117 at PBN1622. As to the

[26] At hearing, Ms. Sanson indicated Petitioners disagreed with EFED's finding and believe the data shows that the pesticide and its metabolite are well below the EPA's level of concern and not increasing over time, but are "still a little bit concerned, based upon the actual use of the product." Tr. 125. Nevertheless, they believe they are entitled to an unconditional registration. Tr. 126.

aquatic risks, EFED noted that prior to Petitioners' submission, the parties had engaged in "a series of back-and-forth comments and responses" with regard to the farm pond monitoring study report. PBNX 36 at PBN1001. EFED concluded that the information in Petitioners' latest submission did not change its prior risk assessment. PBNX 36 at PBN1001–02.

EPA followed that up in August by engaging in more discussions with Petitioners and suggesting certain mitigation measures and studies which might be undertaken to "address the uncertainties related to flubendiamide."[27] PBNX 11; Tr. 127. On August 26, 2015, EPA by letter again extended the registrations by nearly four additional months 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. PBNX 12. In that letter, EPA also stated that "[a]s of July 31, 2012, [the registrants] ha[ve] submitted all data required by the original conditions of registration for flubendiamide." PBNX 12; *see also* PBNX 116 at PBN1602. However, Petitioners, by September 2015, must have suspected the flubendiamide registration was in doubt. This is demonstrated in Nichino's decision to stop making the pesticide: "The last formulation, it was September 28th [2015], and I became aware of the more difficult discussions with EPA on the time limit extension for conditional registration," Mr. Johnson testified. Tr. 173–74.

The parties met again December 1, 2015, to discuss the path forward. PBNX 116 at PBN1604. During this meeting, Petitioners provided EPA a comparative assessment of a competitive pesticide with similar persistence and risk profile to benthic aquatic invertebrates as flubendiamide. PBNX 116 at PBN1604. Petitioners hoped the Agency would analyze the monitoring versus modeling data for flubendiamide as it had the competitive pesticide. PBNX 116 at PBN1604. On December 8, 2015, EPA extended the December 10 expiration date to December 18, 2015, "to provide additional time for BCS [Bayer CropScience] and EPA to discuss areas of uncertainties." PBNX 13; PBNX 116 at PBN1606. This brief extension allowed time for a very high-level meeting held December 15, 2015, between Jim Jones, EPA's Assistant Administrator for the Office of Chemical Safety and Pollution Prevention 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[28] language and

[27] "EPA presented a plan for continuing the registrations for all crop uses that involved reducing exposure by eliminating aerial applications, limiting use to a single application per growing season for all crops, and conducting additional studies." PBNX 11; PBNX 116 at PBN1603. EPA proposed a list of additional toxicity and stream- and pond-monitoring studies and a three-year extension of the registrations for data generation and review. PBNX 11; PBNX 116 at PBN1603. Petitioners were agreeable to the additional studies.

[28] The "precautionary principle" as it relates to environmental risks provides that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Principle 15, *UNEP*, "Rio Declaration on Environment and Development", *(1992)* accessible at:

> 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.

Hr'g Req. ¶ 87; *see also* PBNX 116 at PBN1606. The Petitioners complained of practical difficulties with the imminent timing of the expiration and requested that EPA extend the December 18, 2015, deadline to ensure an orderly process. Hr'g Req. ¶ 88; PBNX 116 at PBN1606. 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. Hr'g Req. ¶ 88; PBNX 116 at PBN1606. "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." Hr'g Req. ¶ 88; PBNX 116 at PBN1606. "The registrants convened their experts and prepared and submitted a further mitigation proposal later the same day." Hr'g Req. ¶ 88; PBNX 116 at PBN1606.

On December 16, 2015, EPA EFED briefed the Assistant Administrator as planned. PBNX 116 at PBN1608. This briefing marked what Petitioners contend was a last-minute, seismic-shift in the Agency's use of the data it was relying on to evaluate flubendiamide's registration. PBNX 116 at PBN1608; PBNX 14. Specifically, EFED "stopped using the directly relevant toxicity endpoint from the des-iodo spiked *sediment* study that had been the basis of the many discussions, technical evaluation, and mitigation plans of the preceding months" and shifted instead to a toxicity endpoint "derived from [a] less appropriate, earlier-conducted spiked *water* study, leading to a toxicity endpoint . . . 70 [seventy] times lower than supported by the more environmentally relevant data conducted using EPA's preferred methodology."[29] PBNX 116 at PBN1608 (emphasis added); PBNX 14; Tr. 127. Ms. Sanson alleges the reversion to the spiked water study "seemed calculated to ensure that EPA could continue to predict exceedances

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http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm. Petitioners contend the Assistant Administrator's use of "precautionary" language connotes the application of a separate, non-FIFRA standard. PBNX 116 at PBN1606.

[29] A toxicity endpoint is a numerical value that establishes a threshold level of a compound below which adverse effects are not seen. PBNX 116 at PBN1607. Bayer undertook two studies to determine the toxicity endpoint of flubendiamide's des-iodo degradate on aquatic invertebrates. The first was a spiked *water* study reported in May 2008, before the registrations were issued (PBNX 33), and the second was a spiked *sediment* study reported in July 2011 (PBNX 34). In the spiked *water* study, the test compound was introduced directly into the water overlaying the sediment. This resulted in a toxicity endpoint of .28ppb. PBNX 116 at PBN1608. In the spiked *sediment* study, the test compound was introduced into the sediment and the system was allowed to equilibrate. The spiked *sediment* study showed no observable adverse effects of the des-iodo to benthic aquatic invertebrates at any level tested, supporting a toxicity endpoint of 19.5 ppb. PBNX 116 at PBN1607–08.

of levels of concern" using its theoretical modeling. PBNX 116 at PBN1608.

Bayer wrote the Assistant Administrator on December 16, 2015, to advise him of the "sudden change in approach." PBNX 14; PBNX 116 at PBN1609. 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." PBNX 15; PBNX 116 at PBN1609. On January 6, 2015, after submitting two formal reports on environmental fate and ecotoxicology data whose conclusions had previously been reviewed by EPA, Petitioners' scientists and others met for an entire day with EFED scientists and others at EPA. RE 10 at 200104–105; PBNX 116 at PBN1609. At the morning meeting, focused on science issues, EPA presented its scientific position on flubendiamide's risks, which relied on the lower toxicity endpoint and theoretical modeling. In the meeting, EPA acknowledged the timing of its shift was unfortunate but necessary due to internal Agency dynamics. PBNX 116 at PBN1609; Tr. 71–72, 91–92. EPA ultimately conceded if it determined the registrations should not continue, it would demand voluntary cancellation or otherwise seek cancellation under FIFRA § 6(e). PBNX 116 at PBN1610.

On January 14, 2016, the January 15 deadline was extended until January 29, 2016, "to accommodate the necessary time needed for EPA to consider [Bayer's] label proposal." PBNX 16; PBNX 116 at PBN1610. On January 28, 2016, EFED issued its Ecological Risk Assessment Addendum Summarizing all Submissions and Discussions to Date regarding flubendiamide. PBNX 31. The assessment considered the various endpoints and monitoring data submitted. PBNX 31. It concluded based on the Petitioners' stream and river monitoring and that of the U.S. Geological Survey over much of the United States that

> 1) the failure of VFSs to contain these chemicals is a widespread occurrence; and 2) the potential for water quality impacts is also widespread . . . . *[S]ignificant effects to aquatic organisms due to the use of flubendiamide could potentially occur in as little as 2 years.* While the registrant has raised many issues as discussed in detail above and in the referenced documents, none have been persuasive that the original and subsequent risk assessment conclusions were inaccurate nor have they diminished confidence in those conclusions. Considering all the evolving lines of evidence, there is increased confidence in the conclusions contained in EFED's past risk assessments for flubendiamide.[30]

[30] At the request of the Registration Division, on January 29, 2015, EFED issued a Memorandum to clarify invertebrate terminology used its Ecological Risk Assessment to better describe the "invertebrates of concern in freshwater systems" and more fully explain how "the risk findings are best related to aquatic invertebrates." PBNX 32 at PBN0906. In the document EFED concludes that undertaking risk assessment for flubendiamide "using water column and pore water estimates of exposure and compared with effects from the benthic macroinvertebrate *C. riparius* are appropriate sensitive indicators of risk to invertebrates occupying the benthos" and "within the water column." PBNX 32 at PBN0909. Such invertebrates include sponges, mussels, oysters, worms, snails, clams, and flounder. PBNX 32 at PBN0908.

PBNX 31 at PBN0870 (emphasis added).

In the end, the Agency did not favor Petitioners' proposals resolving the uncertainties concerning "flubendiamide's mobility, stability/persistence, accumulation in soils, water columns and sediments, and the extremely toxic nature of the primary degradate . . . des-iodo . . . to invertebrates of aquatic systems." PBNX 17. In a Decision Memorandum issued January 29, 2016, Ms. Lewis advised the Director of the Office of Chemical Safety and Pollution Prevention to cancel all flubendiamide registrations "because the risks of allowing the continued use of flubendiamide outweigh the benefits and continued use will result in unreasonable adverse effects to the environment." RE 10 at 200105; RE 5. Consequently, that same day, EPA sent a letter to Respondents requesting that they voluntarily withdraw registration of their flubendiamide products. PBNX 17; PBNX 116 at PBN1610. 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.

RE 6 at 200078; PBNX 17 at PBN0097; PBNX 116 at PBN1610.

In response, Petitioners notified EPA by letter dated February 5, 2016, that they "decline EPA's request to voluntarily cancel all flubendiamide registrations." PBNX 18; RE 7 at 200081; RE 10 at 200105; PBNX 116 at PBN1610 at 18. In the letter, Petitioners raise three points: 1) that the voluntary cancellation provision was unlawful; 2) that cancellation should proceed under FIFRA § 6(b); and 3) that the evidence shows flubendiamide does not pose unreasonable adverse effects to the environment. PBNX 18; PBNX 116 at PBN1610–11.

When it did not receive a voluntary cancellation request, on February 29, 2016, EPA issued a formal notice of intent to cancel Petitioners' conditional flubendiamide pesticide registrations. PBNX 20; RE 10 at 200105; PBNX 116 at 1611. The Notice states that EPA

intends to cancel four pesticide registrations[31] containing flubendiamide "owing to the registrants' failure to comply with a required condition of their registrations." NOIC, 81 Fed. Reg. at 11558; PBNX 20 at PBN0102; RE 8 at 200082. 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." NOIC, 81 Fed. Reg. at 11560; PBNX 20 at PBN0104; RE 8 at 200084. After the NOIC was issued, EPA also posted news releases on its website announcing its decision and reasoning. PBNX 116 at PBN1611.

The NOIC also contains EPA's determination regarding existing stocks[32] of flubendiamide products. This determination was made by Ms. Lewis and other EPA managers. RE 10 at 200106. 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. RE 8 at 200084; PBNX 20 at PBN0104; PBNX 116 at PBN1613. 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:

> [I]f 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

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[31] The four pesticide products to be canceled are 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.

[32] 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; *see also* RE 10 at 200105 ("Existing stocks are those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment before the effective date of cancellation."); PBNX 116 at PBN1612 ("EPA's standard definition includes any product that has been 'released for shipment.'"). 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). A product is "released for shipment" when "the producer has packaged and labeled it in the way it will be distributed or sold and stored it in an area where finished products are ordinarily held for shipment." PBNX 116 at PBN1612 ; 40 C.F.R. § 152.3.

> conditional registration.

Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29362, 29366–67 (June 26, 1991); RE 9 at 200091–92; PBNX 52; PBNX 116 at PBN1613. Ms. Lewis elaborated on this point in her testimony:

> Among the reasons we determined not to allow any further sale or distribution of existing stocks were our belief that registrants should not benefit from failing to follow through with commitments they make to obtain registrations; that much of the existing stocks at the time of a delayed cancellation may well never have entered the channels of trade if the flubendiamide Registrants had complied with the cancellation condition; and the impact that failure of registrants to comply with conditions could have on the registration program in the future.

RE 10 at 200106; *see* RE 8 at 200084. The only distribution that would be allowed, she adds, would be distribution "for the purposes of returning material back up the channels of trade, for purposes of disposal, of for purposes of lawful export." RE 10 at 200106; PBNX 116 at PBN1613.

EPA was further concerned that Petitioners' failure to comply with the voluntary cancellation provision would delay cancellation by at least three months. RE 10 at 200106. Had they followed the agreement and requested cancellation by February 5, 2016, Ms. Lewis states the cancellation notice, following a required publication and comment period, could have issued by late March or early April 2016. RE 10 at 200106. However, by contesting the cancellation, Petitioners are able to continue manufacturing and selling flubendiamide until at least July 2016 based on this proceeding's schedule and statutory timeframe. RE 10 at 200106–107. Additionally, appeals could allow Petitioners to continue funneling flubendiamide into the market for months or years, she notes, long after the release of new existing stocks should have ceased. RE 10 at 200107. In this case,

> because Registrants intentionally reneged on a commitment to cancel their registrations, and as a result of their actions much of the existing stocks in the channels of trade when these registrations are finally cancelled could be material that should never have entered the channels of trade in the first place, we believe it appropriate to not allow sale and distribution by others as well.

RE 10 at 200107.[33] "[The Agency] considers it inappropriate to permit registrants who disregard the terms and conditions of registration, like the condition at issue for flubendiamide, to benefit

[33] Ms. Lewis distinguishes a violation of a *specific* condition in this case from EPA's existing stocks policy, which allows for the sale and distribution of existing stocks of a canceled pesticide for one year after a registrant "fail[s] to satisfy a *general* condition (i.e., a condition which requires a registrant to submit required data when all other registrants of a similar product are required to do so) . . . ." RE 10 at 200107 (emphasis added).

by allowing any distribution or sale of existing stocks." RE 10 at 200108. To respond otherwise has broad implications, Ms. Lewis adds:

> EPA would have to reconsider whether its current practice of approving conditional registrations is adequate to prevent unreasonable adverse effects. If EPA is unable to rely on registrants' compliance with the terms and conditions of registration, EPA will, at least in some circumstances, become less able to make the finding that the terms and conditions of a pesticide's registration are sufficient to conclude that the pesticide will not cause unreasonable adverse effects. Such a scenario could impact many companies and applications not involved in this proceeding, and slow the introduction of promising new pesticide products into the market. . . . While this is hopefully an isolated example, if it is not, OCSPP will need to seriously examine whether we can continue to issue conditional registrations for pesticide products with ostensibly promising new benefits. We do not want to encourage other registrants to ignore conditions of registration. We are concerned that if we do not take a strong position on existing stocks of flubendiamide that may have entered the channels of trade because the Registrants reneged on their commitments, other registrants may be encouraged to ignore their commitments in the future.

RE 10 at 200108–109. Thus, the Agency concluded the continued sale or distribution of existing stocks of canceled pesticides

> would be inconsistent with the purposes of FIFRA because the Registrants have reneged on commitments they made to comply with a specific condition of registration that was material to EPA's approval of the registration. Conditions of registration and the associated commitments by registrants to fulfill those conditions are vitally important to the registration process.

RE 10 at 200109.

Ms. Sanson describes the existing stocks provision as "much more restrictive" than others with which she is familiar and believes it "is intended to be punitive because the registrants are challenging EPA's science in this matter." PBNX 116 at PBN1613 at 21; *see also* PBNX 117 at PBN1632 ("EPA's proposed immediate ban . . . as a means to punish the registrants is unnecessarily disruptive and could be most damaging to growers."). She contends the Agency's decision is inconsistent with its existing stocks policy "[b]ecause EPA identified a particular risk concern here. Under its own policy, it should have made a case-specific determination. The policy lays out the specific considerations, and EPA did not provide any analysis, findings, or conclusions with respect to these factors." PBNX 116 at PBN1614. Petitioners believe they should be allowed to sell and distribute existing stocks, that distributors and retailers should be allowed to sell to their customers, and users should be allowed to use the remaining existing stocks. *Id.* "A cancellation order that immediately banned any further distribution or sale of flubendiamide products could be very disruptive," Mr. Hall stated. PBNX 117 at PBN1630.

Bayer has produced flubendiamide for 2016 according to its normal schedule and made its last purchase order for technical flubendiamide in February. It plans to only formulate end-use product from the amount already ordered. PBNX 116 at PBN1614; PBNX 117 at PBN1632. Bayer will produce no more product this year than it did last year and will likely produce less if the registrations are cancelled. PBNX 116 at PBN1614; PBNX 117 at PBN1632; PBNX 118 at PBN1638. Mr. Hall notes that "[a] more standard existing stocks provision that allowed Bayer and its distributors to sell existing stocks released for shipment at the time of cancellation would provide for a more orderly and controlled phase-out." PBNX 117 at PBN1631; PBNX 118 at PBN1638. As the limited supply moves through the chain, it could be directed to where it is most needed and would provide time for a more orderly transition to other pest control measures. PBNX 117 at PBN1632. "In this way, the stocks that are already produced and released for shipment . . . could be sold, distributed and used in the normal way, without additional transportation to ship them back to the registrant and without any additional impact to the environment by disposal without any beneficial use," Mr. Johnson observed. PBNX 118 at PBN1638.

The Agency reaches a different conclusion with regard to existing stocks of flubendiamide products currently held by end users. RE 10 at 200109–110; PBNX 116 at PBN1613. The end users are generally either the growers themselves or applicators contracted to apply the product. PBNX 117 at PBN1630. 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; PBNX 20 at PBN0104; RE 8 at 200084; RE 10 at 200109–110. Mr. Hall agrees that growers do not typically have a supply on hand because many "wait to see if any caterpillar pest pressure develops for a given crop and season before making the decision to purchase and apply flubendiamide . . . ." PBNX 117 at PBN1630. Similarly, applicators "will not warehouse product and will secure only the amount needed 'per job.'" PBNX 117 at PBN1630-31. But, he contends, because only small quantities are controlled by end users, "growers may find themselves without the product they need when pest problems arrive," the supply chain will be disrupted, and growers will be punished with higher costs, uncertainty, lower yields, and potential crop damage. PBNX 117 at PBN1631 As to existing stocks in the hands of end users, 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 significant costs on state and federal authorities. NOIC, 81 Fed. Reg. at 11560; PBNX 20 at PBN0104; RE 8 at 200084; RE 10 at 200110. 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." NOIC, 81 Fed. Reg. at 11560; PBNX 20 at PBN0104; RE 8 at 200084.

IV. ISSUES FOR CONSIDERATION

As indicated above, during prehearing motions practice, this Tribunal ruled as a matter of law that the Agency was authorized to bring this FIFRA section 6(e) action to cancel the Petitioners' conditional pesticide registrations. *See* Order on Petitioners' Motion for Accelerated Decision at 28 (April 25, 2016). Further, this Tribunal ruled that the voluntary cancellation

conditions placed on their conditional registration were lawful and that there was "no reason to allow Petitioners out of the 2008 legal agreement they knowingly made for a 'fast death' cancellation arrangement." *Id.* Consequently, at this point, only two issues remain for consideration: 1) whether Petitioners "initiated and pursued appropriate action to comply" with the voluntary cancelation provision of their conditional flubendiamide registration; and 2) whether the Agency's determination regarding existing stocks of the pesticide was consistent with FIFRA. *Id.*

V. WHETHER PETITIONERS INITIATED AND PURSUED APPROPRIATE ACTION TO COMPLY WITH THE VOLUNTARY CANCELLATION PROVISION OF THEIR CONDITIONAL FLUBENDIAMIDE REGISTRATION

A. Agency's Arguments

The Agency argues it has established all the necessary elements of a prima facie case showing that Petitioners "have failed to comply with the conditions of the flubendiamide registrations within the time provided." Agency's Post-Hearing Brief ("AB") at 2. Specifically, the Agency contends it has shown "that it informed registrants of its determination that further registration of the flubendiamide products would result in unreasonable adverse effects on the environment . . . and called for the Registrants to submit requests for FIFRA section 6(f) voluntarily cancellation of their flubendiamide registrations pursuant to condition 6(d) and 8(d) of the PAL." AB at 6. When Petitioners "informed the Agency . . . that they would not comply with the voluntary cancellation condition," the Agency continues,

> the conditions precedent to the voluntary cancellation request [were] satisfied: EPA completed its review of all of the studies and information submitted by the [Petitioners]; EPA scientists and Registrants' scientists engaged in dialogue about the data and the Agency's conclusions; EPA made a determination that further registration of the flubendiamide products would result in unreasonable adverse effects on the environment; and EPA communicated that finding to the [Petitioners] no earlier than September 1, 2013.

AB at 6–7. The Agency further asserts that Petitioners' suggestion at hearing that the Agency had not satisfied a necessary precondition of voluntary cancellation was untimely and improper because it was not raised in Petitioners' refusal letter or Request for Hearing and Statement of Objections, and inaccurate given the uncontroverted evidence of scientific discussions that took place between the parties. AB at 8–9. Finally, Petitioners' characterization of the decision to cancel the pesticide as "political" in nature is not supported by the evidence and ultimately irrelevant, the Agency adds. AB at 9–10.

B. Petitioners' Arguments

Petitioners contend the Agency did not comply with obligations it had to meet as a prerequisite to issuing a voluntary cancellation demand. Petitioners' Post-Hearing Brief ("PB")

at 1. In particular, Petitioners argue that the Agency "did not engage in a good faith, 'measured dialogue' among scientists regarding the data and EPA's conclusions, and had no intent to do so once the Agency decided to proceed toward cancellation." PB at 2. Regarding the data, Petitioners allege the Agency, without disclosure or explanation, reverted to relying on a toxicity endpoint "70 times lower than the one which had been the basis of the parties' ongoing discussions" so that the Agency "'could continue to 'predict' exceedances of levels of concern even after making overdue and necessary corrections to its theoretical modeling,' and to achieve the 'preordained, political result' of cancelling the flubendiamide registrations, regardless of the science." PB at 3–4. The January 6, 2016, meetings after this decision was made were merely for show and did not provide "the required good faith scientific dialogue" that had to occur prior to the request for voluntary cancellation, Petitioners state. PB at 4. Similarly, the Agency did not provide its conclusions and unreasonable adverse effects determination until the day it asked for Petitioners' voluntary cancellation request, "thus foreclosing any meaningful dialogue on EPA's conclusions," and its conclusions relied on modeling data and results not previously disclosed to Petitioners. PB at 6. It is important to enforce provisions that require the Agency to review data and engage in open, measured scientific dialogue because if the voluntary cancellation provision is ultimately found to be lawful, this "will be the only restraint on EPA's discretion to cancel registrations on the Agency's whim and say-so, regardless of the science," Petitioners declare. PB at 6–7. The Agency cannot be permitted to invoke and enforce its voluntary cancellation condition where it "actively withholds information . . . that is critical to its cancellation decision, provides its conclusions, analysis, and modeling simultaneously with its cancellation demand, and does not explain or even describe a change in the critical endpoint driving the cancellation determination in its decision document," Petitioners conclude. PB at 7.

C. Analysis and Conclusion

Petitioners offered three reasons in their February 5, 2016, letter affirmatively announcing their intention to not comply with the Agency's request for voluntary cancellation.[34] RE 7 at 200079-80. They raised the same three issues in their Request for Hearing and Statement of Objections, their initial pleading in this case filed in response to EPA's NOIC. Petitioners subsequently moved for accelerated decision based upon those same reasons, a motion denied by this Tribunal, which found no justification for Petitioners claim and determined that "Petitioners . . . do not dispute that 'voluntary withdrawal' was a condition of their conditional registration and that they did not comply with that condition." Order on Petitioners' Motion for Accelerated Decision at 28. After failing to advance these arguments, Petitioners raised new claims at hearing, the first of which is that their compliance with the

[34] The reasons offered were that: (1) the voluntary cancellation provision was "illegal" as it bypassed statutory cancellation proceedings; (2) EPA was required to utilize FIFRA section 6(b) cancellation proceedings because of its finding of an unreasonable adverse effect on the environment; and (3) the determination of the registrations posing unreasonable adverse effects to the environment was erroneous. RE 7 at 200079–80.[35] The PAL contains duplicate provisions in section 8 that refer to Bayer instead of Nichino. RE 2 at 200012. As noted above, the deadlines set forth in the PAL for Petitioners' data submission and EPA's review thereof were repeatedly extended at the Petitioners' request. PBNX 10–16

voluntary cancellation condition was excused because "EPA was required to engage in open, measured scientific dialogue before demanding cancellation" and did not do so. PB at 1–6.

As the Agency observes, this new argument is untimely. The Rules of Practice provide that "[a]ny document containing objections to an order of the Administrator of . . . his intent to cancel the registration . . . *shall clearly and concisely set forth such objections* and the basis for *each* objection, including relevant *allegations of fact* concerning the pesticide under consideration." 40 C.F.R. § 164.22(a) (emphasis added). The Rules of Practice do not state the significance of a party's noncompliance with this requirement. However, Rule 164.22 is similar to Rule 9(c) of the Federal Rules of Civil Procedure, which provides that "when denying a condition precedent has occurred or been performed, a party must do so with particularity." Fed. R. Civ. P. 9(c). Further, caselaw holds that a party failing to deny with particularity in its answer that a condition precedent has been fulfilled is precluded from subsequently raising that issue. *See, e.g.*, *Digital Ally, Inc. v. Z3 Tech., LLC*, 2010 U.S. Dist. LEXIS 103715, *12 (D. Kan. Sept. 30, 2010) (citing *Myers v. Cent. Fla. Invs., Inc.*, 592 F.3d 1201 (11th Cir. 2010)). Applying a similar reading to Rule 164.22 would be especially appropriate here in light of the short 75 day period for holding a hearing and making a determination in this case. 7 U.S.C. § 136d(e). Thus, Petitioners' are prohibited from raising any objections to the notice of cancellation not set forth in their initial objections to the NOIC. As all objections raised at hearing and in their post-hearing brief appear to be new, the Agency's claim that it has established all the necessary elements of a prima facie case showing that Petitioners failed to comply with the conditions of the flubendiamide registrations stands unopposed.

However, even if Petitioners were permitted to raise their new objections to the cancellation notice at this point, this Tribunal is not persuaded by the merits of these objections.

With regard to Petitioners' first argument that a condition precedent to voluntary cancellation was not satisfied, it is instructive to consider the PAL, which was signed by both parties, incorporated into the conditional registrations, and contains the following provisions:

> 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 EPA's subsequent review of such additional data during the term of the time-limited registration, as follows:
>
> (a) Nichino . . . shall submit all data identified in paragraphs 2-4, on or before July 31, 2012 . . . .
>
> (b) The EPA shall complete its review of the entire required data set and will consider any additional data and supporting information voluntarily submitted by Nichino . . . . EPA scientists and Bayer scientists, as agents for Nichino, shall engage in dialogue about the data and the Agency's conclusions.
>
> * * *

(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.

RE 2 at 200011–12.[35]

At hearing, Nichino's President Mr. Johnson agreed that a fair narrative characterization of the PAL's terms would be that "if after scientific discussions with Bayer and Nichino, if EPA still determines that flubendiamide causes unreasonable adverse effects on the environment, and notifies Nichino about the termination, Nichino must submit a voluntary request for cancellation within seven days." Tr. 144.

There is no dispute that over the 7½ years that the conditional registrations existed, Petitioners submitted the study data required of them under the PAL. Tr. 103, PBNX 12 (Petitioners "ha[ve] submitted all data required by the original conditions of registration for flubendiamide."). There also does not seem to be any dispute that EPA completed its review of the entire required data set Petitioners submitted. Tr. 103, 126 (Ms. Sanson acknowledging EPA has evaluated all the data submitted); *see also* PBNX 21 (EPA BEAD Review of Bayer Benefits Document); PBNX 25 (EPA EFED Response to Bayer White Paper); PBNX 31, 32 (EPA EFED Ecological Risk Assessment and Addendum), PBNX 30 (EPA Decision Memorandum). Further, Petitioners acknowledge multiple in-person meetings occurred between EPA and Nichino/Bayer scientists about the data. Tr. 71, 126, 152, 185; RE 6 at 200077 ("A series of meetings between EPA scientists and BCS/NAI scientist have occurred since March 2015 where the Agency and BCS/NAI have continued to engage in dialogue about the referenced conditional data, various label mitigation proposals, and all the Agency's conclusions regarding the same."). Finally, Petitioners do not dispute that after reviewing the data, EPA made a determination, as evidenced by its January 29, 2016 letter to them that further registration of the flubendiamide products "will result in unreasonable adverse effects on the environment." RE 6 at 200078; Tr. 185. As such, it is abundantly clear that all possible conditions precedent to Petitioners' obligation to submit the request for voluntary registration set forth in the PAL were fulfilled. Restatement 2d of Contracts, § 224 (2d 1981) ("A condition is an event, not certain to occur, which must occur, unless its non-occurrence is excused, before performance under a contract becomes due.").

Nevertheless, Petitioners now argue otherwise, primarily on the basis that "EPA did not engage in a good-faith, 'measured dialogue' among scientists regarding the data and EPA's

[35] The PAL contains duplicate provisions in section 8 that refer to Bayer instead of Nichino. RE 2 at 200012. As noted above, the deadlines set forth in the PAL for Petitioners' data submission and EPA's review thereof were repeatedly extended at the Petitioners' request. PBNX 10–16

conclusions" and "refused to engage in transparent scientific dialogue and refused to present its unreasonable adverse effects conclusion for discussion." PB at 2. This argument has no support in the record.

First, the PAL does not clearly require a dialogue between scientists to occur before EPA makes its determination, only that such determination occur "*after* EPA's review of *the data*." RE 2 at 200012. The parties could have included the requirement for a dialog to occur before the determination was made in provision 6(d), but clearly did not do so. As such, no dialog between the parties was a necessary pre-condition to the determination.

Second, even if a dialogue among scientists was required to occur before EPA made its determination, the PAL does not in any way explicitly require that such dialogue be "measured" or "transparent." In particular it is noted that the term "measured" comes only from Petitioners' self-generated e-mail communications with the Agency. *See, e.g.*, RE 4 at 200036. It is not a term the parties' agreed upon and incorporated into the PAL or the conditional registrations.

Third, the evidence indicates that Petitioners' and EPA's scientists *did* engage in a good faith dialogue. A "dialogue" is nothing more than a "conversation between two people." 373 Webster's II New Riverside Dictionary (1984). "Good faith' is defined as "an intangible and abstract quality with no technical meaning or statutory definition," "encompass[ing] among other things, an honest belief, the absence of malice and the absence of design to defraud or to seek an unconscionable advantage . . .". 623 Black's Law Dictionary (5th Ed. 1979). The record here indicates that the parties' scientists were engaged in dialogue through the exchange of lengthy written analysis on the data, particularly in the months immediately prior to EPA's determination being made. *See, e.g.*, PBNX 11, 14, 22–25, 31–32, 35–36. Further, the parties' respective scientists met *in person* at least *twice*, including on January 6, 2016, for no less than half a day, followed by a non-science discussion among the parties for the balance of the day. Tr. 71–72.

Mr. Johnson acknowledged that scientific discussion between the parties occurred on both December 15, 2015, and January 6, 2016, but claimed discussions "broke down" and Petitioners' felt their "most relevant points in terms of the degradates and their persistence . . . were being ignored," and the parties "were a bit at loggerheads." Tr. 152, 185. As such, he felt they never got to the point where the "scientific discussion concluded" and a "sound scientific conclusion" was reached, and thus, in his opinion, the condition for cancellation was not triggered. Tr. 152–53. *See also* Tr. 185 (Johnson noting the scientists had "discussions over time," "that they were not always fruitful," and "[t]here was not necessarily agreement around the science, the use of the studies, and it's really . . . the crux of the issue why we're here"). However, there is nothing in the requirement of a "dialogue" in the PAL that requires an extended series of conversations between the parties, that EPA give significant weight to Petitioners' points made during such dialogues, or that a mutual agreement or understanding be reached on the data, as Ms. Sanson acknowledged at hearing.[36] Tr. 106–07. There is certainly

[36] To the extent Petitioners want to argue the Agency's scientific conclusions are erroneous or challenge EPA's determination that flubendiamide will result in unreasonable adverse effects on the environment is wrong, those are not issues to be addressed in this proceeding.

no evidence of a lack of good faith, *i.e.*, dishonesty, malice, or fraud, on the part of EPA's scientists engaged in discussion with Petitioners.

This conclusion is not undermined by Petitioners' repeated claim that the Agency's decision on its registrations was "political." Tr. 17 (Petitioners' counsel: "This is an extreme example of EPA elevating a political objective over science."); Tr. 128 (Sanson: "I would say it was a scientific, but more of a political decision."); Tr. 198 (Johnson: "The goal post got moved and, at that time, it was apparent to us that it was starting to be more of a political issue and not a science issue."). Mr. Johnson testified that Petitioners' claim in this regard is based upon EPA Assistant Administrator Jones emphatically stating during the December 15, 2015 meeting that "he personally didn't believe this compound should ever have been registered" based upon its persistence, and intimating that "persistence in and of itself should be a reason to not allow the product on the market, regardless of whether there's risk or not." Tr. 188, 91. As a result of these comments, Mr. Johnson testified it was his personal impression that the Agency was trying to "make an example out of the [flubendiamide] compound" in order "to drive a new persistence policy within EPA" and on this basis were moving the "goalposts" regarding the toxicity endpoint. Then, regardless of the science offered by Petitioners, EPA would "deem this as a persistent pesticide and take it off the market," regardless of whether there's a risk or not. "And that's very much against the risk approach that EPA takes." Tr. 190–91.

Unfortunately for Petitioners, there is no evidence in the record supporting their suspicions that persistence alone, and not risk, was the motive behind EPA's actions. Conversely, there is much evidence that ecological risk to benthic invertebrates, derived from the pesticide and its des-iodo persistence in water, sediment, and pore water, drove the finding of unreasonable adverse effects triggering the voluntary cancellation. Nowhere is that more clearly and efficiently set forth than in EPA's January 29, 2016 Decision Memorandum, which lays out the whole history of the pesticide and registration, including the testing to determine persistence in soil, sediment and pore water and its effect on aquatic insects:

> EPA has identified chronic concerns for Flubendiamide to aquatic system invertebrates for both parent and its des-iodo degradate. . . . [W]ith each successive flubendiamide application, more flubendiamide is transported to aquatic environments via runoff and spray drift where it accumulates and slowly degrades to des-iodo, which in turn accumulates, causing unreasonable adverse effects to aquatic environments.

RE 5; *see also* PBNX 31 (EFED Ecological Risk Assessment Addendum Summarizing all Submissions and Discussions to Date).

Finally, Petitioners cannot persuasively claim the Agency in January 29, 2016, made its unreasonable adverse effects determination based upon a new toxicity endpoint "without disclosure or explanation." Both the spiked water study (PBNX 33) and spiked sediment study (PBNX 34), establishing endpoints, were undertaken by Petitioners in 2008 and 2011, respectively, and submitted to EPA. The record clearly reflects that Petitioners were made aware of the toxicity endpoints being used by the Agency by mid-December 2015. PBNX 14. The

end-points were a topic of discussion at meetings held between the parties and their scientists in mid-December 2015 and January 2016. *Id.*; Tr. 187–89. The Petitioners were granted an extension of their registrations so as to allow them time to submit additional documentation in response. PBNX 15. Petitioners did not request any additional time to address the toxicity end-point in their February 5, 2016, response to EPA's Request to Submit Voluntary Cancellation. PBNX 18. As to the determination, the record evidences that starting from February 2015, when EFED issued its review of Petitioners' pond water monitoring report, Petitioners knew their registrations were in jeopardy. PBNX 35. In response, they started actively generating documentation and aggressively meeting and corresponding with the Agency in the hope of persuading it to continue the registrations while additional studies were done in lieu of cancellation. PBNX 14, 22, 24. Thus, while it is clear from the record that Petitioners were not in agreement with EPA as to the toxicity end-points chosen or the Agency's ultimate determination, they clearly were aware of them, and the rationale behind them, and had an opportunity to respond to EPA and engage in dialogue with Agency officials about these issues.[37]

Consequently, I find that the voluntary cancellation provision was a condition of Petitioners' registrations from which Petitioners were not excused. All of the preconditions to Petitioners' obligations to submit the requests for voluntary withdrawal of their flubendiamide registrations within seven days were fulfilled as of January 29, 2016. RE 5. Petitioners did not submit a request for voluntary cancellation within seven days and have not done so to date. RE 7; Tr. 148, 159. Thus, I find Petitioners did not initiate and pursue appropriate action to comply with that condition of their conditional registrations, subjecting those registrations to cancellation under 7 U.S.C. § 136d(e).

VI. WHETHER THE ADMINISTRATOR'S EXISTING STOCKS DETERMINATION IS CONSISTENT WITH FIFRA

As noted above, the NOIC contains the determination made by EPA regarding whether, and to what extent, it will permit the continued sale, distribution and use of the existing stocks of Petitioners' flubendiamide products whose registrations are being cancelled. NOIC, 81 Fed. Reg. 11558 (Mar. 4, 2016). Specifically, the Agency indicated that it intends to prohibit the use of the flubendiamide technical registration product and to prohibit the further distribution and sale of end use registration products, but allow the use of products held by end-users. *Id.* at 11560. Petitioners have challenged this determination. PB 8–15. FIFRA Section 6(e) provides that in this proceeding this Tribunal need decide only whether the Administrator's determination is "consistent with [FIFRA]." 7 U.S.C. § 136d(e).

[37] The record evidences that Petitioners did not want a few more *months* to submit a response to the toxicity end-points as determined by EPA or final determination. What Petitioners' wanted, but were not granted by EPA, after the submission of their water monitoring study in December 2014 (which evidenced pesticide persistence and accumulation), was another two to three *years* extended to their conditional registration justified based upon the need to undertake even more testing and in the meantime, to sell their pesticide. RE 5 at 200066–67; PBNX 35 (February 20, 2015) (EPA review of pond monitoring data), PBNX 24 at PBN0438 (Bayer White Paper June 29, 2015).

A. Agency's Arguments

In its Brief, the Agency suggests its existing stocks determination is consistent with FIFRA, offering three main points in support. AB at 10–12. First, the determination is consistent with the Agency's published Statement of Policy on Existing Stocks "in that it would generally prohibit sale or distribution by registrants who have failed to comply with a specific, as opposed to general, condition of registration." AB at 11. Second, the Agency's determination is intended to underscore "the importance of deterring registrants from intentionally violating important, specific conditions of registration, especially where the Registrants were clearly aware of how important that condition was to EPA's decision to approve the registration." AB at 11–12. The Agency observes that its decision here is in response to Petitioners "reneg[ing] on commitments they made to comply with a specific condition" and is not punishment for Petitioners exercising their right to a hearing, because "they had several other legitimate ways to challenge the conditions" of the registration. AB at 12, 13. Third, the Agency determined, based on prior experience, that end users possess only small quantities of the flubendiamide pesticide products "and the cost and risks associated with returning them for disposal would be high compared with the use of the cancelled product in accordance with its labeling." AB at 12.

B. Petitioners' Arguments

Petitioners argue the Agency's existing stocks determination is "arbitrary and capricious" because it is based "on a desire to punish Registrants for exercising their statutory rights." PB at 9. According to Petitioners, the evidence demonstrates that

> (i) Registrants had a good faith basis to contest EPA's cancellation determination; (ii) EPA never sought information from Registrants on the amount of flubendiamide available at the time cancellation was sought; (iii) EPA could have made a risk-benefit based existing stocks determination without delay; (iv) EPA instead ignored entirely the impact that its existing stocks determination would have on growers who depend upon the product; and (v) EPA declined to exercise the only lawful means for immediately stopping Registrants from selling flubendiamide while the cancellation proceeding was pending, a suspension order under FIFRA § 6(c), 7 U.S.C. § 136d(c).

PB at 9–10. Petitioners further contend that the Agency's claim that it did not consider the risks and benefits of sale and distribution of existing stocks is not credible. PB at 12. "As a practical matter, Ms. Lewis and other EPA decision-makers could not erase from their minds EPA's unsound determinations that use of flubendiamide results in unreasonable adverse effects, is already causing 'adverse impacts,' and provides minimal, if any, benefits compared to alternatives," Petitioners add. PB at 12. This has led to an existing stocks determination that is inconsistent with FIFRA because "FIFRA is a risk-benefit statute," Petitioners declare. PB at 13. Petitioners also complained they were prejudiced at hearing, because when the Agency asserted it had made its existing stocks determination without considering flubendiamide's risks and

benefits, several witnesses and exhibits were excluded from the hearing as irrelevant. PB at 14. Petitioners suggested that Ms. Lewis's testimony regarding the risks and benefits of the Administrator's determination "to prohibit sale and distribution of existing stocks . . . opened the door to a hearing on that issue." PB at 14 (citing Lewis's testimony that "EPA had 'consulted with our experts in the Biological and Economic Analysis Divison' on its existing stocks proposal).[38] On the other hand, without that evidence, "the only relevant information on existing stocks provided at the hearing" is that Petitioners' limited production, "resulting in a limited amount of product to move through the channels of trade," and Nichino cannot sell its stocks outside of the United States, so they "will need to be collected and disposed of as waste, creating additional environmental risk that will not be offset by beneficial use." PB at 15. "These facts alone justify an existing stocks provision allowing for sale, distribution, and use of the limited existing stocks available at the time of cancellation," Petitioners conclude.

C. Analysis and Conclusion

FIFRA's "principal purpose" is the registration and regulation of pesticides that do not pose an unreasonable risk to man or his environment. *Riden v. ICI Americas, Inc.*, 763 F. Supp. 1500, 1506 (W.D. Mo. 1991). More specifically, it has been said that "Congress' purpose in enacting FIFRA was to protect consumers 'by keeping unhealthy or unsafe pesticides off the market and by preventing deceptive labeling."' *Hurt v. Dow Chemical Co.*, 759 F. Supp. 556, 559 (E.D. Mo. 1990) (quoting *Fisher v. Chevron Chemical Co.*, 716 F. Supp. 1283, 1287 (W.D. Mo. 1989)). *See also Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 531 (9th Cir. 2001) ("FIFRA's objective is to protect human health and the environment from harm from pesticides, and to that end the statute establishes a nationally uniform pesticide labeling system requiring the registration of all pesticides and herbicides sold in the United States and requiring users to comply with the national label.").

Consistent therewith, the statute provides that "no person in any State may distribute or sell to any person any pesticide that is not registered [under FIFRA]." 7 U.S.C. § 136a(a). Thus, if the Agency cancels the registration for a pesticide, it cannot be legally sold or distributed at all, anywhere, in this country.

However, the statute provides an exception to this broad general prohibition, which is that "[t]he Administrator *may* permit the continued sale and use of existing stocks of a pesticide

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[38] There is no merit to Petitioners' suggestion that the Agency opened the door to the consideration of risks and benefits of the Agency's existing stocks determination because the passage relied on in the Petitioners' Brief (Tr. 80:34) is taken out of context. Ms. Lewis responded to questions about the usage patterns of farmers, i.e., end users, which was not a determination to which Petitioners objected. Tr. 79–80 (Q: "[D]o you think that farmers usually hold significant quantities of pesticide? Do they . . . typically use pesticides shortly after they've purchased them? A: It depends on the pesticide. . . . [T]ypically farmers are not going to want to invest the money until they know they need to use them. Q: And why do you expect that that would be the case? A: Because it depends on the pest pressure every year. We also consulted with our experts in the Biological and Economic Analysis Division, and I believe they generally thought it wouldn't be extensive."); *See also* Hr'g Req. ¶¶ 196–215.

whose conditional registration has been canceled under this subsection . . . *if the Administrator determines that such sale or use is not inconsistent with the purposes of this Act* . . . ." 7 U.S.C. § 136d(e)(1) (emphasis added); *see also* 7 U.S.C. § 136d(a)(1) ("The Administrator *may* permit the continued sale and use of existing stocks of a pesticide whose registration is . . . canceled under this section . . . to such extent, under such conditions, and for such uses as the *Administrator determines that such sale or use is not inconsistent with the purposes of this Act*.") (emphasis added).

"May" is permissive language. *See Conant v. Wells Fargo Bank, N.A.*, 60 F. Supp.3d 99, 118 (D.D.C. 2014), quoting *Bennett v. Panama Canal Co.*, 475 F.2d 1280, 1282 (D.C. Cir. 1973) ("Ordinarily 'may' is a permissive not a mandatory term."). Thus, the statute grants the Agency the discretion to allow the continued sale and use of a cancelled pesticide but does not require a determination to be made. The language of the statute indicates that *if* the Administrator desires to exercise her discretion to permit the continued sale or use of existing stocks, *then* she must make a "determination that such sale or use is not inconsistent" with FIFRA's purposes, *i.e.*, to protect human health and the environment from pesticides which cause an unreasonable risk.

In this case, the Administrator *has not* exercised her discretion *to permit* the continued distribution, sale and use of existing stocks of flubendiamide, except use of the product presently in the hands of end-users. As such, she need not make any "determination" that continued use and sale is consistent with FIFRA's purposes. Therefore, arguably my query ends here (except as to the product in the hands of end users), because there is no determination to review. Moreover, although the statute provides the Administrator *may* permit the sale of existing stock upon a determination that such sale is not inconsistent with FIFRA, the statute does not require her to do so, nor does it mandate she even make a "determination" on any criteria in regard to whether to permit the continued sale of a cancelled pesticide, or justify her reasons for not doing so. 7 U.S.C. § 136d(e)(1). Furthermore, the statute does not provide any cause of action or remedies to the registrant where the Administrator has not made a determination to allow the continued distribution, sale, and use of existing stocks. Under such circumstances the permissive language does not result in an unreviewable discretionary "decision" on the Agency's part, as Petitioners argue. PB at 13. Rather, upon cancellation, it simply puts into effect FIFRA's primary statutory provision prohibiting the sale of unregistered pesticides, in the absence of an affirmative discretionary act taken by the Administrator.

But even if the Administrator is required to make a "determination" whether or not to allow the sale of existing stocks, and to prove that determination is consistent with the purpose of FIFRA, the record supports that conclusion. In 1978, Congress amended FIFRA by adding the conditional registration regime "to address the backlog that existed in the registration process" and bring new products to market by eliminating the higher standards new registrants faced compared to producers of older pesticides with existing registrations. Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 819 (1978); *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174, 176–77, 181 (D.D.C. 2012) (quoting S. Rep. No. 95-334 at 3) ("'An overriding concern of FIFRA is that pesticides should be available to meet pest control needs.'"). "[T]he overall approach in the legislative history shows that Congress was concerned with the 'lack of middle ground' in the registration process between totally denying registration and granting it – that middle ground being conditional registration." *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d at

181 (citing S. Rep. No. 95-334 at 4). One way Congress addressed that concern was by amending FIFRA to allow for registration of pesticide products under special circumstances. *Id.* at 176. By "crafting registration conditions rather than simply denying an application," the Agency has the flexibility to make pesticides available for use while also evaluating their safety and efficacy. *Id.* at 181. *Cf. Connecticut Fund for the Env't, Inc. v. EPA*, 672 F.2d 998, 1006 (2d Cir. 1982) ("Conditional approval offers administrative agencies a measured course that may be more precisely tailored to particular circumstances than the all-or-nothing choice of outright approval or disapproval."); *McManus v. Civil Aeronautics Bd.*, 286 F.2d 414, 419 (2d Cir. 1961) (noting that an agency's power to condition approval is "necessary for flexible administrative action and is inherent in the power to approve or disapprove"). In short, "'[s]ince registration is critical, this program must be made to work.'" *Woodstream*, 845 F. Supp. 2d at 181 (quoting S. Rep. No. 95-334 at 3).

In this case, more than seven years ago, the Administrator took a leap of faith and took advantage of the "middle ground" by allowing flubendiamide to be conditionally registered while Petitioners and the Agency gathered additional data on its long-term effects. This was to Petitioners' clear benefit, as the Administrator could have simply denied the application based on then-existing data that suggested environmental risk. Consistent therewith, certain specified conditions were imposed on the registration with the agreement of both parties. The Petitioners have not abided by those conditions and so the Agency has sought involuntary cancellation. Further, the Administrator decided not to exercise her discretion to allow the sale of existing stocks of pesticide it intends to cancel. Under such circumstances, this outcome *is consistent* with the purpose of FIFRA Section 3, which was to allow the temporary sale of new pesticides, while the registrant stayed in compliance with conditions set under registration. The Petitioners here are intentionally out of compliance, and have no intention of coming into compliance. There is no reason to allow them to continue to sell and distribute their pesticides beyond the effective date of cancellation. Furthermore, I agree with the Agency that its positive view of the conditional registration program, and potentially compliance therewith, would collapse if the Agency were forced to allow sale of existing stocks even by those registrants who refuse to comply with the terms of their registration – a scenario distinct from penalizing a registrant for challenging the lawfulness of the condition in the first place – and the deterrence purpose behind the penalty is consistent with FIFRA. Tr. 156 (Johnson noting "integrity is important all the way around" in the registration process.)

The Agency's decision here is also consistent with its Statement of Policy published in 1991. RE 8 at 200084; RE 9; PBNX 20 at PBN0104; PBNX 52. Under the Policy, the Agency states it will base its existing stocks determination "on the nature of any conditions that have not been met by the registrant," distinguishing between general and specific conditions. RE 9; PBNX 52. Conditions that require "the submission of specified studies or information by specified dates" are specific conditions. RE 9; PBNX 52.

> [I]f 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.

RE 9 at 200090–91; PBNX 52 at PBN1555–56. As the Agency noted in the NOIC issued here, "[t]he registration condition in the instant case is specific and was identified at the time the registration was issued, so the Agency does not intend to allow any sale or distribution of existing stocks." RE 8 at 200084; PBNX 20 at PBN0104.

As such, I find that the Administrator not permitting the use of the flubendiamide technical registration product or the further distribution and sale of end use products to be consistent with FIFRA. As to permitting use of the pesticide by end-users, no party has challenged this determination. Consequently, I also find allowing this use to be consistent with FIFRA.

VII. ORDER

Regarding the following conditionally registered pesticide products containing the insecticide flubendiamide, (1) EPA Reg. No. 264–1025—BELT SC Insecticide; (2) EPA Reg. No. 71711–26—FLUBENDIAMIDE Technical; (3) EPA Reg. No. 71711–32—VETICA Insecticide; and (4) EPA Reg. No. 71711–33—TOURISMO Insecticide, I find, for the reasons set forth above:

(1) Petitioners have not initiated and pursued appropriate action to comply with the condition or conditions set forth within their conditional registrations within the time provided;

(2) The condition or conditions set forth within Petitioners' conditional registrations have not been satisfied within the time provided, and

(3) The Administrator's determination with respect to the disposition of existing stocks of the Petitioners' conditionally registered flubendiamide products is consistent with FIFRA.

Accordingly, Petitioners' objections to the NOIC are dismissed, the Agency's NOIC is approved, and cancellation of the registrations for the above-listed flubendiamide products shall immediately become effective when this Initial Decision becomes a final order under 40 C.F.R. § 164.90(b) and 7 U.S.C. § 136d(e)(2).

Pursuant to the Rules of Practice, this "initial decision shall become the decision of the Environmental Appeals Board without further proceedings unless an appeal is taken from it or the Environmental Appeals Board orders review of it, pursuant to §164.101." 40 C.F.R. § 164.90(b).[39]

SO ORDERED.

Susan L. Biro
Chief Administrative Law Judge

Dated: June 1, 2016
Washington, D.C.

[39] On May 12, 2016, the Environmental Appeals Board issued an Order Establishing Deadlines and Procedures for Appeals to clarify the procedures and timelines for an appeal of this Initial Decision. I note the existence of this Order only to ensure the parties are aware of it, because the appellate procedures in the Board's Order deviate significantly from the regulations at 40 C.F.R. Part 164.

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 **Initial Decision**, dated June 1, 2016, issued by Chief Administrative Law Judge Susan L. Biro, was served on this 1st day of June 2016 in the following manner to the addressees listed below:

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