UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

MOTION FOR AN ACCELERATED DECISION
BY BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

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INTRODUCTION

Bayer CropScience LP ("Bayer") and Nichino America, Inc. ("Nichino") hereby move for an accelerated decision pursuant to 40 C.F.R. § 164.91(a)(7) and Section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§ 136-136y, "FIFRA"). Bayer and Nichino request that the Administrative Law Judge ("ALJ") find unlawful and deny the proposed cancellation of registrations for pesticide products containing the active ingredient flubendiamide. At issue in this hearing and on this threshold motion is whether the United States Environmental Protection Agency ("EPA") can implement an unlawful forced "voluntary" cancellation provision to bypass cancellation process and due process rights guaranteed by statute and to shield its cancellation decision from review and challenge by Bayer, Nichino, and all other affected stakeholders.

EPA seeks to cancel the registrations based on an unsound determination that continued registration of the flubendiamide products would cause unreasonable adverse effects on the environment, yet the Agency chose not to follow the process required under FIFRA § 6(b) for cancellation on that basis. EPA did not submit its cancellation determination for scientific peer review by the Scientific Advisory Panel ("SAP") and did not solicit comments from the United States Department of Agriculture ("USDA") on the benefits and importance of flubendiamide products before issuing the Notice of Intent to Cancel ("NOIC").[1] In pursuing cancellation through the inapplicable streamlined cancellation process under FIFRA § 6(e), EPA seeks to deny registrants, growers, and other affected stakeholders the right to request an administrative hearing on the scientific and regulatory merits of the cancellation determination.

[1] Exhibit 20 (Flubendiamide; Notice of Intent to Cancel Pesticide Registrations, 81 Fed. Reg. 11,558 (Mar. 4, 2016)).

It is undisputed that EPA seeks to cancel flubendiamide based on a determination that flubendiamide no longer meets the FIFRA registration standard. On January 29, 2016, EPA issued a letter notifying Bayer and Nichino that 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," and asking Bayer and Nichino to "voluntarily" relinquish all of their flubendiamide registrations on that basis. Exhibit 17 at 2. Simultaneously with its March 1, 2016 delivery of the NOIC to Bayer and Nichino, EPA issued press releases and posted information on its website stating that EPA had "concluded that continued use of the product would result in unreasonable adverse effects on the environment."[2]

Yet, instead of following the process required under § 6(b) for cancellation based on a determination that continued use will "cause[] unreasonable adverse effects on the environment," EPA has sought to enforce its unlawful "voluntary" cancellation condition and seeks cancellation through § 6(e). In a prior proceeding before the ALJ, EPA acknowledged that § 6(b) governs "risk-based cancellations" where a product "ha[s] been determined to pose unreasonable risks to man or the environment that require that they be removed from commerce," while "a section 6(e) cancellation is about the *registrant's* failure to meet its obligations, and not about a problem with *the pesticide product itself*." Exhibit 55 at 4-5 & n.2 (emphasis in original). Through its unlawful "voluntary" cancellation scheme and invocation of § 6(e), EPA now seeks the opposite result, and claims the right to cancel a product based on an unreasonable adverse risk determination through § 6(e).

EPA is not free to reinterpret or ignore these same statutory provisions when it wishes to evade required process and shield its cancellation determination from review that the

[2] Exhibit 19 (EPA Moves to Cancel the Insecticide Flubendiamide (Mar. 1, 2016).

determination would not withstand. EPA cannot demand the right to bypass the cancellation process required by Congress, cannot evade independent scientific peer review and input from other federal agencies, cannot deny registrants, growers, and other stakeholders the due process rights they possess by statute, and cannot preclude the ALJ from reviewing the lawfulness of EPA's approach. The ALJ should hold EPA to its statutory obligations and require EPA to follow the process granted by FIFRA § 6(b) prior to any cancellation of the flubendiamide registrations.

The ALJ need not reach the merits of EPA's proposed cancellation or determine whether flubendiamide meets the FIFRA registration standard to grant this motion and deny the proposed cancellation. However, in assessing the lawfulness of EPA's approach and the importance of the cancellation process required by EPA, it is telling that the Agency's cancellation determination is not supported by the science and would not withstand required review. EPA's unreasonable adverse effects determination relies on exposure estimates based on overly conservative theoretical modeling that is contradicted by real-world data and the Agency's sudden reversion to a toxicity level of concern that is 70 times lower than the science supports. EPA also ignores or discounts the significant agricultural and environmental benefits of flubendiamide compared to available alternatives. Under FIFRA § 6(b), EPA was required to submit its determination for scientific peer review by the SAP and consideration by USDA *before* issuing the NOIC, which would have addressed and exposed these fundamental flaws in EPA's determination. If EPA chose nonetheless to proceed with cancellation, that process would have provided the proper record for a hearing addressing the merits of the cancellation decision under FIFRA § 6(b).

For these reasons, Bayer and Nichino respectfully request that the ALJ issue an accelerated decision finding that EPA's forced "voluntary" cancellation provision is unlawful,

denying the proposed cancellation of the registrations under § 6(e), and requiring EPA to follow the process required under § 6(b) if it wishes to cancel the flubendiamide registrations for failure to meet the FIFRA registration standard.

STATEMENT OF FACTS

I. FLUBENDIAMIDE

A. Development of Flubendiamide

Flubendiamide is a highly effective insecticide that is approved for use on over 200 crops and provides excellent, targeted control of lepidopteran pests (caterpillars). Exhibit 1 ¶¶ 10, 12 (Declaration of Lee Hall). Flubendiamide is consistent with and furthers the goals of modern Integrated Pest Management ("IPM") practices and is an important tool for resistance management. *Id.* ¶ 6. Flubendiamide has an excellent safety profile. *Id.* ¶ 22. EPA has repeatedly confirmed that flubendiamide poses no human health or safety concerns and no direct regulatory concerns for mammals, birds, fish, crustaceans, mollusks, beneficial insects, pollinators, and plants.[3] EPA also has determined that flubendiamide has a favorable risk profile compared to alternatives. Exhibit 21 at 5 (BEAD Public Interest Finding for Flubendiamide (Apr. 15, 2008)).

Flubendiamide was invented by Nihon Nohyaku Co., Ltd. ("NNC") and was first registered by EPA in 2008. Exhibit 3 ¶¶ 4-5 (Declaration of Lydia Cox); Exhibit 7 (Notices of Registration for Flubendiamide Technical and Belt® SC Insecticide (Aug. 1, 2008)). Nichino is a wholly owned subsidiary of NNC. Exhibit 3 ¶ 4. Bayer has a licensing, product development,

[3] Exhibit 27 at PDF p. 2 (EFED Risk Assessment for the Section 3 New Chemical Registration of Flubendiamide (June 23, 2008)); Exhibit 28 at 3-8 (PDF pp. 22-27) (EFED Risk Assessment for Legume Vegetable and Christmas Tree New Uses for the Insecticide Flubendiamide (May 17, 2010)); Exhibit 29 at 38-41 (EFED Ecological Risk Assessment for the New Use of Flubendiamide on Alfalfa and Certain Other Crops (Dec. 16, 2010)).

and marketing agreement with NNC and Nichino pursuant to which Bayer serves as Nichino's regulatory agent for flubendiamide. Exhibit 1 ¶ 7. Bayer and Nichino are the original and current holders of the flubendiamide registrations that are the subject of EPA's proposed cancellation action. *Id.* ¶ 8. Bayer sells flubendiamide products under the Belt® brand name, and Nichino sells flubendiamide products under the Vetica® and Tourismo® brand names. *Id.* ¶ 7.

Bayer and Nichino have made significant investments to obtain and maintain the flubendiamide registrations. Bayer spent more than $60 million in data and development costs to obtain the initial registrations and to support the expansion and continuation of the registrations. Exhibit 1 ¶ 9. NNC and Nichino have spent more than $65 million on the initial discovery, data, and development costs to obtain the US registrations and to bring flubendiamide to the US market. Exhibit 3 ¶ 5.

Flubendiamide products are sold by Bayer and Nichino throughout the country, with their primary use running across the South and up the West Coast (south of the Mason-Dixon line and from Virginia through California). Exhibit 1 ¶ 11. Growers use flubendiamide on a wide range of crops throughout the year. *Id.* ¶ 13. It is used on winter vegetables in Arizona and Florida from January through March, on tree fruits and nuts in California from March through June, on soybeans, cotton, and alfalfa from June through August, and on fall vegetables from September through December. *Id.*

B. Benefits of Flubendiamide

Registrants submitted a comprehensive summary of flubendiamide's human health, environmental, safety, and pest management benefits to EPA in May of 2015, complete with citations to articles published in scientific journals, field study results, and crop-specific testimonials from growers, grower organizations and experts in the field of entomology. Exhibit

22; Exhibit 1 ¶ 14. This submission included over 300 pages of comparative health and safety information, use information, and third party data, articles, and letters of support demonstrating flubendiamide's current use and benefits and its important current and future role for IPM and resistance management. Exhibit 1 ¶ 14. Bayer subsequently submitted a concise overview of flubendiamide's benefits, which included a table comparing the toxicity and benefits of flubendiamide to eight other compounds. *Id.*; Exhibit 24 at 9 (Bayer CropScience LP, White Paper: Flubendiamide Benefits, Aquatic Risk Assessment Summary and Proposed Path Forward (June 29, 2015)).

Dr. Ames Herbert, a professor of entomology at the Tidewater Agricultural Research and Extension Center at Virginia Tech University and the Commonwealth of Virginia's Integrated Pest Management Coordinator, has opined on the many benefits of flubendiamide that make it a critical tool for IPM and IRM, and which will be lost to growers if EPA proceeds with cancellation. These benefits, which are also discussed in greater detail in Dr. Herbert's attached Declaration,[4] are summarized below. Dr. Herbert's opinions join those of the many entomologists and crop specialists from across the country who have reached out to EPA directly to express support for flubendiamide's continued registration because of its demonstrable benefits to growers and the environment.[5]

Over 30 organizations, representing a wide variety of grower associations, food processors, and food retailers from across the United States, have spoken up in support of the

[4] Exhibit 4 (Declaration of Ames Herbert).

[5] Exhibit 22 at 253-54 (Correspondence from Eric T. Natwick), 235-36 (Correspondence from Hannah J. Burrack, Ph.D.), 240-41 (Correspondence from Frank G. Zalom), 244-45 (Correspondence from Dr. Jeremy K. Greene and Dr. Francis Reay-Jones).

continued registration of flubendiamide.[6] The grower *amici* (the "Growers") have come together to deliver an important and unified message – that pest control is the biggest problem they face[7] and that flubendiamide is an important part of the solution.[8] The benefits described by the Growers are not theoretical or hypothetical; they are substantiated by (1) the real-world documented experiences of growers using flubendiamide to combat crop pests and deliver high quality crops at affordable prices to consumers around the globe; and (2) the field work and scientific study of entomologists specializing in insecticide efficacy and integrated pest management.

The Inter-Regional Research Project Number 4 ("IR-4"), a federal and state "cooperative research program in the United States that is funded by the US Congress to develop data to support registrations of crop protection products on specialty crops and minor uses," has added its voice to the chorus criticizing EPA for failing to account for flubendiamide's many benefits in reaching its cancellation decision. Exhibit 26 (Letter from Jerry Baron (IR-4) re Comments on NOIC (Mar. 28, 2016)). As the IR-4 Project notes, flubendiamide's benefits to specialty crops are so well-recognized that growers continue to request IR-4's assistance to *expand* the registration of Belt to support new crops (*e.g.*, blueberries) and *reduce* limitations on the application of Belt for other crops (*e.g.*, shortening the pre-harvest interval for the brassica leafy vegetable crop group and for strawberries from 8 days to 1 day). *Id.* at 2. These proposed uses

[6] *See* Amicus Curiae Brief of the Growers in Support of Objections to EPA's Notice of Cancellation (Apr. 7 2016) ("Growers' Brief").

[7] Growers' Brief at 23.

[8] *Id.* at 24 ("Flubendiamide provides growers with a necessary weapon in their arsenal of strategies for IPM and Insect Resistance Management (IRM).").

were reviewed by over 200 participants at IR-4's Food Use Workshop and deemed "highest priority."[9]

Flubendiamide's proven benefits include:

- **An Excellent Human Safety Profile:** Flubendiamide has an excellent safety profile compared to alternatives such as organophosphates, carbamates, and pyrethroids, and poses no risks of concern to humans.[10] In addition to its safety benefits, flubendiamide's lower risk profile allows for more flexible use because of fewer restrictions on timing of application (*e.g.*, shorter pre-harvest intervals and restricted entry intervals for workers). Exhibit 22 at 22; Exhibit 1 ¶ 24. Growers have a strong interest in using pesticides that they can be confident do not pose any health or safety risk to themselves or their employees. Growers' Brief at 24-25; Exhibit 1 ¶ 22. These considerations are particularly pronounced for tobacco farmers, as it is "a hand labor-intensive crop," where "[w]orkers may come into direct contact with plants several times during the growing season."[11] As Cliff Keel, a North Carolina tobacco farmer, explained: "We rely on Belt because it is safe for my workers, my family and my farm." Growers' Brief, Exhibit 7 ¶ 3 (Declaration of Cliff Keel).

- **Targeted Control of Lepidopteran Pests**: Flubendiamide narrowly targets caterpillars by affecting certain receptors in those species, stopping feeding within minutes. Exhibit 1 ¶ 10; Exhibit 4 ¶¶ 14-15; Exhibit 22 at 21. By contrast, broader-spectrum alternatives like pyrethroids, organophosphates, and carbamates affect a much wider range of insects, including beneficial species. Exhibit 4 ¶ 28; Exhibit 22 at 22. Broader-spectrum pesticides can cause new pest problems when populations of fast-reproducing species, such as aphids and mites, recover and grow unchecked in the absence of slower-reproducing insect predators.[12] Even the other two diamides

[9] IR-4 has committed $1.2 million of its limited direct funding and in-kind resources to conduct this brassica leafy vegetable and strawberry research, which began in January, in addition to hundreds of thousands of dollars already spent to support flubendiamide's use on blueberries. *Id.* at 2.

[10] Exhibit 22 at 235-36 (Correspondence from Hannah J. Burrack, Ph.D., North Carolina State University, to Carmen J. Rodia, Jr., EPA (Apr. 22, 2015)).

[11] *Id.*

[12] *See* Exhibit 22 at 232-33 (Correspondence from Jeffrey Gore, Mississippi State University Delta Research and Extension Center, to Carmen J. Rodia, Jr., EPA (Apr. 29, 2015)) ("[W]e are also concerned with the disruption of natural enemy complexes with alternative insecticides. In particular, spider mites can be one of the most devastating arthropod pests of peanut and they occur almost exclusively in fields that have received a spray with a broad spectrum insecticide. We rarely see spider mites in peanut fields where natural enemy complexes have not been disturbed. This is especially important because there are currently no miticides labeled in peanut that will effectively manage a spider mite infestation.").

compounds on the market -- chlorantraniliprole and cyantraniliprole -- target a broader range of pests than flubendiamide. Exhibit 4 ¶ 15.

- **Efficacy in Controlling Damaging Pests:** Flubendiamide is commonly used to control the Corn earworm, which is one of the most destructive caterpillar pests in the southeast and mid-southeastern U.S. Exhibit 4 ¶ 17. Field trials conducted by Dr. Herbert in Virginia and by other entomologists elsewhere in the country show that flubendiamide consistently controls Corn earworm infestations in cotton, peanuts, and soybeans (i.e. it eliminates the large majority of the caterpillar pests in a crop after application and continues to protect the crop through its residual activity). *Id.* ¶ 18.[13] Flubendiamide's efficacy in treating a variety of other lepidopteran pests that threaten important crops such as almonds and other tree nuts in California,[14] apples in New York,[15] tobacco in Virginia and North Carolina,[16] and sunflowers in Washington State[17] is documented in Bayer's benefits submission and the Growers' Brief and accompanying exhibits and declarations.

- **Low Toxicity to Natural Enemies and Pollinators:** Because of the specificity of flubendiamide's activity against caterpillars, this compound has virtually no negative impact on natural enemy populations (i.e. arthropods that naturally prey on crop pests). Exhibit 4 ¶ 15. When natural enemy species are conserved, they can aid growers in the control of crop pest populations. *Id.*[18] Flubendiamide is also essentially non-toxic to honey bees and other pollinators, a critical attribute given how many of the crops on which it is applied flower and the important role pollinators play in crop reproduction. *Id.* ¶ 23.

- **Non-Systemic Activity:** Flubendiamide, unlike chlorantraniliprole, is non-systemic and therefore is not taken up by the plant via the roots to be incorporated into the above-ground plant parts. Exhibit 4 ¶ 19. This is significant because prolonged pest exposure to systemic insecticides, which can expose multiple generations of the pests,

[13] *See also* Exhibit 22 at 244-45 (Correspondence from Dr. Jeremy K. Greene and Dr. Francis Reay-Jones, Clemson University, to Carmen J. Rodia, Jr., EPA (Apr. 16, 2015)).

[14] Exhibit 22 at 240-41 (Correspondence from Frank G. Zalom, University of California at Davis, to Carmen J. Rodia, Jr., EPA (Apr. 22, 2015)).

[15] Growers' Brief, Exhibit 31 (Correspondence from W.H. Palmer and Scott Palmer, Springbrook Orchards, to Frank Rittemann, Bayer CropScience (Mar. 14, 2016)) (indicating that researchers conducting efficacy trials on the control of insect pests on apples "have not found any registered insecticide equal to Belt for control of late season Codling Moth and Oblique-banded Leafroller damage.").

[16] *See* Exhibit 22 at 235-36 (Correspondence from Hannah J. Burrack. Ph.D.).

[17] Growers' Brief at 43.

[18] *See also* Exhibit 22 at 253-54 (Correspondence from Eric T. Natwick, University of California Cooperative Extension, to Carmen J. Rodia, Jr., EPA (Apr. 17, 2015)).

has resulted in the development of resistance by some insects to certain products. *Id.* ¶¶ 12-13, 19.

- **Optimal Residual Activity:** Flubendiamide does not have the season-long residual activity of a systemic pesticide (or the resulting risk of resistance development), but it does have longer residual activity than other non-systemic compounds. Exhibit 4 ¶ 20.[19] When applied as a foliar spray and once dried on the leaf surface, field trials have shown that caterpillars feeding on treated leaf surfaces are killed for up to three weeks. *Id.*[20] Flubendiamide's longer residual activity offers a huge advantage to growers because it requires fewer applications. *Id*. If applied at the right time in the pest cycle (when pests are first encountered), a single application of flubendiamide can provide season-long control. *Id.* ¶ 21. The fewer the applications of a pesticide that are required, the less active ingredient that is released into the environment. *Id.* ¶ 20. Pyrethroids, in contrast, only remain active for hours or days and therefore must often be reapplied. *Id.*

- **No Known Cross Resistance:** As Dr. Herbert explains, the repeated use of broad-spectrum pyrethroids over many years has resulted in Corn earworm populations developing resistance to those products. *Id.* ¶¶ 12-13. As a result, growers are experiencing control failures and in some cases, requiring retreatment of problem fields. *Id*. In contrast, because of flubendiamide's mode of action and its non-systemic activity,[21] no cross-resistance to flubendiamide has been observed in any lepidopteran pests to date. Exhibit 22 at 39. This attribute is one of the key reasons why entomologists and IPM specialists such as Dr. Herbert recommend flubendiamide's use and why it has become such an important tool for growers. Exhibit 4 ¶¶ 25-26.

- **Low Cost Compared to Other IPM–Recommended Compounds:** Growers[22] and grower organizations have identified flubendiamide's competitive pricing compared to IPM alternatives such as chlorantraniliprole as a key benefit. Growers' Brief at 42; Exhibit 1 ¶ 25. Cost control is a particularly important factor for growers of broad acre crops such as alfalfa, peanuts, and soybeans because of the low margins.[23]

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[19] *See also* Exhibit 22 at 244-45 (Correspondence from Jeremy K. Greene and Francis Reay-Jones).

[20] *See also* Exhibit 22 at 134-38 (2013 Almond Insecticide Research, Frank Zalom and Nicole Nicola, University of California at Davis).

[21] Exhibit 4 ¶¶ 15, 19.

[22] *See* Growers' Brief, Exhibit 24 ¶ 5 (Declaration of Chris Ward) ("Belt [] costs less than other options."); Growers' Brief, Exhibit 14 ¶¶ 3-4 (Declaration of Mike Sturdivant, III) ("I have no other tools in my arsenal that are as effective as Belt, especially from a cost standpoint. . . . Available alternatives are much more expensive than Belt.").

[23] *See* Growers' Brief, Exhibit 24 (Declaration of Chris Ward); Growers' Brief, Exhibit 8 (Declaration of Edward Greer).

Because of the above attributes, flubendiamide has become a critical tool for growers practicing IPM and IRM[24] – practices that EPA claims to encourage.[25] EPA has long recognized the importance of IPM in helping to:

- Reduce the number of pests.
- Reduce the number of pesticide applications.
- Save money while protecting human health.

Flubendiamide reduces lepidopteran pests, requires fewer applications than its pyrethroid and organophosphate competitors, is competitively priced, and is protective of human health.[26] With respect to resistance management, flubendiamide can be rotated (*i.e.*, alternated) with other pesticides with different modes of action to avoid resistance issues that can arise from the repeated use of a single mode of action. Exhibit 4 ¶¶ 11, 19. Its specificity and non-systemic activity make it a far lower resistance risk than chlorantraniliprole. *Id.* ¶ 19.[27] Resistance management is impossible unless growers have the ability to rotate the application of a sufficient number of pesticides with different MOAs. *Id.*[28]

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[24] As the IR-4 Project explained, in summary: "Flubendiaminde [sic] has been a priority for IR-4 because our stakeholders indicate that it is a very important IPM tool that act[s] specifically on lepidoptera (worms) pest, while not impacting beneficial insects such as predatory mites or other beneficial arthropods. As well, this product does not 'flare' mites as is often the case with other lepidoptera pesticides." Exhibit 26.

[25] *See* "Introduction to Integrated Pest Management", Environmental Protection Agency, https://www.epa.gov/managing-pests-schools/introduction-integrated-pest-management (last updated Apr. 28, 2015) (EPA describing IPM as "an environmentally friendly, common sense approach to controlling pests.").

[26] *See* Exhibit 4 ¶ 25; Exhibit 1 ¶ 25; Exhibit 22 at 235-36 (Correspondence from Hannah J. Burrack, Ph.D.).

[27] *See also* Exhibit 22 at 253-54 (Correspondence from Eric T. Natwick).

[28] *See also* Exhibit 22 at 242-43 (Correspondence from Don Parker, Ph.D).

EPA does not dispute that flubendiamide provides the above benefits. Rather the Agency acknowledges that flubendiamide poses no risk of concern to humans (either through diet or worker exposure), fish, mammals, crustaceans, mollusks, beneficial insects, and plants. *See, e.g.*, Exhibit 9 at 2-8 (EPA Flubendiamide Pesticide Fact Sheet (Aug. 1, 2008)). The Agency acknowledges that because flubendiamide is selective, it has minimal impact on beneficial insects, including predatory species. Exhibit 23 at 4 (BEAD Review of Bayer CropScience Flubendiamide Benefits Document (July 24, 2015)). The Agency acknowledges that flubendiamide's selectivity encourages natural or biological pest control, and makes flubendiamide an important tool for modern IPM approaches. *Id.* EPA acknowledges that flubendiamide's "translaminar characteristic is unique . . . and makes it very suitable for IRM [Insect Resistance Management] and IPM strategies in many crops." *Id.* Therefore, even among the limited subset of pesticides available to growers using IPM to control lepidopteran pests (such as chlorantraniliprole), flubendiamide presents distinct advantages for resistance-avoidance. Exhibit 4 ¶¶ 19, 26.

At a time when both EPA and USDA are expressing increasing concern over the potential effects of certain pesticides on pollinators,[29] EPA acknowledges that flubendiamide is one of the rare insecticides that has been shown to have little to no toxicity to pollinators. Exhibit 21 at 5.[30] Flubendiamide's most likely replacements, pyrethroids and organophosphates, are, in contrast, toxic to pollinators and have restrictions on their use as a result. Exhibit 4 ¶ 23. EPA further

[29] *See, e.g.*, EPA, EPA Takes Strong Steps to Better Protect Bees from Pesticides (May 28, 2015), https://www.epa.gov/pesticides/epa-takes-strong-steps-better-protect-bees-pesticides; Exhibit 41 ("Preventing or Mitigating Potential Negative Impacts of Pesticides on Pollinators Using Integrated Pest Management and Other Conservation Practices," United States Department of Agriculture (Feb. 2014)).

[30] *See also*, Exhibit 27 at 63 (PDF p. 68) ("Significant side effects to bumble bees and honey bees are not expected following application of both formulations to the proposed crops.").

agrees that the remaining IPM alternatives are more costly than flubendiamide,[31] and that for many crops, growers deprived of the use of flubendiamide will turn to less costly organophosphates and pyrethroids. Exhibit 23 at 2. EPA agrees that cancellation of flubendiamide would "reduce[] the ability to manage" insecticide resistance and that likely alternatives including pyrethroids "do not fit well with most IPM practices." *Id.* at 8. In summary, flubendiamide's many benefits are generally not in dispute; what is in dispute is the legal significance of those benefits.

II. REGISTRATION UNDER FIFRA

All pesticide products sold or distributed in the United States must be registered with EPA under FIFRA § 3(a), 7 U.S.C. § 136a(a). "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) (citing FIFRA §§ 3(a), (c)-(e), 7 U.S.C. §§ 136a(a), (c)-(e)).

Registrations are difficult and costly to obtain and valuable assets to hold. Exhibit 1 ¶ 9; Exhibit 3 ¶ 5. Courts have recognized that registrants hold property rights in their registrations. *See, e.g., Reckitt Benckiser*, 613 F.3d at 1133 ("A FIFRA registration is a product-specific license."); *Ctr. for Biological Diversity v. EPA*, No. 11-CV-00293-JCS, 2013 WL 1729573, at *6 (N.D. Cal. Apr. 22, 2013) ("The applicants are owners of the pesticide registrations, and thus have property and financial interests in the registrations.").

A. Registration Process

FIFRA § 3 provides that EPA "shall register" a pesticide if EPA determines, among other things, that the product "will perform its intended function without unreasonable adverse effects

[31] Exhibit 23 at 6.

on the environment" and "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." FIFRA § 3(c)(5)(C)-(D), 7 U.S.C. § 136a(c)(5)(C)-(D). "Unreasonable adverse effects on the environment" are defined as "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." FIFRA § 2(bb), 7 U.S.C. §136(bb).

Congress thus established a risk-benefit standard (the "Registration Standard"), requiring EPA to weigh the potential health and environmental risks of a pesticide against its economic, social and environmental benefits. *See, e.g., Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005) (citing *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 532 (9th Cir. 2001)).

The permissible uses of a pesticide product are described in detailed labels that are reviewed and approved by EPA as part of the registration. FIFRA § 3(c)(1)(C), 7 U.S.C. § 136a(c)(1)(C). It is unlawful to distribute or sell a pesticide product that is not registered with EPA, or to use a registered product in a manner inconsistent with its labeling. FIFRA §§ 12(a)(1)(A), (a)(2)(G), 7 U.S.C. §§ 136j(a)(1)(A), (a)(2)(G).

Registrants must generate and submit to EPA a broad range of substantial health and safety data regarding the properties and potential effects of a pesticide, which informs EPA's assessment of whether the pesticide meets or continues to meet the Registration Standard. FIFRA § 3(c)(1)(F), 7 U.S.C. § 136a(c)(1)(F) (data required to support an application for registration); 40 C.F.R. Part 158 ("Data Requirements for Pesticides"). EPA has developed standard guidelines for the conduct of required studies and frequently requires additional data to address product-specific or newly arising issues. 40 C.F.R. Part 158; Exhibit 2 ¶ 18 (Declaration

of Charlotte Sanson). EPA works with registrants to review and approve any departure from standard guideline protocols and to develop, review, and approve protocols as needed for additional studies. *See, e.g.*, Exhibit 2 ¶ 13. The data package required to support a new pesticide takes years to develop at costs that can reach $100 million or more. Exhibit 1 ¶ 9; Exhibit 3 ¶ 5.

The obligation to submit data continues beyond registration. FIFRA §§ 3(c)(2)(B) ("Additional data"), 3(g) ("Registration review"), 7 U.S.C. §§ 136a(c)(2)(B), 136a(g).

B. Conditional Registrations

FIFRA Section 3(c)(7) allows EPA to issue "conditional registrations" under three circumstances. EPA may grant conditional registrations: (1) if "the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof" with the condition that the applicant must submit all pending required data for its registration no later than the time required for similar products; (2) to conditionally amend a registration to allow additional uses even if required data are pending, with the condition that the applicant must submit all pending required data for its registration no later than the time required for similar products; and (3) for "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 [EPA] first imposed the data requirement)." FIFRA § 3(c)(7)(A)-(C), 7 U.S.C. § 136a(c)(7)(A)-(C).

EPA may issue conditional registrations for pesticides containing an active ingredient not contained in any currently registered pesticide under Section 3(c)(7)(C) only if it makes an affirmative finding that "use of the pesticide is in the public interest" and the product "will not

cause any unreasonable adverse effect on the environment" during the time period set for generation and submission of the data. FIFRA § 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C).

C. Cancellation and Suspension of Registrations

Under FIFRA, Congress provided specific procedures that must be followed if EPA wishes to cancel or suspend an existing pesticide registration. FIFRA § 6 "establishes a detailed, multi-step process that EPA must follow when it wants to cancel or suspend a registration." *Reckitt Benckiser, Inc. v. Jackson,* 762 F. Supp. 2d 34, 42 (D.D.C. 2011) (emphasis in original).

These cancellation and suspension provisions not only ensure that registrants receive due process but also that cancellation and suspension decisions are based on consideration of both the risks and the benefits of the registration under the Registration Standard, are subject to scientific and interagency review and input and, if requested, can be tested and challenged through a *de novo* administrative hearing. The procedures and requirements for cancellation of an existing FIFRA registration are set forth in FIFRA § 6, 7 U.S.C. § 136d, and EPA's implementing regulations at 40 C.F.R. Part 164.

Many stakeholders have an interest in cancellation proceedings and the continued availability of safe, effective, and beneficial pesticide products, including the registrants, the United States Department of Agriculture, the United States Department of Health and Human Services, the National Institutes of Health, the National Science Foundation, growers, agricultural workers, food processors, distributors, retailers, and the general public. *See, e.g.*, FIFRA §§ 6(b)-(f), 25(d), 7 U.S.C. §§ 136d(b)-(f), 136w(d).

1. Cancellation Procedures Under FIFRA § 6(b)

FIFRA's cancellation provisions include a standard cancellation process under FIFRA § 6(b), and a streamlined process for cancellations that are based on the failure to meet conditions of registration under FIFRA § 6(e).

FIFRA § 6(b) applies when cancellation is based on a determination by EPA that an existing registration no longer meets the Registration Standard. "If it appears to the Administrator that a pesticide . . . does not comply with the provisions of [FIFRA] or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either—(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or (2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed." FIFRA § 6(b).

The cancellation process established by Congress under FIFRA § 6(b) is well-defined and thorough:

- In deciding whether to issue a notice of intent to cancel, EPA must consider "the impact [of cancellation] on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." FIFRA § 6(b).

- At least 60 days before providing the notice to the registrant and the public, EPA must provide the notice of intent to cancel and its analysis for review by the Secretary of Agriculture and, if comments are received from the Secretary, publish them and EPA's response in the Federal Register. *See* FIFRA § 6(b). This ensures that EPA's determination is informed by the USDA's views on and consideration of the role and benefits of the affected pesticides, and that USDA has early notice of any possible cancellation determination by EPA.

- Under FIFRA § 25(d), EPA must also provide the notice of intent to cancel to the Scientific Advisory Panel ("SAP"), a multi-disciplinary panel of experts nominated by the National Institutes of Health and the National Science Foundation. The SAP's comments and EPA's response are published in the Federal Register. FIFRA § 25(d). This ensures that the scientific findings underlying any cancellation decision are sound and are subject to open, transparent, and independent scientific review before any administrative hearing that may be requested.

- Under FIFRA § 6(b), if the proposed cancellation would affect a public health use, EPA must provide similar notice and an opportunity to comment to the Secretary of Health and Human Services ("HHS"). FIFRA § 6(b). This ensures that any cancellation decision is informed by HHS's consideration of and

comment on any public health impacts, and that HHS has early notice of any pending cancellation determination by EPA.

- After these independent reviews and comments, if EPA issues a notice of intent to cancel, registrants and any other adversely affected parties have 30 days to request a public administrative hearing. Such hearings involve a full, *de novo* evidentiary hearing before an ALJ on the merits of the proposed cancellation action, with subpoena power to compel testimony and the production of documents. FIFRA §§ 6(b), (d), 7 U.S.C. §§ 136d(b), (d); 40 C.F.R. Part 164.

- Any party to the proceeding may request that "relevant questions of scientific fact" be referred to a Committee of the National Academy of Sciences, which will issue a public report that "shall be considered as part of the hearing record." FIFRA § 6(d).

- Decisions of the ALJ may be appealed to the Environmental Appeals Board. 40 C.F.R. §§ 164.100-111.

- Under FIFRA § 16(b), after completion of the hearing and any appeal, EPA may issue its final cancellation order which in turn is subject to judicial review by the federal Court of Appeals. FIFRA § 16(b), 7 U.S.C. § 136n(b).

2. Cancellation Procedures Under FIFRA § 6(e)

FIFRA § 6(e) provides a much more limited process that applies in carefully limited circumstances to FIFRA § 3(c)(7) conditional registrations. FIFRA § 6(e). It allows EPA to issue a notice of intent to cancel a registration under that section only: (1) if EPA determines "at any time during the period provided for satisfaction of any condition imposed" that "the registrant has failed to initiate and pursue appropriate action toward fulfilling" the condition; or (2) if EPA determines "at the end of the period provided for satisfaction of any condition imposed, that condition has not been met." FIFRA § 6(e)(1), 7 U.S.C. § 136d(e)(1).

A FIFRA § 6(e) cancellation notice becomes final unless the registrant or other adversely affected party requests a hearing within 30 days. FIFRA § 6(e)(2), 7 U.S.C. § 136d(e)(2).

Any such hearing is conducted as a public hearing under the process described in FIFRA § 6(d), except that the matters for consideration at the hearing are whether the registrant initiated and pursued the actions required to comply with the conditions or whether the conditions were

satisfied within the specified time period, and whether the proposed existing stocks determination is consistent with FIFRA. A § 6(e) hearing must be held and the final determination made within 75 days of the request for the hearing. FIFRA § 6(e)(2).

To the registrants' knowledge, there has never been a hearing conducted under FIFRA § 6(e).

FIFRA § 6(e) does not apply where EPA determines that a registration does not meet the Registration Standard. In such cases, EPA must proceed with full cancellation proceedings under FIFRA §§ 6(b) & (d).

3. Suspension of Registrations Under FIFRA § 6(c)

If EPA determines immediate action "is necessary to prevent an *imminent hazard*," EPA may issue an order to "suspend the registration of the pesticide immediately." FIFRA § 6(c)(1), 7 U.S.C. § 136d(c)(1) (emphasis added).

EPA must provide the registrant a notice of intent to cancel including the "imminent hazard" finding and the registrant can request an expedited hearing before suspension "on the question of whether an imminent hazard exists." FIFRA § 6(c)(1)-(3), 7 U.S.C. § 136d(c)(1)-(3).

EPA can proceed without an "imminent hazard" hearing only under emergency conditions, in which case a notice of intent to cancel, initiating full cancellation proceedings, must be issued within 90 days. FIFRA § 6(c)(3), 7 U.S.C. § 136d(c)(3).

D. Existing Stocks Under FIFRA § 6(a)(1)

If EPA cancels or suspends a registration, EPA may allow "the continued sale and use of existing stocks of a pesticide." FIFRA § 6(a)(1), 7 U.S.C. § 136d(a)(1). EPA's general policy is to allow for existing stocks to be sold and used if "the benefits associated with such sale, distribution, or use exceed the risks." Exhibit 52 (Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29,362, 29,362 (June 26, 1991)).

Distribution or sale of existing stocks of cancelled or suspended pesticides is unlawful unless expressly authorized in an existing stocks order. *Id.* at 29,363. The use of existing stocks is permitted, unless "specifically prohibited" by EPA in the cancellation or suspension order. *Id.* In determining whether to allow the distribution, sale, or use of existing stocks, "EPA must apply the same risk-benefit considerations that are applicable to other Agency actions under FIFRA." *Id.* In situations "where the Agency has identified particular risk concerns," the existing stocks determination will be based on consideration of the quantity of existing stocks, the risks and benefits from use of such stocks, including the existence of alternatives and cost and efficacy of such alternatives, the amount invested in existing stocks, risks and costs of disposal or alternate disposition, and the practicality of implementing restrictions. *Id.* at 29,364.

III. REGULATORY HISTORY

A. Conditional Registration of Flubendiamide

EPA registered flubendiamide in 2008 under FIFRA § 3(c)(7)(C) (conditional registration of a new active ingredient), applying FIFRA's risk-benefit Registration Standard. Exhibit 2 ¶ 8. EPA's conditional registration included requirements to generate additional data, as set forth in EPA's July 31, 2008 preliminary acceptance letter. *Id.* ¶ 9.

At the time of the first approval in 2008, EPA made an affirmative finding, as required under FIFRA, that registration of flubendiamide was in the public interest. Exhibit 21; Exhibit 2 ¶ 10. It granted FIFRA registration for five years to allow the registrants to generate and submit additional data to address potential persistence, consistent with FIFRA § 3(c)(7)(C). Exhibit 21; Exhibit 8 (July 31, 2008 Preliminary Acceptance Letter); Exhibit 7 (Aug. 1, 2008 Notices of Registration referring to July 31, 2008 letter).

At the same time, EPA established "permanent tolerances" (the limit of residues allowed on food or food crops) for flubendiamide under the Federal Food, Drug, and Cosmetic Act (21

U.S.C. §§ 301-399) ("FFDCA"). Exhibit 2 ¶ 11. Over the years, numerous additional permanent tolerances have been established through rulemakings under the FFDCA as new crops have been registered and added to the flubendiamide labels. *Id.* The tolerance-setting process is primarily focused on human health impacts through the diet. *Id.* Given flubendiamide's very favorable human health profile, EPA has not proposed any changes to flubendiamide's tolerances, and none is warranted. *Id.* However, EPA must take flubendiamide's very favorable human health profile into account in evaluating whether flubendiamide meets FIFRA's risk-benefit standard for registration. *Id.*

The only potential risk of concern identified by EPA was that flubendiamide and its degradate des-iodo may persist and accumulate over time in farm ponds surrounded by treated fields, potentially to a level that may impact freshwater benthic (bottom-dwelling) invertebrates. Exhibit 9 at 8-9. EPA issued the flubendiamide registrations while requiring the registrants to develop data to better understand this potential. *Id.* at 10.

EPA's July 31, 2008 letter included a schedule for the registrants to submit proposed protocols for the required data, so that EPA could review the study designs and plans and request modifications as appropriate. Exhibit 8 at 1; *see also* Exhibit 2 ¶ 13. EPA also committed to review the data generated and submitted by the registrants, and to engage in discussion with the registrants about the data and EPA's conclusions. Exhibit 8 at 3. The letter outlined three potential outcomes, including: (1) unconditional registration; (2) EPA and the registrants agreeing on a path forward, revising or providing additional data under a conditional registration; or (3) EPA accepting voluntary cancellation of the flubendiamide registrations. *Id.*

EPA stated in the July 31, 2008 letter: "No cancellation shall occur if EPA determines, after review of the data, that the flubendiamide technical product registration could meet the

standards for registration set forth in section 3(c)(5) of FIFRA" and Bayer and Nichino agree "to comply with any conditions (including, but not limited to, revised label language, use deletions or conditions of registration) that EPA finds necessary in order to make the registration determination." Exhibit 8 at 3.

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 request "voluntary" cancellation of the registrations. *Id.* at 1, 3. EPA threatened that, absent this provision, it would not grant the registrations. *Id.* In doing so, EPA claimed the right to require registrants to forgo statutorily guaranteed rights and accept upfront and sight unseen whatever determination EPA might make in the future, no matter its basis. *Id.* EPA threatened to deny issuance of registrations EPA had already determined were in the public interest absent this purported "condition[] of registration." *Id.* at 4; Exhibit 2 ¶ 15.

B. Data Submission, Evaluation, and Registration Extensions

Consistent with the July 31, 2008 letter, the registrants generated the required data. Exhibit 2 ¶ 16. EPA and Bayer communicated about study protocols, study conduct, study reports, and interpretation of the study results. *Id.* Over time EPA approved expansion of flubendiamide's registrations to over 200 crops. *Id.* EPA repeatedly extended the registrations beyond the original September 1, 2013 "expiration" date, up until the issuance of its January 29, 2016 Decision Memorandum and demand for voluntary cancellation. *Id.* ¶ 17.

EPA commonly uses its authority to request additional data to refine its risk assessments and to identify risk mitigation consistent with FIFRA. *Id.* ¶ 18. EPA often communicates with registrants to evaluate potential mitigation options and implement them. *Id.* In light of flubendiamide's favorable human health and non-target organism safety profile and its value to

agriculture, and the substantial amount of scientific data supporting its registration, it is consistent with EPA's fulfillment of its responsibilities under FIFRA that right up until the end of 2015 EPA repeatedly expressed its intention to adopt further risk mitigation measures and extend the registrations to allow the generation of additional data. *Id.*

During its ongoing review and discussion of the submitted data and continued monitoring, EPA repeatedly confirmed that the registrants have satisfied the conditional registration requirements and agreed to extend the registrations. *Id.* ¶ 19. In a July 18, 2013 letter extending the registrations to August 31, 2015, EPA confirmed that "[a]s of July 31, 2012, [the registrants] . . . ha[ve] submitted all data required by the original conditions of registration for flubendiamide." Exhibit 10. On August 26, 2015, EPA extended the registrations to December 10, 2015 to "provide time for [the registrants] and the EPA to discuss whether potential additional data requirements and label amendments are necessary to address areas of uncertainty," and again confirmed that "[a]s of July 31, 2012, [the registrants] ha[ve] submitted all data required by the original conditions of registration for flubendiamide." Exhibit 12.

In discussions with the registrants in July and August 2015, 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. Exhibit 11 (Aug. 4, 2015 email from C. Rodia to N. Delaney). EPA provided a specific list of proposed additional studies, including an expanded stream and pond monitoring program and toxicity studies on additional aquatic species. *Id.* EPA proposed a three-year extension of the registrations to allow the data to be generated and reviewed. *Id.* EPA and the registrants reached an agreement regarding what studies would be performed and work

was underway to develop and deliver for EPA's review protocols and scoping documents for the studies. Exhibit 2 ¶ 20.

EPA and the registrants continued to have discussions into December 2015. *Id.* ¶ 21. Bayer agreed to eliminate certain uses and to work with EPA to refine limitations on use rates and applications for remaining uses to reduce exposure while meeting commercial needs. *Id.* Bayer also agreed to conduct additional studies, including the additional ecotoxicity studies and the expansion and continuation of the monitoring program, which was anticipated to cost millions of dollars. *Id.* EPA indicated that it planned to extend the registrations for three years while the registrants generated the additional data. *Id.*

On December 1, 2015, Bayer and Nichino met with EPA to discuss the path forward and to reiterate the registrants' commitment to generate the additional scientific data EPA had identified. *Id.* ¶ 22. The registrants also provided a comparative assessment with a competitive pesticide, methoxyfenozide, that has nearly the same persistence and risk profile to benthic aquatic invertebrates as flubendiamide. *Id.* ¶ 23. EPA required similar water monitoring studies for that compound, resulting in levels of detection that, like flubendiamide, were below levels of concern at all of the monitoring sites tested. *Id.*

For methoxyfenozide, EPA chose to rely on the actual monitoring data showing no levels of concern rather than Agency modeling which predicted much higher exposures that exceeded levels of concern. Exhibit 49 at 21 (Preliminary Environmental Fate and Ecological Risk Assessment for Methoxyfenozide (Sept. 16, 2015)). EPA's risk assessment for methoxyfenozide explained that the modeling results "likely overestimate concentrations in streams and various other kinds of water bodies" for a number of reasons, including "washout, dispersion, burial of sediment and other dissipative processes that aren't simulated." *Id.* EPA also determined that

methoxyfenozide concentrations in flowing water bodies are not expected "to accumulate at such a high concentration[] from year to year because of downstream advective removal." *Id.*

For methoxyfenozide, EPA properly focused on the higher-tier, actual monitoring data rather than its overly conservative modeling, and has not taken steps to cancel the methoxyfenozide registrations. *Id.*; Exhibit 2 ¶ 25. EPA appears to have singled out flubendiamide for different, extreme treatment that is not consistent with FIFRA nor is it fair in light of how EPA is approaching its overall risk-benefit regulation of pesticides. *Id.*

Up until early December 2015, EPA was consistent in discussing with the registrants EPA's plan to extend the flubendiamide registrations for three years until 2018 and to require additional data. *Id.* ¶ 26. EPA and the registrants also discussed potential mitigation. *Id.* The registrants proposed mitigation through changes to the product label and conducted calculations to confirm that the mitigated label would pass EPA's risk assessment, even using a methodology the registrants believe to be more conservative than required. *Id.*

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." Exhibit 13. At a high-level meeting on December 15 involving the Assistant Administrator of EPA responsible for all pesticides and the CEOs of both Bayer and Nichino, the Assistant Administrator described his view of flubendiamide, repeatedly using precautionary language and contending that flubendiamide should be cancelled based on its persistence alone, even though no harm had been identified, to eliminate any possibility of future harm. Exhibit 2 ¶ 27. This is contrary to the risk-benefit approach required by FIFRA. *Id.* The Assistant Administrator contended that, absent any action by EPA beforehand, the registrations would

expire on December 18, 2015 and indicated that EPA would consider whether to take action and would inform the registrants of its decision by the end of the day on December 18, 2015. *Id.*

The registrants raised the practical difficulties of that timing and requested that EPA extend the December 18, 2015 date to help ensure an orderly process and that EPA advise the registrants promptly when a decision had been made. *Id.* ¶ 28. EPA committed to respond on the extension and suggested that the registrants submit the best, final mitigation proposal they could develop, as promptly as possible, in light of an internal briefing of the EPA Assistant Administrator the following day. *Id.* The registrants quickly convened their experts and prepared and submitted a further mitigation proposal later the same day. *Id.*

C. Change in EPA's Toxicity Endpoint

Up to this point, the open scientific question concerned whether the modeling and monitoring data suggested that flubendiamide or the des-iodo metabolite might accumulate to a level of concern based on the toxicity data. *Id.* ¶ 29. These data include a 2010 spiked sediment study Bayer conducted specifically to focus on the area of EPA's concern: the level of toxicity to benthic aquatic invertebrates in pore water and sediment. *Id.* As EPA confirmed in its May 21, 2008 review of a spiked water study submitted in 2004, the Agency prefers the spiked sediment methodology for this purpose. Exhibit 33 at 2.

In a spiked sediment study, the test compound is introduced into the sediment and the system is allowed to equilibrate. Exhibit 2 ¶ 30. In a spiked water study, the chemical is introduced directly into the overlying water. *Id.* For the reasons discussed below, a spiked sediment study is a higher-tier, more relevant study for assessing potential toxicity from accumulation of runoff residues in sediment pore water.

On December 16, 2015, EPA's Environmental Fate and Effects Division ("EFED") briefed the EPA Assistant Administrator as planned. *Id* ¶ 31. In a new development, after years

of discussion, the high level meeting the day before, and visibility of the registrants' submission of a "final" mitigation plan that passed even EFED's conservative, theoretical modeling approach, 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 evaluations, and mitigation plans of the preceding months. *Id.* It based the briefing on a different endpoint that appeared to be designed to ensure, after the fact, that the registrants' "final" mitigation proposal would not be sufficient. *Id.*

The spiked sediment study specifically conducted to assess the potential toxicity of des-iodo to benthic aquatic invertebrates in pore water in sediment showed no observable adverse effects at any of the levels tested, supporting a level of concern for des-iodo of 19.5 parts per billion ("ppb") (as calculated by EPA using a time-weighted average approach) or 22 ppb (as calculated in the report based on measured concentrations). *Id.* ¶ 32; Exhibit 5 ¶¶ 35-36 (Declaration of Dwayne Moore, Ph.D.). Although this is the most appropriate study to measure potential toxicity from the relevant route of exposure, EPA chose at the eleventh hour to ignore this study and revert to an endpoint derived from the less appropriate, earlier-conducted spiked water study, leading to a toxicity endpoint of 0.28 ppb, 70 times lower than the more environmentally relevant data conducted using EPA's preferred methodology support. Exhibit 2 ¶ 32; Exhibit 5 ¶ 9, 38-43, 54-55, 60. This reversion ensured that EPA could continue to "predict" exceedances of levels of concern even after making overdue and necessary corrections to its theoretical modeling. *Id.*

D. EPA's Cancellation Determination and Notice of Intent to Cancel

This dramatic change in the ground rules for an apparently preordained result was shocking to the registrants. *Id.* ¶ 33. Bayer wrote to the Assistant Administrator on December

16 to seek to confirm whether he was aware of this sudden change in approach and lack of transparency, and to request the underlying science. Exhibit 14.

On December 18, 2015, EPA provided a letter "extending the expiration date of December 18, 2015 to January 15, 2016." Exhibit 15. EPA also scheduled a meeting with the registrants for January 6, 2016 at which EPA EFED would present its evaluations. Exhibit 2 ¶ 34.

The registrants reviewed the information provided by EPA over the holidays and also submitted two formal reports on environmental fate and ecotoxicology data whose conclusions had previously been previewed with EPA. *Id.* ¶ 35. In particular, one of the studies showed that des-iodo, the flubendiamide metabolite whose potential toxicity forms the basis for EPA's proposed cancellation, degrades when exposed to sunlight. *Id.* This is helpful to understanding the degree to which it may persist in the environment. Exhibit 6 ¶ 22 (Declaration of Bernard Engel, PhD.). Bayer submitted both study reports to EPA on January 5, 2016. Exhibit 2 ¶ 35.

At the January 6 meeting, EPA presented its scientific position, relying on the lower toxicity endpoint and theoretical modeling to support its position that flubendiamide is accumulating or will accumulate in vulnerable water bodies above a level of concern. *Id.* ¶ 36 EPA acknowledged that things were "very dynamic" and the timing of its change was "unfortunate." *Id.* It sought to explain what activities had taken place within the Agency at the end of the year that had not been visible to the registrants. *Id.*

The registrants asked EPA to confirm, if EPA decided the flubendiamide registrations should not continue beyond the January 15, 2016 date, whether the Agency: (1) would pursue "automatic" expiration without further action; (2) would seek to implement the unlawful forced "voluntary" cancellation condition; or (3) would issue a proper notice of intent to cancel and

follow the cancellation proceedings required by FIFRA § 6(b). *Id.* ¶ 37. EPA ultimately confirmed that it would demand "voluntary" cancellation and seek cancellation under FIFRA § 6(e) if Bayer and Nichino refused to request "voluntary" cancellation. *Id.* On January 14, 2016, EPA again extended the conditional registration for flubendiamide, this time to January 29, 2016. Exhibit 16; Exhibit 2 ¶ 37.

On January 29, 2016, EPA issued a letter, formally notifying Bayer and Nichino that it determined flubendiamide poses unreasonable adverse effects to the environment and requesting that Bayer and Nichino "voluntarily" cancel their registrations for flubendiamide within one week of the letter. Exhibit 17. EPA further stated that the failure to submit the requested voluntary cancellation would cause EPA to initiate a cancellation proceeding consistent with FIFRA § 6(e). *Id.* at 2.

On February 5, 2016, Bayer and Nichino responded to EPA's request. Exhibit 18. The response stated: (1) that the "voluntary" cancellation condition was an unlawful condition of registration; (2) that if EPA determined flubendiamide poses unreasonable adverse effects to the environment, the proper procedure is to issue a Notice of Intent to Cancel pursuant to FIFRA § 6(b); and (3) that the available evidence shows that flubendiamide does not pose unreasonable adverse effects to the environment. *Id.* at 1-2.

On March 1, 2016, EPA provided its Notice of Intent to Cancel the flubendiamide registrations to Bayer and Nichino. Exhibit 20. The NOIC was dated February 29, 2016, and was published in the Federal Register on March 4, 2016. *Id.*

Also on March 1, 2016, EPA issued press releases and posted information on its website announcing that EPA was seeking cancellation because flubendiamide products "pose a risk to aquatic invertebrates that are important to the health of aquatic environments." Exhibit 19. EPA

asserted that "[r]equired studies showed flubendiamide breaks down into a more highly toxic material that is harmful to species that are [an] important part of aquatic food chains, especially for fish, and is persistent in the environment." *Id.* EPA "concluded that continued use of the product would result in unreasonable adverse effects on the environment." *Id.* EPA posted the NOIC and 11 other documents totaling 504 pages regarding the merits of its cancellation decision. [32]

Despite posting this decision and the supporting documents for public review, EPA studiously avoided any discussion in the NOIC of the basis and justification for its substantive cancellation determination. Instead, the NOIC asserts that its cancellation determination is a foregone and unchallengeable decision that is beyond review by the SAP, the USDA, or the ALJ, and that Bayer, Nichino, and other affected parties have no right to a hearing on the merits of EPA's decision. Exhibit 20 at 11,560.

E. EPA's Cancellation Determination Is Contrary to the Science and the FIFRA Registration Standard.

EPA has failed to satisfy statutory prerequisites to the issuance of the NOIC, including providing its cancellation determination for review by the SAP and USDA. FIFRA §§ 6(b) & 25(d). By seeking cancellation through the FIFRA § 6(e) process and contending that the merits of the cancellation decision are beyond the scope of this hearing, EPA seeks to deny Bayer and Nichino the right to address the merits of EPA's cancellation determination in the context of a full and proper hearing under FIFRA § 6(b) & (d). Moreover, the 75-day time limit of the FIFRA § 6(e) process EPA has invoked makes a proper hearing on the scientific and regulatory merits of its cancellation decision impossible.

[32] Flubendiamide – Notice of Intent to Cancel and Other Supporting Documents, https://www.epa.gov/ingredients-used-pesticide-products/flubendiamide-notice-intent-cancel-and-other-supporting (last updated Mar. 4, 2016).

Nonetheless, if this Motion is denied and the matter proceeds to a § 6(e) hearing, Bayer and Nichino intend to present evidence and witnesses, to the degree possible within the severe time constraints of the expedited process, challenging the scientific and regulatory merits of EPA's proposed cancellation. Such evidence is relevant to establishing that EPA's existing stocks proposal is inconsistent with FIFRA and EPA's own existing stocks policy. For the purposes of this Motion, it also is relevant to showing that EPA's decision is not sound and why substantive review is important, to demonstrate the harm caused by EPA's unlawful "voluntary" cancellation provision to registrants and all affected stakeholders, and to develop the record for appeal should the ALJ determine – as it should not – that EPA's approach is lawful and the registrations must be cancelled.

1. EPA's Lower Aquatic Endpoint Ignores the Best Available Science.

Dr. Dwayne Moore, a biologist with over 25 years of experience working on ecological risk assessments, including 6 years at Environment Canada (the Canadian equivalent to EPA), has evaluated EPA's determinations with respect to the toxicity of flubendiamide and des-iodo, EPA's calculation and selection of toxicity endpoints to guide its cancellation determination, and the scientific support for EPA's toxicity determinations. Exhibit 5. Dr. Moore's opinions and the basis for them are described in detail in Dr. Moore's Declaration and are summarized below.

Based on his review, Dr. Moore concluded that EPA's use of the 0.28 ppb endpoint derived from the spiked water study to reach its cancellation determination, instead of the 19.5 ppb endpoint from the subsequent, more relevant spiked sediment study, is not scientifically justified. *Id.* ¶¶ 9, 38-47, 70. Dr. Moore identified other flaws in the spiked water study, including a flawed statistical analysis and the incorrect combining of controls that, if corrected, would lead to a higher endpoint. *Id.* ¶¶ 48-53. Dr. Moore concluded that EPA's risk assessments for flubendiamide and des-iodo are flawed, and provide no reliable scientific basis

to conclude that benthic invertebrates are at significant risk from the continued registration and use of flubendiamide products. *Id.* ¶ 9, 25, 70.

The risk assessment issued by EPA in 2008 in connection with the first flubendiamide registrations considered the potential impact of flubendiamide and its degradate des-iodo on benthic aquatic invertebrates and identified as the most sensitive ecotoxicological endpoint a No Observed Effect Concentration ("NOEC") of 0.28 ppb of des-iodo in pore water in the sediment. Exhibit 27 at 4 (PDF p. 9). This endpoint was derived from a spiked water study, in which concentrations of des-iodo were introduced into the water column above a thin layer of pond sediment, and the effects of flubendiamide or des-iodo on a representative benthic aquatic invertebrate species were measured. Exhibit 5 ¶¶ 28, 33, 46. This type of study is designed to address deposition of flubendiamide or des-iodo directly into the water, for example, through spray drift that can occur as the product is applied. *Id.* ¶ 29. As explained in Dr. Moore's Declaration, this route of exposure is not significant for flubendiamide or des-iodo. *Id.* ¶ 9, 38-43.

In its May 21, 2008 review of the spiked water study, EPA identified the spiked water methodology as a "major guideline deviation," noting that the "[o]verlying water was spiked," and that EPA "prefer[s] that the sediment is spiked." Exhibit 33 at 2. EPA's 2008 risk assessment noted that the flubendiamide and des-iodo spiked water studies did not "follow[] sediment toxicity guidelines which require the sediment to be spiked as opposed to the overlying water." Exhibit 27 at unnumbered p. 3. However, EPA found that the studies provided "sufficient information to reach a risk conclusion for benthic invertebrates" for the 2008 risk assessment. *Id.*

Pursuant to EPA's indicated preference, EPA and OECD guidance, and well-accepted toxicological practice, levels of concern for the potential toxicity of residues in pore water in sediment are most appropriately measured using a spiked sediment study, in which flubendiamide or des-iodo is introduced into the sediment and allowed to equilibrate and partition between the sediment and pore water. Exhibit 2 ¶¶ 29-30, Exhibit 5 ¶¶ 38-40. As described by Dr. Moore in his declaration, this test system better represents the manner in which benthic aquatic invertebrates will be exposed to des-iodo in the environment–through agricultural runoff that carries flubendiamide into a farm pond or other water body where it will degrade over time in the sediment into des-iodo. *Id.* ¶¶ 41-42. Thus, the spiked sediment study provides higher-tier results with regard to the route of exposure to the benthic organisms. *Id.* ¶ 43.

Bayer submitted to EPA in August 2010 precisely such a study. *Id.* ¶¶ 28, 54. This study tested des-iodo at concentrations higher than the spiked water study and it showed *no observable adverse effects* at any of the concentrations tested, including the maximum level of 22 ppb. *Id.* ¶ 35. Thus, it establishes for regulatory purposes a NOEC of 22 ppb, although the actual level at which adverse effects could occur may be even more favorable. *Id.* EPA issued its formal review of this study in July 2011, which confirmed the findings. Exhibit 34. Due to methodological differences and the use of time-weighted average rather than measured concentrations, EPA set the NOEC slightly lower, at 19.5 ppb. *Id.* at 2; Exhibit 5 ¶ 36.

All subsequent analyses and discussions between the registrants and EPA – until December 2015 – were based on a foundation that the level of concern for des-iodo in sediment pore water was at the 19.5 or 22 ppb level, based on the higher-tier spiked sediment study. Exhibit 2 ¶ 31-32. For example, in a February 2015 review of the ongoing monitoring data,

EFED noted that "[s]ome of these registrant-calculated endpoints *differ slightly* from the Agency determined endpoints" and that the Agency "will use the registrant-calculated endpoints." Exhibit 35 at 17.

Nonetheless, at the eleventh hour and after requesting the registrants' final analysis and mitigation proposal, EPA suddenly and remarkably chose to revert to the pore water endpoint of 0.28 ppb from the superseded spiked water study, an endpoint that is 70 times lower than the current science based on the higher-tier spiked sediment study. Exhibit 2 ¶ 32. The timing suggests EPA made this change to offset the drop in predicted exposures that resulted from EPA implementing necessary refinements to its still overly conservative exposure modeling. *Id.*

The documents provided by EPA in support of the January 29, 2016 cancellation determination identify the 22, 19.5, and 0.28 ppb endpoints, and identify the 19.5 and 0.28 as among the "final suite of available effects endpoints." *See* Exhibit 31 at 9-10 (Flubendiamide Ecological Risk Assessment Addendum (Jan. 28, 2016)), Exhibit 30 at 5 (Decision Memorandum (Jan. 29, 2016)). Yet EPA provides no discussion, explanation, or justification for its sudden reversion to the superseded and unsound 0.28 ppb endpoint and its use of that endpoint to guide its cancellation determination. Exhibit 30.

The results of real-world monitoring conducted at EPA's request and direction, as discussed further below, show that after almost five years of monitoring and the analysis of more than 1,000 overlying and pore water samples, all measured concentrations are well below even the 0.28 ppb endpoint for des-iodo that EPA wrongly relies on. Exhibit 5 ¶ 68; Exhibit 6 ¶¶ 67-70. The highest measured concentration was 0.17 ppb, and only five pore water samples had concentrations of des-iodo at or above 0.10 ppb. Exhibit 5 ¶ 68. The 0.17 ppb maximum concentration is below EPA's incorrect 0.28 ppb endpoint, and 115 times lower than the proper

19.5 ppb des-iodo pore water endpoint based on the spiked sediment study. *Id.* In light of these results, measured against the correct endpoint, it is questionable whether further monitoring is necessary. *Id.* ¶ 69. The observed levels do not suggest any risks of concern that could provide a scientific basis to justify a cancellation determination. *Id.*

EPA did not provide its 0.28 ppb endpoint determination or any other scientific determination related to the potential environmental toxicity of flubendiamide for review by the SAP before issuing the NOIC.

2. EPA Relies on Theoretical Modeling Rather Than Actual Monitoring Data Showing No Accumulations of Concern.

Dr. Bernard Engel, Professor and Head of the Department of Agricultural & Biological Engineering at Purdue University, with over thirty years of experience working on issues related to hydrology, water quality monitoring and modeling, environmental decision support systems, and soil and water conservation, evaluated the monitoring studies and data and EPA's use of theoretical modeling to predict exposure to flubendiamide and des-iodo, and the merits of EPA's determination that exposures have exceeded or will exceed toxicity endpoints. Exhibit 6. Dr. Engel has served as a panel member on six SAPs conducted between 1999 and 2015 to address issues related to pesticide risk assessment, exposure, and modeling. Exhibit 50 at 2. Dr. Engel's opinions and the basis for them are described in detail in Dr. Engel's Declaration and are summarized below.

To address concerns regarding potential accumulation in farm ponds and other water bodies, EPA required the registrants to conduct multi-year water monitoring studies assessing the accumulation of flubendiamide and des-iodo in real-world conditions. Exhibit 2 ¶¶ 9, 12-13, 16; Exhibit 6 ¶ 17; Exhibit 8 at 1-2; Exhibit 9 at 10-11. These monitoring studies were conducted by the registrants at significant expense at the direction of EPA and using test locations and

protocols confirmed by the Agency before the testing was initiated. Exhibit 2 ¶ 16; Exhibit 6 ¶¶ 17-19. They have continued for almost five years and are ongoing even after the issuance of the NOIC as this monitoring is the best data source available for exposure evaluations. Exhibit 6 ¶¶ 19, 67, 71. In addition, at EPA's request, the United States Geological Survey ("USGS") generated and provided data on flubendiamide and des-iodo concentrations as part of its nationwide water monitoring that includes key agricultural areas where flubendiamide is used. *Id.* ¶ 36.

As discussed above and detailed in Dr. Engel's declaration, after five years of monitoring data and the analysis of more than 1,000 samples, all measured concentrations are well below even the incorrect 0.28 ppb des-iodo endpoint that EPA selected. Exhibit 6 ¶¶ 67-70. The monitoring data also provide insight into seasonal and annual trends of flubendiamide and des-iodo concentrations and show clear declines in flubendiamide and des-iodo levels after seasonal applications that EFED misses or ignores in contending that des-iodo will accumulate indefinitely in the environment. *Id.* ¶¶ 25-26.

After seven years of product use, and nearly four years of monitoring, the USGS data show that concentrations of flubendiamide and des-iodo are found infrequently and only at parts per trillion levels. *Id.* ¶ 36, 67. The results from the USGS data, like the registrant monitoring data, are well below "no effect" levels. *Id*. The maximum measured concentrations of flubendiamide (0.93 ppb) and des-iodo (0.07 ppb) in the water column were 16 times and 27 times lower than EPA's stated levels of concern of 15.5 ppb for flubendiamide and 1.9 ppb for des-iodo. *Id.* ¶ 67.

As expected, the monitoring data show some variability in concentrations from year to year. *Id.* ¶¶ 24-25. As Dr. Engel explains, this can be caused, among other things, by product

application rates and timing of application, which can vary based on growing conditions and pest pressure, and the weather, which can affect the amount of runoff based on the timing of application and of rainfall events. *Id.* ¶¶ 26-29. For example, year-over-year increases in observed flubendiamide and des-iodo concentrations are associated with increased application rates in the later years. *Id.* ¶¶ 28-29. Increases in application rates are capped by the pesticide product labels and will not cause unbounded increases in concentrations.

Any observed increases in pore water flubendiamide and des-iodo concentrations in the monitoring data could also be caused by the sampling approach and the accumulation of sediment over time. *Id.* ¶¶ 24, 32-33. Pore water sediment concentrations are measured by sampling pore water from sediment down to a depth of 5 cm of sediment. *Id.* ¶ 32. As new sediment containing flubendiamide and des-iodo is deposited into the pond, the concentrations from the sediment samples can appear to increase until 5 cm of sediment have built up since application of flubendiamide began in the watershed. *Id.* This layering effect and the burying of older sediment means that concentrations of des-iodo and flubendiamide would not continue to increase indefinitely as EPA's models predict. *Id.* ¶ 33.

EPA's theoretical modeling, including updated modeling belatedly disclosed in documents supporting the January 29, 2016 Decision Memorandum, does not fit the existing field data and does not perform well under standard statistical tests. *Id.* ¶¶ 47-63. The real-world monitoring data, which are not depicted in any of the tables in EPA's Decision Memorandum (Exhibit 30) supporting the cancellation determination, show that accumulation, if any, is minimal and that EPA's modeling is inaccurate. *Id.* ¶¶ 9, 67-68 and Figures 1 & 2. The monitoring results and USGS data do not show the rapid accumulation towards exceedance of toxicity endpoints predicted by EPA's modeling. *Id.* ¶¶ 42, 68.

It is not surprising that EPA's theoretical modeling is not consistent with observed results. The potential for accumulation of flubendiamide and des-iodo is constrained by very specific climactic, hydrologic, and agronomic conditions. Exhibit 6 ¶¶ 12-16. In most agricultural settings where flubendiamide is used, farm ponds have sufficient flow-through of water that will prevent significant accumulation. *Id* ¶ 16. In the years leading up to its decision, EPA defended a modeling approach that assumed 30 years of runoff from maximum pesticide applications would accumulate in a farm pond, without any corresponding outflow. Exhibit 35 at 14-15. In other words, the model assumes that chemicals and sediments that enter the pond never leave. Exhibit 6 ¶ 16. In the real world, residues that enter a pond also may exit a pond through regular or periodic outflow and can be expected to disperse through hydrologic processes rather than accumulate. *Id.* This is consistent with the USGS data, in which flubendiamide and des-iodo, if detected, are present in minute quantities at concentrations in the parts per trillion, far below any levels of concern. *Id.* ¶ 36.

Recognizing its position was untenable, EPA finally modeled ponds with outflow, but did not disclose its updated modeling until the eve of its January 29, 2016 cancellation determination, and only after the Agency reverted to the 0.28 ppb endpoint apparently to ensure predicted exposures still exceeded levels of concern. Exhibit 31 at 4-5, 18-26. EPA never conducted a quantitative evaluation of the model performance using an appropriate statistical test. Exhibit 6 ¶¶ 47-50. As such, the predictive power of the model was never established within any measure of sound science. *Id.* ¶¶ 50-51. This should have been done before making any decision to cancel based on the modeling. *Id.* ¶ 50.

EPA's updated modeling remains overly conservative and is based on unrealistic assumptions that ignore actual agricultural conditions and practice, and thus significantly

overstates levels observed in the real world. Among other things, many of EPA's recent modeling assessments assume an initial seven years of flubendiamide use at maximum annual application rates, which is not consistent with actual use. Exhibit 31 at Appendix 1. The highest predicted accumulations occur in drier climates, such as California's Central Valley. Exhibit 6 ¶ 65. Theoretical modeling input and outflow in these climates can lead to theoretical accumulations of residues, particularly as the lack of precipitation and evaporation causes farm ponds to periodically dry up. *Id.* These theoretical accumulations ignore the fact that few, if any, farm ponds exist near agricultural fields in these areas precisely because of the lack of precipitation and irrigation management practices. *Id.*; Exhibit 24 at 11. Therefore, the theoretical accumulations predicted by EPA's models in drier climates are not evidence of any significant real-world risk. Exhibit 6 ¶ 65. The registrants provided EPA with information related to the lack of ponds in proximity to key areas of commercial agriculture in California, but EPA did not refine its modeling or risk assessment approach to take that fact into account. Exhibit 24 at 11.

EPA defends its model based on repeated, qualitative assertions that the modeling performs well and that the observed data "track[] reasonably well," "provide a good match" or "largely match[]" the predicted results. Exhibit 6 ¶¶ 47-79; Exhibit 35 at 12, 18; Exhibit 25 at 3-4; Exhibit 31 at 12. However, analysis by Dr. Engel confirms that EPA's modeling does not perform well based on commonly used statistical measures. Exhibit 6 ¶¶ 52-63. The modeling is strongly biased towards overpredicting concentrations, often by huge margins, and standard measures of statistical fit are well below acceptable levels. *Id.* ¶¶ 58, 61. Most notably, statistical analysis shows that simply calculating the mean (average) of the observed data is a

better estimate of the observed data than the model, which means that the model has no value as a predictive tool. *Id.* ¶¶ 59, 61, 63.

It is contrary to sound science and regulatory principles for EPA to continue to base its registration decision on overly conservative theoretical modeling that fails standard statistical performance tests when there are now years of actual monitoring data that the Agency specifically required to resolve uncertainty in its modeling and ensure that its registration decision was based on actual rather than theoretical concerns. *Id.* ¶ 67. EPA cannot require registrants to generate millions of dollars of higher-tier monitoring data to resolve the uncertainty created by theoretical modeling and then revert to its models when the actual results do not support its apparent wished-for outcome.

EPA did not provide its modeling, the monitoring data, or any of its determinations with respect to potential accumulation and aquatic environmental exposure to flubendiamide and des-iodo for review by the SAP before issuing its NOIC.

3. EPA's Cancellation Determination Discounts or Ignores Significant Benefits EPA Must Consider Under FIFRA.

EPA determined to cancel flubendiamide without "taking into account the economic, social, and environmental . . . benefits of" flubendiamide as required by FIFRA. FIFRA § 2(bb), 7 U.S.C. §136(bb). Had EPA proceeded with a cancellation decision under 6(b), it would have been required to take "into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." FIFRA § 6(b)(2); 7 U.S.C. § 136d(b)(2). At least 60 days prior to issuing a cancellation notice, EPA would have provided the Secretary of Agriculture with a copy of that notice and an opportunity to provide comments on the notice and on EPA's agricultural impacts analysis. *Id.* EPA would have been required to publish USDA's comments and EPA's

response to those comments. *Id.* Stakeholders and the public would have had an opportunity to comment on the proposed cancellation decision, including on EPA's analysis of the impact of its decision on the agricultural economy.

Because EPA instead proceeded with cancellation through 6(e), no agricultural impacts analysis was performed, and flubendiamide's many benefits to agriculture and the environment were largely ignored. EPA unlawfully deprived the growers – who, other than the registrants, are the stakeholders most directly impacted by cancellation and most knowledgeable regarding the benefits flubendiamide provides – of a voice in EPA's cancellation decision. *See* Growers' Br. at 17- 24. The Agency declined to seek input from the government agencies (*e.g.*, USDA) and organizations (*e.g.*, the IR-4 Project) best suited to comment on flubendiamide's agricultural benefits and the consequences of cancellation on the agricultural economy:

> [I]t seems that in the move to cancel the flubendiamide registration, a risk/benefit assessment was not completed with consideration of the need for this product in specialty crop production. The IR-4 Project was not consulted for benefits information and to the best of our knowledge, neither were our colleagues at USDA's Office of Pest Management and Policy or any of the specialty crop commodity associations.

Exhibit 26.[33] Rather than listen to and consider the input of the growers, USDA, and IR-4, EPA covered its ears to flubendiamide's benefits and proceeded with cancellation.

In addition to denying interested governmental and non-governmental stakeholders any input on flubendiamide's benefits, EPA discounted or outright ignored the comprehensive benefits information that the Registrants submitted for its consideration. Exhibits 22 and 23. EPA's Decision Memorandum in support of cancellation addresses the benefits of flubendiamide in a single, dismissive paragraph without actually addressing any of Bayer's benefits analysis.

[33] That IR-4 – a project that is dependent upon federal grant money for its operations, and which strives to work collaboratively with EPA whenever possible – has publicly voiced its concerns, exemplifies the degree of alarm within U.S. agriculture over EPA's cancellation process.

Exhibit 30. EPA concedes flubendiamide's benefits in promoting IPM and resistance management, its targeted control of lepidopteran pests, its non-systemic properties, and its low impacts to beneficial insects. *Id.* at 9-10. EPA agrees that pyrethroids are "most likely to be the alternative chemistry used by growers." *Id.*at 9. EPA neither acknowledges nor discusses the crop-specific data and analysis that Bayer provided for fifteen representative crops. Exhibit 22; Exhibit 1 ¶ 14. EPA ignores entirely flubendiamide's relative human health and environmental benefits compared to those alternatives. Exhibit 22 at 235-36; Exhibit 1 ¶ 22. EPA ignores that flubendiamide, unlike many of the compounds EPA identifies as alternatives, is rainfast once dried on the leaf surface and would therefore not need to be reapplied after it rains. Exhibit 1 ¶ 26. EPA reaches its cancellation decision without having conducted a comparative product performance analysis of flubendiamide and its leading competitors, leaving the Agency "unable to quantify whether multiple applications of alternatives would be necessary to control target pests in the respective crops." Exhibit 23 at 5. Despite all the attention EPA has devoted in recent years to concerns regarding the alleged impacts of pesticides on pollinators, EPA's Decision Memorandum nowhere mentions that flubendiamide is one of the rare insecticide compounds with no toxicity to pollinators. In summary, there is no substantive benefits analysis (or weighing of those benefits against any costs) in EPA's Decision Memorandum; only a single, vague and unsubstantiated conclusion that "there are efficacious alternatives for flubendiamide." Exhibit 30 at 10.

FIFRA requires EPA to have done more than merely identify whether an efficacious alternative exists. FIFRA requires EPA to have considered and weighed the economic, environmental and human safety benefits that flubendiamide provides. FIFRA requires EPA to

have considered the impact that flubendiamide's removal from the market will have on growers, on human health and the environment. The consequences of EPA's failure to do so are manifold.

This failure led EPA to wrongfully conclude that growers would simply substitute an "efficacious alternative" such as chlorantraniliprole for flubendiamide without consequence. Had EPA listened to the growers,[34] grower organizations and entomologists, they would have informed EPA that: (1) growers were more likely to abandon IPM and IRM for cheaper pyrethroids and organophosphates[35] than to switch to a product that costs up to twice as much as flubendiamide, and that (2) chlorantraniliprole's systemic activity does not permit grower use of a treatment window approach and presents resistance-development risks that flubendiamide does not.[36]

This failure led EPA to wrongfully conclude that flubendiamide's modest sales meant that it was not an important tool for growers. Had EPA instead listened to the growers, to the entomologists and IPM specialists, and to IR-4, it would have had to consider that flubendiamide's value is not derived from the breadth of its use but from its very narrowness.[37]

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[34] Declaration of Mike Sturdivant at 3 in support of Growers' Brief, Exhibit 14 ("I have no other tools in my arsenal that are as effective as Belt, especially from a cost standpoint.").

[35] Exhibit 4 ¶ 28 ("Based on my direct knowledge of soybean, peanut, and cotton crops in Virgina, the most common and destructive pest threats to those crops, and historic grower practices, the lack of access to Belt® could result in movement of growers back to more broad-spectrum insecticides, reversing important progress made toward grower adoption of IPM management practices. Prior to the advent of Belt®, many growers relied on the use of insecticides in the pyrethroid class for controlling caterpillar pests and would likely resort to those if Belt® was no longer available.")

[36] Exhibit 4 ¶ 19.

[37] *See, e.g.*, Exhibit 22 at 234 (Correspondence from Mark R. Abney) ("[P]roblems associated with pyrethroid use in peanut are significant, and the availability of alternate chemistries like flubendiamide is important.") and at 254 (Correspondence from Eric T. Natwick) ("[T]he narrow spectrum of flubendiamide gives this diamide compound an advantage over broader spectrum diamides for inclusion into IPM schemes because flubendiamide is less likely to impact beneficial insect/arthropod populations including pollinators.")

Flubendiamide is undoubtedly not a mass-market product used in all seasons on all crops and all pests; yet when it is needed and applied, flubendiamide can be the difference between a successful harvest and a failed crop.[38]

This failure led EPA to ignore entirely the impact that flubendiamide's cancellation will have on pollinators and the crops that depend on them for successful production. Had EPA listened to Bayer, to the growers, the grower organizations and IPM specialists it would have had to consider the advantages for agriculture and the environment of using a compound that does not harm pollinator species. EPA would have had to consider that despite its own[39] and USDA's[40] stated preferences for pesticide compounds and practices that minimize impacts to pollinators, its cancellation decision would drive growers to use compounds that are toxic to pollinators.[41] Indeed, had EPA not denied USDA its statutory right to review and comment on EPA's NOIC, USDA may well have raised such concerns itself.

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[38] *See, e.g.*, Exhibit 4 ¶ 25 ("Belt is . . . a 'smart bomb' that targets caterpillar pests with no collateral damage to important natural enemies or pollinators."); Exhibit 22 at 237, Correspondence from Renee T. Rianda, The Morning Star Company, to Carmen J. Rodia, Jr., EPA (Apr 22, 2015) ("IPM programs are key to the success of USA farming, specifically California due to limited chemical options, BELT is a product that keeps IPM programs intact."); Growers' Brief quoting correspondence from W.H. Palmer, Reality Research, and Scott Palmer, Springbrook Orchards, to Frank Rittemann, Bayer CropScience (Mar. 14, 2016) ("[R]esearchers conducting efficacy trials on important insect pests on apples 'have not found any registered insecticide equal to Belt for control of late season Codling Moth and Oblique-banded Leafroller damage.'").

[39] EPA, EPA Takes Strong Steps to Better Protect Bees from Pesticides (May 28, 2015), https://www.epa.gov/pesticides/epa-takes-strong-steps-better-protect-bees-pesticides).

[40] Exhibit 41 (United States Department of Agriculture, Preventing or Mitigating Potential Negative Impacts of Pesticides on Pollinators Using Integrated Pest Management and Other Conservation Practices (Feb. 2014)).

[41] Exhibit 4 ¶¶ 22, 23; *see also* Exhibit 22 at 227, Correspondence from Angus Catchot to EPA ("Belt offers our growers a level of caterpillarcontrol that they have never seen before while at the same time reducing the risk to pollinators compared to more disruptive products.")

EPA did not want to hear from Bayer, from the growers, or from IR-4, because it knew that if it was forced to consider the comparative benefits of flubendiamide over IPM and non-IPM alternatives, the Agency would have had to acknowledge that its cancellation would deprive growers of numerous economic, environmental and human health benefits.

ARGUMENT

I. STANDARD OF REVIEW

FIFRA regulations permit the ALJ to issue an accelerated decision similar to a summary judgment under the Federal Rules of Civil Procedure. Consistent with 40 C.F.R. § 164.91, "[t]he Administrative Law Judge, in his discretion, may at any time render an accelerated decision in favor of Respondent as to all or any portion of the proceeding, including dismissal without further hearing or upon such limited additional evidence such as affidavits as he may receive." The ALJ may issue an accelerated decision under a number of conditions, including where "there is no genuine issue of any material fact and . . . the respondent is entitled to judgment as a matter of law," or for "[s]uch other and further reasons as are just." 40 C.F.R. § 164.91(a)(7) & (8); *c.f.* Fed. Rul. Civ. P. 56(a) (providing for summary judgment where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.").

When considering requests for accelerated decisions, the Environmental Appeals Board ("EAB") has confirmed that "although the Federal Rules of Civil Procedure do not apply to the proceedings before us, we look to the Federal Rules, including the summary judgment standard in Rule 56, for guidance." *In Re: Consumers Scrap Recycling, Inc.*, 11 E.A.D. 269, 2004 WL 326954 at *13 (EAB Jan. 29, 2004) (citing *In re BWX Tech., Inc.*, 9 E.A.D. 61, 74 (EAB 2000)); *see also In re Clarksburg Casket Co.*, 8 E.A.D. 496, 501-02 (EAB 1999) (the standard for granting an accelerated decision is "similar to the summary judgment standard set forth in Rule 56").

This Motion turns on the dispositive legal question of whether, as a matter of law, EPA can bypass required cancellation procedure through its "voluntary" cancellation scheme, and is thus appropriate for resolution through an accelerated decision. An accelerated decision will also serve fairness and efficiency by resolving the lawfulness of EPA's proposed cancellation approach before the hearing is conducted, thus avoiding the potential unnecessary burden on the parties and the ALJ of conducting an unlawful hearing. *See, e.g., Merit Motors, Inc. v. Chrysler Corp.*, 417 F. Supp. 263, 267 (D.D.C. 1976), *aff'd*, 569 F.2d 666 (D.C. Cir. 1977) ("Summary judgment is a valuable instrument for avoiding unnecessary, lengthy, and costly trials.").

II. EPA CANNOT CANCEL THE FLUBENDIAMIDE REGISTRATIONS WITHOUT PROVIDING THE PROCESS REQUIRED BY FIFRA.

A. Cancellation of Existing Registrations for Failure to Meet the Registration Standard Requires the Full Cancellation Process Under FIFRA §§ 6(b) & (d).

Courts have recognized that registrants hold property rights in their registrations. *See, e.g., Reckitt Benckiser*, 613 F.3d at 1133 ("A FIFRA registration is a product-specific license."); *Ctr. for Biological Diversity v. EPA*, No. 11-CV-00293-JCS, 2013 WL 1729573, at *6 (N.D. Cal. Apr. 22, 2013) ("owners of the pesticide registrations . . . have property and financial interests in the registrations."). This property interest cannot be annulled without due process of law. *See, e.g., Bell v. Burson*, 402 U.S. 535, 539 (1971); *see also* Administrative Procedure Act, 5 U.S.C. § 558(c) (requiring that licenses cannot be withdrawn or revoked with notice and the "opportunity to demonstrate or achieve compliance with all lawful requirements.").

Congress has spoken in creating specific cancellation procedures under FIFRA §§ 6(b)-(e) and determining when they apply. FIFRA's cancellation requirements are not optional and go beyond the minimum rights guaranteed under general due process law. Congress

"establish[ed] a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration." *See Reckitt Benckiser*, 762 F. Supp. 2d at 42 (emphasis in original).

As detailed above, if EPA determines that it wishes to cancel existing registrations based on a determination that use of the registrations "generally causes unreasonable adverse effects on the environment" (the Registration Standard), EPA *must* issue a notice of intent to cancel and provide the right to request a hearing under FIFRA §§ 6(b) & (d), and comply with all accompanying process, including consulting with USDA and HHS, if applicable, before issuing the NOIC, submitting its determination for review by the SAP, and defending the merits of its cancellation decision in a full administrative hearing.

EPA's January 29, 2016 Decision Memorandum, its press release and statements issued on March 1, 2016, and the voluminous scientific and regulatory documents EPA has made available in support of its decision render beyond dispute the fact that EPA has made a substantive – albeit incorrect – determination that use of flubendiamide will cause "unreasonable adverse effects." Thus, the only proper process for EPA to cancel the registrations under the plain language of FIFRA is through §§ 6(b) & (d).

Due to an apparent unwillingness to subject its positions to peer review and public scrutiny in compliance with FIFRA, EPA has sought to force the cancellation process down a different and inappropriate path. By law, and to ensure that it is not used to shield substantive EPA cancellation decisions from required process and review, the streamlined cancellation process under FIFRA § 6(e) applies only when EPA determines that a registrant "has failed to initiate and pursue appropriate action toward fulfilling any condition imposed" or that "at the end of the period provided . . . that condition has not been met." FIFRA § 6(e)(1). In this case, EPA has repeatedly confirmed that Bayer and Nichino have satisfied the substantive conditions EPA

imposed on the flubendiamide registrations. *See* Exhibit 10; Exhibit 12. EPA's request for cancellation under § 6(e) is inappropriate on its face.

To serve its purposes, EPA devised and imposed an unlawful "condition[] of registration" that purports to require "voluntary" cancellation upon the mere announcement by EPA that it has reached a negative registration determination. Exhibit 8. This provision was designed to create a mechanism by which EPA could seek to short circuit the statutory process and claim the right to cancel a product it believes no longer meets the Registration Standard without any outside review of its reasoning or any substantive cancellation process. This unlawful approach reveals EPA's wish to shield its scientific and regulatory determinations from rigorous, independent scrutiny. The suggestion by EPA in the NOIC that affected parties cannot challenge, and the ALJ cannot review, the merits and lawfulness of the "voluntary" cancellation provision shows a similar desire to shield from rigorous, independent scrutiny the cancellation approach it has chosen to pursue.

EPA cannot invent its own process to bypass statutory rights through forced "voluntary" cancellation. Whatever the scope of EPA's authority under FIFRA § 3(c)(7)(C) may be to impose "such other conditions as the Administrator may prescribe," it must fall well short of granting itself the authority to preclude the specific cancellation rights and procedures Congress chose to require and cut others – in addition to the registrants – out of the process. Otherwise, EPA could bypass the cancellation and suspension requirements in FIFRA § 6 at will, rendering them meaningless.[42]

[42] "It is 'a cardinal principle of statutory construction' that 'a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.'" *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (quoting *Duncan v. Walker*, 533 U.S. 167, 174 (2001)).

This principle was confirmed in a recent decision rejecting a different attempt by EPA to cancel registrations without cancellation process. *Reckitt Benckiser*, 762 F. Supp. 2d at 49. In that case, EPA concluded that certain rodenticides no longer met the Registration Standard, and that some could be "brought into compliance" while others "will require cancellation." *Id.* at 39. However, EPA refused to initiate cancellation and instead informed registrants that non-complying products would be deemed "misbranded" as of a date certain, making further distribution unlawful and subject to civil and criminal penalties. *Id.*

The Court of Appeals for the D.C. Circuit rejected EPA's efforts to shield this unlawful approach from judicial review based on assertions that the Agency had not yet taken "final action" on its misbranding scheme, and characterized the question on the merits as whether EPA could "bypass[] cancellation proceedings." *Reckitt Benckiser*, 613 F.3d at 1136. The answer on remand was a resounding no:

> It is undisputed that plaintiff holds valid registrations for products that EPA believes must be cancelled because they do not comply with the RMD. Yet, if EPA also has the authority to bring misbranding enforcement actions after June 4, 2011 . . . based on non-compliance . . ., it will be able to "bypass[] cancellation proceedings" and "effect[ively] cancel[] the registrations without following the regulatory procedures provided in Section 6." *See Reckitt*, 613 F.3d at 1136. To interpret FIFRA to give EPA that authority not only renders Section 6 superfluous; it also allows EPA to avoid the rigorous cancellation process Congress provided for in the statute.

Reckitt Benckiser, 762 F. Supp. 2d at 43. The statute was "not ambiguous" and EPA's creative "interpretation" was entitled to no deference. *Id.* at 49. EPA did not appeal.

The same result applies here. The plain language of FIFRA's cancellation provisions, Congress's intent in establishing robust due process rights for existing registrations, and the logic of the *Reckitt Benckiser* decisions make clear that EPA cannot circumvent required process by seeking to implement a substantive cancellation determination through a forced "voluntary" cancellation condition.

In another recent action, the Ninth Circuit denied EPA's efforts to avoid its obligations before cancellation of existing registrations. That action involved a petition for review filed in the Ninth Circuit challenging EPA's issuance of certain registrations. In light of new information received, EPA asked the Court to remand and to grant voluntary vacatur of the registrations. The registrant objected, arguing that EPA's request that the Court summarily vacate the registrations was an attempt to cancel the registrations without providing any of the process required under FIFRA § 6, and that EPA should not be allowed to "short-circuit" the statutory cancellation process in this way.[43]

On January 25, 2016, the Ninth Circuit remanded the matter to EPA and summarily denied the motion for vacatur "without prejudice to the rights of either party to litigate that question before the agency."[44] The Ninth Circuit's order confirms that existing registrations cannot be "vacated" without following the prescribed administrative process, and rejects another creative yet unlawful attempt by EPA to achieve cancellation while bypassing required cancellation procedure.

B. EPA Previously Confirmed That FIFRA § 6(b) Applies When Proposed Cancellation Is Based on a Determination Under the Registration Standard.

In the only other FIFRA cancellation proceeding to have been conducted in at least two decades, EPA drew a sharp distinction between FIFRA§§ 6(b) and 6(e) and confirmed that when EPA makes a cancellation decision based on a Registration Standard determination, the proper process is for EPA to proceed with cancellation under § 6(b).

[43] Exhibit 53 (Intervenor's Response to Respondents' Motion for Voluntary Vacatur and Remand at 3-7, 9-11, Dkt. #122, *NRDC v. EPA*, No. 14-73353 (9th Cir. Dec. 7, 2015)).

[44] Exhibit 54 (*NRDC v. EPA*, No. 14-73353, Dkt. #128 (9th Cir. Jan. 25, 2016) (order remanding registrations)).

After the *Reckitt Benckiser* decisions rejected EPA's misbranding scheme, EPA issued a notice of intent to cancel Reckitt Benckiser's registrations for certain rodenticides. In the notice of intent to cancel, EPA indicated that its existing stocks determination would not be included in the scope of the § 6(b) hearing. The registrant filed a motion challenging that position. Among other things, CropLife America noted in an amicus brief that § 6(e) grants the right to a hearing on existing stocks, and the § 6(b) process should, if anything, be broader. In defending its approach, EPA distinguished the purposes of a § 6(b) hearing from a § 6(e) hearing in a manner that precludes the approach it has taken here.[45]

As EPA explained in the *Reckitt Benckiser* proceeding, the "provisions governing risk-based cancellations" are contained in § 6(b) and pesticides "cancelled pursuant to section 6(b) have been determined to pose unreasonable risks to man or the environment that require that they be removed from commerce."[46] EPA asserted that, in contrast, "a section 6(e) cancellation is about the *registrant's* failure to meet its obligations, and not about a problem with *the pesticide product itself*."[47] EPA argued that the scope of the hearings available under §§ 6(b) and 6(e) correctly reflect that distinction.

In the flubendiamide NOIC, EPA implicitly disavows its earlier representations to the ALJ and turns that distinction on its head. It is indisputable that EPA seeks to cancel the flubendiamide registrations due to its risk concerns and for failure to meet the Registration Standard. In the NOIC, EPA explicitly acknowledged that it "determined the registrations did not meet the FIFRA standard for registration" on January 29, 2016. Exhibit 20 at 11,559. Its

[45] Exhibit 55 (EPA's Conditional Opposition to CropLife America's Motion to File an Amicus Curiae Brief at 4-5 & n.2, Dkt. #24, *In re Reckitt Benckiser*, EPA FIFRA Dkt. 661 (May 6, 2013)).

[46] *Id.* at 4 n.2 & 5.

[47] *Id.* at 4 n.2 (emphasis in original).

carefully segregated press releases and postings about that determination leave no doubt on this score. Thus, the proper forum for EPA's "risk-based cancellation" is § 6(b). Yet in the NOIC EPA takes the position that it can cancel the registrations under § 6(e) and preclude any consideration or review of its January 29, 2016 Decision Memorandum and its determination under the Registration Standard. This is flatly inconsistent with the statutory language and intent that EPA previously recognized and relied on, when it suited its purpose.

III. THE "VOLUNTARY" CANCELLATION CONDITION IS UNLAWFUL.

A. The Purpose of EPA's Forced "Voluntary" Cancellation Condition Is to Bypass Required Cancellation Process.

Rather than follow the § 6(b) process, EPA seeks to force cancellation through its purported "voluntary" cancellation provision. EPA cannot be permitted to avoid its obligations by presenting powerless entities the Hobson's choice of either accepting conditions designed to bypass the cancellation process or receiving no registration at all. The July 31, 2008 letter purported to require Nichino and Bayer to submit irrevocable requests for "voluntary" cancellation of the registrations if EPA later "makes a determination that further registration of the flubendiamide end-use products will result in unreasonable adverse effects on the environment." Exhibit 8 at 3. If found lawful, this type of "condition" would allow EPA to obtain cancellation by fiat, without providing any of the required process. EPA cannot circumvent the due process required by FIFRA for its own convenience. As discussed above, courts in the D.C. Circuit and the Ninth Circuit have recently confirmed that EPA cannot invent alternative cancellation mechanisms to avoid the statutory process.[48]

[48] *See Reckitt Benckiser*, 613 F.3d at 1136 (remanding for determination whether EPA can "bypass[] cancellation" through misbranding scheme); *Reckitt Benckiser*, 762 F. Supp. 2d at 43 (confirming that EPA's misbranding enforcement authority cannot be used to circumvent "the rigorous cancellation process Congress provided for in the statute"); *NRDC v. EPA*, No. 14-

In the NOIC, EPA contends that "[w]ithout that condition, the registration would likely not have been approved by EPA." Exhibit 20, at 11,559. Yet EPA provides no explanation as to why the "voluntary" cancellation condition would be necessary.

The "voluntary" cancellation provision serves no valid regulatory purpose. In granting the conditional registrations, EPA necessarily and expressly determined that issuance of the registrations was in the public interest and that the registrations would not pose unreasonable adverse effects on the environment.[49] If Bayer and Nichino refused to generate the data required, EPA could have sought prompt cancellation under FIFRA § 6(e), while FIFRA § 6(b) provides the mechanism for achieving cancellation if EPA subsequently determined that continued registration would not meet the Registration Standard. FIFRA § 6(c) would allow EPA to promptly suspend the registrations during the cancellation process if the Agency identified an "imminent" hazard.

In short, there was no need for EPA to invent and impose the "voluntary" cancellation condition, and EPA has no basis to contend that the registrations might not have been issued without that condition. The only purpose it could serve is to allow EPA to evade statutory obligations and deny registrants and other affected parties due process. Allowing EPA to proceed in this fashion would render the cancellation provisions in § 6 meaningless and would deny the cancellation due process protections Congress chose to provide.

B. The "Voluntary" Cancellation Process Eliminates Required Review and Rights Afforded Registrants and Other Stakeholders

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73353, Dkt. #128 (9th Cir. Jan. 25, 2016) (order remanding the registrations for further administrative action and denying EPA's request for "voluntary vacatur") (Exhibit 54).

[49] *See* FIFRA § 3(c)(7)(C); Exhibit 21 (Apr. 15, 2008 Public Interest Finding for Flubendiamide); Exhibit 8 (July 31, 2008 Letter re Approval of Registrations Under 3(c)(7)(C), with Public Interest Finding enclosed).

The "voluntary" cancellation condition circumvents procedural requirements Congress intended to ensure that cancellation decisions are subject to interagency review by the Secretary of Agriculture and independent scientific peer review by the SAP *before* the cancellation order issues. FIFRA §§ 6(b), 25(d). This review helps to ensure that the benefits of the product to the agricultural community and the potential agricultural and commercial harm cancellation could cause are fully considered, and that the scientific grounds for the proposed cancellation are subject to and can withstand independent scientific peer review *before* the cancellation order issues.

This review process ensures that stakeholders considering whether to object to a proposed cancellation have the benefit of independent peer review of complex scientific determinations. It also ensures that a robust and transparent record will be available to the parties and the ALJ in a cancellation hearing.

Because EPA did not follow this process, the ALJ is denied such a record in this proceeding, and thus, for example, does not have an independent scientific review to gauge the strength of EPA's scientific conclusions in support of its proposed cancellation. The strength and merits of EPA's cancellation determination are relevant here for two purposes. First, they are relevant to determining the lawfulness of EPA's approach, because subjecting EPA's determination to critical review will provide insight on EPA's motives in seeking to shield its conclusions from scrutiny and will illustrate the harm that will occur if EPA is allowed to avoid proper process and review. Second, even under the § 6(e) process EPA has wrongly invoked, EPA's overestimation of the risks and discounting of the benefits of the flubendiamide products are relevant to ruling on EPA's existing stocks proposal.

By demanding that registrants accept the "voluntary" cancellation condition, the Agency is not only holding registrations that should issue under FIFRA hostage to its demands for powerless entities to waive their due process rights, it is also effectively asking pesticide companies to waive the rights of other important stakeholders to object to any future determination by EPA that the registrations should be cancelled. Setting aside EPA's unlawful coercion, these companies have no authority to waive the important procedural protections Congress created under FIFRA § 6 for USDA, HHS, growers, and other adversely affected parties. By inserting this "voluntary" cancellation provision as a purported condition of registration, EPA eliminates any mechanism for these stakeholders to participate in the evaluation of whether the pesticide meets the Registration Standard. Yet Congress was explicit in including rights and process for these stakeholders in the Act. *See id.* §§ 6(b), 25(d); *see also Envtl. Def. Fund, Inc. v. Costle*, 631 F.2d 922, 936-37 (D.C. Cir. 1980) (noting the Congressional objective in amending FIFRA in 1972 was "to broaden the category of hearing requesters" beyond just registrants).

IV. THE REGISTRANTS HAVE SATISFIED ALL THE LAWFUL CONDITIONS OF THE CONDITIONAL REGISTRATION.

Beyond the unlawful "voluntary" cancellation condition, the registrants diligently complied with all the lawful conditions of the flubendiamide registrations.

The original conditional registrations required the generation of significant data, including a "small-scale run-off/vegetative buffer strip study" and a monitoring program intended to generate additional data to evaluate any remaining risk concerns after the initial study. Exhibit 8. EPA recognized that as of July 31, 2012, Bayer "ha[d] submitted all data required by the original conditions of registration for flubendiamide." Exhibit 10.

On July 18, 2013, EPA agreed to extend the registrations for flubendiamide to August 31, 2015. *Id.* This allowed for additional data generation under the monitoring program and for the registrants to submit a report on those data by December 31, 2014. Throughout 2015, scientists from the registrants and EPA engaged in discussions about both the benefits and the risks of flubendiamide. Exhibit 2 ¶¶ 20-22. On August 26, 2015, EPA again confirmed that "[a]s of July 31, 2012, BCS [Bayer CropScience] has submitted all data required by the original conditions of registration for flubendiamide." Exhibit 12.

EPA has no basis to seek cancellation under § 6(e) for failure to meet any valid condition of registration.

V. CONTINUED REGISTRATION OF FLUBENDIAMIDE MEETS THE REGISTRATION STANDARD.

To be clear, the ALJ need not determine that EPA's cancellation determination was wrong on the merits in order to grant an accelerated decision finding that the "voluntary" cancellation scheme and its invocation of § 6(e) are unlawful. That said, the fact that EPA's cancellation determination is not supported by the science and is not consistent with the FIFRA Registration Standard – as shown by EPA's own documents and the expert analysis and opinions presented in the attached declarations of Dr. Moore, Dr. Engel, and Dr. Herbert – is relevant to understanding the importance of the § 6(b) process EPA has sought to bypass.

A. EPA's Efforts to Show That Flubendiamide No Longer Meets the Registration Standard Demonstrate Why a § 6(b) Cancellation Process Is Necessary.

While EPA takes the position in the NOIC that the registrations "should be cancelled" because the registrants declined to cancel their registrations pursuant to EPA's unlawful "voluntary" cancellation provision, the NOIC itself acknowledges that the actual substantive basis for EPA's proposed cancellation is EPA's January 29, 2016 determination that "continued

registration of flubendiamide products will result in unreasonable adverse effects on the environment." Exhibit 20 at 11,559. In its March 1, 2016 press release announcing the NOIC, EPA asserted that flubendiamide breaks down into a "more highly toxic material," that flubendiamide products "pose a risk to aquatic invertebrates," and that EPA "concluded that continued use of the product would result in unreasonable adverse effects on the environment." Exhibit 19. The January 29, 2016 Decision Memorandum documents EPA's determination that "the risks of allowing the continued use of flubendiamide outweigh the benefits, and will result in unreasonable adverse effects to the environment." Exhibit 30 at 10.

When it announced the NOIC, EPA posted on its website the NOIC, the Decision Memorandum, and 10 other "supporting documents" totaling 504 pages.[50] These documents reflect EPA's scientific and regulatory analysis and conclusions, including a January 28, 2016 Ecological Risk Assessment Addendum (Exhibit 31) that includes previously undisclosed modeling of predicted flubendiamide and des-iodo exposure levels and a January 29, 2016 Addendum to Clarify Invertebrate Terminology (Exhibit 32) that seeks to redefine the term "benthic" aquatic invertebrates to cover all aquatic invertebrates and thus to expand retroactively the scope of EPA's stated ecological concerns.

Other than the registrants' letter declining to "voluntarily" cancel the registrations, EPA has not provided for public review any of the documents, white papers, and presentations that the registrants provided in response to EPA's flawed scientific determinations through their years of discussion and scientific exchange on these issues.

After making public claims about the risks posed by flubendiamide and its lack of offsetting benefits, determining that the flubendiamide registrations should be cancelled because

[50] *See supra* note 32.

they do not meet the Registration Standard, and publishing incorrect, eleventh-hour scientific and regulatory assessments in support of that determination, EPA now seeks through its unlawful "voluntary" cancellation scheme to deny everyone – the USDA, the SAP, growers, the registrants, other interested stakeholders, the general public, and the ALJ – any opportunity to review and challenge EPA's scientific conclusions and regulatory determination.

Congress established that *every* EPA cancellation determination based on the Registration Standard must undergo thorough review subject to FIFRA §§ 6(b)&(d), and 25(d). This is particularly important here, as any rigorous review encompassing EPA's Decision Memorandum, the supporting documents, and the remainder of the record not disclosed by EPA would show that EPA's cancellation determination relies on unsound scientific and regulatory assessments.

If afforded a proper FIFRA § 6(b) hearing and after required USDA and SAP review, Bayer and Nichino would present fact and expert evidence and testimony establishing that EPA's cancellation determination: (1) ignores the most recent and definitive data and relies on a toxicity endpoint that is 70 times lower than the current science supports; (2) ignores the real-world monitoring data that show no accumulation to a level of concern and contradict the overly conservative and inaccurate theoretical exposure modeling the Agency relies on; and (3) dismisses without justification the significant benefits of flubendiamide, including the lack of *any* human health concerns, an ecological risk profile that is very favorable and better than many likely alternatives, and its critical and unique role as a tool for growers practicing both IPM and IRM. Expert opinions summarizing the basis for these conclusions are provided in the attached declarations of Dr. Moore, Dr. Engel, and Dr. Herbert. Exhibits 5, 6, and 4.

If this matter proceeds to an evidentiary hearing under § 6(e) – even though it should not – the registrants and the ALJ will be denied the benefits of USDA and SAP review and input, but the registrants will nonetheless present evidence and testimony establishing the unsoundness of EPA's determination. Such evidence and testimony are relevant to EPA's motives in shielding its cancellation determination from required review, which bears on the lawfulness of EPA's "voluntary" cancellation scheme (if not already resolved through this motion), and also will be relevant to the merits of EPA's existing stocks determination.

Without waiving the right to a full and proper hearing on the merits of EPA's cancellation decision *after* USDA consultation and SAP review, the errors in EPA's cancellation determination are summarized below.

B. EPA's Selection of the Lower Endpoint Is Not Consistent with Sound Science and Regulatory Process.

1. The Sudden Switch to the Lower Endpoint Undermined Transparency and Precluded Appropriate Review.

As described above, EPA's cancellation determination relies on EPA's sudden reversion in mid-December 2015 to a toxicological endpoint of 0.28 ppb for the flubendiamide degradate des-iodo in pore water in sediment, which is 70 times lower than the 19.5 ppb endpoint based on a more definitive and appropriate 2010 study that EPA had reviewed and approved in 2011. While EPA took the position that the endpoint should be 19.5 ppb rather than the 22 ppb endpoint the registrants calculated due to the Agency's use of time-weighted average rather than measured concentrations, before December 2015 EPA never suggested that it would revert to the superseded and incorrect 0.28 ppb endpoint.[51]

[51] *See, e.g.*, Exhibit 35 at 17 (reflecting EFED's position in February 2015 that "[s]ome of these registrant-calculated endpoints *differ slightly* from the Agency-determined endpoints" but that the Agency "will use the registrant-calculated endpoints.") (emphasis added).

As a result, through 2015, EPA's discussions with the registrants focused on whether the modeling and monitoring data suggested that flubendiamide or des-iodo might accumulate to a level of concern, not whether the most critical endpoint should be drastically reduced. Exhibit 2 ¶ 29. Even as EPA changed course and prepared to take action against the registrations, EPA asked the registrants to prepare their final analysis and mitigation proposals, and scheduled and conducted a high-level meeting on December 15, 2015, involving EPA's Assistant Administrator and the CEOs of Bayer and Nichino, yet failed to disclose it was changing the most critical endpoint in this remarkable way. *Id*. ¶¶ 27-28, 31.

The day after the high-level meeting, EPA's EFED briefed the Assistant Administrator on its ecological risk determinations using the lower endpoint which had not been disclosed to the registrants just the day before. *Id*. ¶ 31. This maneuvering by EPA undermined a years-long transparent process of scientific review and exchange between EPA and the registrants, and precluded the registrants from addressing EPA's most critical scientific position before it was presented to the Assistant Administrator in support of the cancellation decision that he apparently desired. In the January 6, 2016 meeting, EPA acknowledged that the timing of its change was "unfortunate," but provided no justification for the lack of disclosure even as it asked the registrants to provide their final mitigation analyses. *Id*. ¶ 36.

The January 29, 2016 Decision Memorandum wrongly implies that the only area of dispute between EPA and the registrants was the use of time-weighted average versus nominal or measured concentrations, and does not defend or provide *any* discussion of EPA's reversion to the lower endpoint from the superseded spiked water study. The Decision Memorandum includes a table of the "final suite" of available endpoints that lists both the superseded 0.28 ppb endpoint under the spiked water study and the 19.5 ppb endpoint under the spiked sediment

study, both calculated under EPA's time-weighted average approach. Exhibit 30 at 5; Exhibit 5 ¶ 64. Only by examining the underlying data and modeling and comparing them to EPA's statements regarding the exceedances is it clear that EPA selected the superseded 0.28 ppb endpoint as an "Agency LOC" [level of concern] and the basis for its cancellation determination, while rejecting and incorrectly characterizing the 19.5 ppb endpoint as a "[Bayer/Nichino]-suggested" endpoint with which EPA did not agree. Exhibit 30 at 7; Exhibit 5 ¶ 64.

This level of obfuscation is antithetical to scientific and regulatory transparency, let alone accuracy. Scientific peer review by the SAP – which EPA goes to great lengths to avoid – would require EPA to confirm and explain its use of the lower endpoint. The ALJ should deny EPA's proposed cancellation under § 6(e) and require EPA to subject its scientific determinations to the § 6(b) process, which would include review by the SAP of EPA's endpoint selection.

2. EPA's Selection of the Lower Endpoint Was Outcome Driven and Is Not Supported by the Science.

As discussed above, the timing of EPA's sudden reversion to a 70 times lower endpoint was necessary in order for EPA's modeling to continue to predict exceedances after EPA made necessary corrections to its overly conservative modeling. Exhibit 2 ¶ 32.

Throughout EPA's discussions with the registrants, it defended its use of a modeling approach that predicted concentrations based on a model assuming 30 years of agricultural runoff into a farm pond *with no corresponding outflow*. Exhibit 35 at 14-15. At the final hour, in modeling EPA disclosed only in connection with its cancellation determination, EPA finally addressed this methodological error. Exhibit 31 at 4-5, 18-26. However, to ensure that the modeling still "predicted" widespread exceedances, EPA at the same time reverted to the incorrect lower endpoint. Exhibit 2 ¶ 32. EPA asked the registrants to provide their final

analysis of the viability of flubendiamide and proposed mitigation measures without informing them of either change. *Id*. ¶ 28.

As described in Dr. Moore's declaration, EPA's use of the lower endpoint is contrary to the definitive, spiked sediment study reviewed and approved by EPA that showed no observable effects at 22 ppb, the highest level tested. Exhibit 5 ¶¶ 54-60. EPA's use of an endpoint from the superseded and less applicable spiked water study is contrary to the weight of the evidence and is inconsistent with EPA and OECD guidance and well-accepted toxicological practice. *Id.* ¶ 9, 38-53, 70.

C. EPA Wrongly Relies on Theoretical Modeling That Is Contradicted by Real-World Data Showing No Accumulation of Concern.

1. EPA's Theoretical Modeling Relies on Highly Unrealistic Assumptions and Has No Predictive Value.

The second leg supporting EPA's cancellation determination is equally unsound. For the reasons set forth in Dr. Engel's Declaration, EPA's theoretical modeling is overly conservative, unrealistic, and has no predictive value.

EPA's cancellation decision relies wholly on its theoretical modeling predicting rapid accumulation of residues of flubendiamide and des-iodo that are not connected to real-world use conditions and have not been observed in any monitoring and sampling. Exhibit 6 ¶ 11. Even EPA's eleventh-hour, more refined modeling has little to no predictive value, as confirmed when compared to the real-world monitoring data generated at EPA's direction. *Id.* ¶¶ 52-63. Among other things, the modeling all proceeds from the assumption that there have been seven years of use with the maximum application rate and number of applications each year. Exhibit 31 at Appendix 1. This is not consistent with actual, known historic use rates, data that are available to EPA.

EPA's updated modeling also predicts the highest exceedances in drier climates such as California's Central Valley where very few, if any, farm ponds exist due to the arid conditions and where very little runoff will occur due to irrigation practices in those regions. Exhibit 6 ¶ 65. For the reasons provided in Dr. Engel's declaration, EPA's decision to cancel flubendiamide based on "predicted" exceedances from the overly conservative theoretical modeling is contrary to sound science and reasonable regulatory practice. *Id.* ¶¶ 11, 23, 59, 63.

EPA failed to perform any statistical analysis comparing the predicted results of the model to the real-world monitoring data to quantify how well the modeling performed in predicting actual exposures. *Id.* ¶ 50. Statistical analysis conducted by Dr. Engels reveals, among other things, that the modeling not only significantly overstates the actual results but also that the mean value of the observed data is a better predictor than the modeled values. *Id.* ¶¶ 58, 62. In other words, simply taking the average of the observed data is a better predictor than EPA's modeling. *Id.* ¶ 59. This unacceptable performance confirms that EPA's modeling is not a sound basis for making regulatory determinations, and that the Agency's registration determination should instead be based on the monitoring data. *Id.* ¶ 11.

2. Real-World Data Show No Accumulation Above a Level of Concern.

As discussed above, the registrants were required to conduct monitoring studies to address the uncertainties posed by EPA's theoretical modeling and measure the actual amount of flubendiamide and des-iodo accumulating in aquatic environments. At EPA's direction and at significant expense, the registrants generated almost five years of monitoring data. Exhibit 6 ¶17. They are continuing to conduct the monitoring. These data, and additional analysis conducted by USGS at EPA's request, have not uncovered a single sample showing an exceedance of any level of concern. *Id.*¶¶ 42, 70.

Moreover, the year-over-year monitoring data do not show the rapid accumulation toward a level of concern that EPA's modeling predicted would occur. The variability observed in the monitoring results is likely due to factors including different use rates caused by growing conditions and pest pressures, and different weather patterns and application timing which can result in different amounts of agricultural runoff. *Id.* ¶ 24-31. The data do not support the conclusion that flubendiamide or des-iodo is accumulating or will accumulate to a level of concern. *Id.* ¶ 23.

Finally, it is unsound scientific and regulatory practice for EPA to require registrants to conduct higher-tier monitoring studies to address and resolve uncertainties in theoretical models, and then ignore the results obtained from the monitoring when they do not show the theoretical accumulation predicted. EPA should not ignore the higher-tier monitoring data and cannot justify the cancellation of a valuable agricultural tool using "predicted" exceedances from theoretical models whose predictive accuracy has been discredited by the very data EPA required to be generated. *Id.*¶ 11.

D. The Human Health, Environmental, and Economic Benefits of Flubendiamide Outweigh Any Alleged Risks.

EPA's determination of whether the continued registration of a product causes "unreasonable adverse risks on the environment" must "tak[e] into account the economic, social, and environmental costs *and benefits* of the use of any pesticide." FIFRA § 2(bb) (emphasis added). Flubendiamide is proven to narrowly and effectively target lepidopteran insects, while posing minimal risk to beneficial insects. Exhibit 1 ¶ 10, 16-18; Exhibit 4 ¶¶ 15-18, 22. It is one of a limited set of IPM options for growers seeking to control lepidopteran insects and its non-systemic properties render it far less likely to result in resistance than its IPM-friendly systemic alternatives. Exhibit 1 ¶ 21; Exhibit 4 ¶ 19. Flubendiamide has an excellent safety profile,

posing no risk to humans, and for certain crops it is less than half the cost of chlorantraniliprole, its major phthalic diamide competitor. Exhibit 1 ¶ 25. Unlike certain of the alternative compounds identified by EPA, flubendiamide poses minimal risk to pollinator species, and it is rainfast once dried on the leaf surface and therefore less likely to require repeated treatments than alternatives. *Id.* ¶ 26; Exhibit 4 ¶ 23.

Had EPA undertaken the analysis required by FIFRA, it would have had to consider the drawbacks of cancelling such a unique compound with a unique array of benefits that render it an essential tool for both IPM and IRM. While there may be efficacious alternatives to flubendiamide, none present the full array of benefits to growers and to the environment as flubendiamide. Flubendiamide's cancellation will likely deter growers from applying the very IPM and IRM practices that EPA claims to be promoting, in place of disfavored organophosphates and pyrethroids. Exhibit 4 ¶ 28. Cancellation will increase the likelihood for lepidopteran insects to develop resistance to the remaining compounds available to growers. *Id.* ¶ 19. If EPA had properly weighed flubendiamide's *unproven* environmental risks against its *proven* benefits to human health, the environment, and the agricultural economy, the Agency would have had to conclude that flubendiamide continues to meet the Registration Standard.

CONCLUSION

It is undisputed that EPA's decision to cancel the flubendiamide registrations is based on its determination that continued registration of flubendiamide will cause "unreasonable adverse effects on the environment" and thus no longer meets the FIFRA Registration Standard. EPA's January 29, 2016 letter to Bayer and Nichino requesting voluntary cancellation stated unequivocally that "the Agency has made a determination that the continued use of the currently registered products *will result in unreasonable adverse effects on the environment*." Exhibit 17 at 2 (emphasis added). Likewise, on March 1, 2016, the same day that EPA delivered the NOIC

to Bayer and Nichino, the Agency issued press releases and posted information on its website stating that EPA had "concluded that continued use of the product *would result in unreasonable adverse effects on the environment.*" (emphasis added).

FIFRA makes clear that the proposed cancellation of a registered insecticide based on a determination that the product no longer meets the FIFRA Registration Standard must comply with the robust and specific process granted to the registrants, other federal agencies, and public stakeholders by FIFRA § 6(b): "If it appears to the Administrator that a pesticide . . . *generally causes unreasonable adverse effects on the environment*, the Administrator may issue a notice of the Administrator's intent either (1) to cancel its registration or . . . (2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed." FIFRA § 6(b) (emphasis added).

EPA's scheme to achieve cancellation of the flubendiamide registrations through implementation of a purported "voluntary" cancellation condition and improper invocation of FIFRA § 6(e)'s narrow cancellation process is precluded as a matter of law. The FIFRA § 6(b) process was enacted expressly to ensure that an EPA finding of "unreasonable adverse effects on the environment" is made in a transparent manner, based on a thorough scientific and economic assessment of the pesticide's risks and benefits, and informed by the review and input of relevant governmental and non-governmental stakeholders. If EPA is permitted to demand the authority to sidestep its statutory obligations and dispense with the statutory process for flubendiamide, then Section 6 of FIFRA and the rights it affords registrants and the American public will soon exist only on paper.

EPA may seek to reframe its conduct as a product of necessity, arguing that it requires the means to quickly cancel pesticide registrations if and when an environmental concern

arises. Yet Congress only granted EPA the authority to quickly remove products from the market in a very particular circumstance and based on a very specific finding. Under FIFRA § 6(c), EPA could only lawfully suspend Registrants' flubendiamide registrations based on a finding that flubendiamide presents an "imminent hazard." Even after suspension, EPA must proceed with the cancellation process to determine the ultimate fate of the registrations. Because EPA has not claimed (nor could it) that flubendiamide presents an imminent hazard, FIFRA mandates a longer, multi-tiered process, with opportunities for inter-agency and public review and scrutiny of EPA's scientific and economic findings. That EPA, in its role as gatekeeper of all Federal pesticide registrations, was able to extract involuntary cancellation terms from Registrants and call them "voluntary" is therefore immaterial; EPA cannot make new law through the conditions to a pesticide registration.

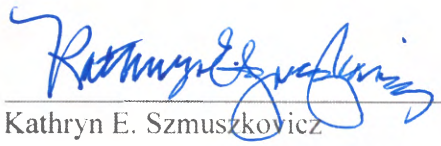
Bayer, Nichino, and the countless other companies holding FIFRA registrations are looking to this proceeding to see whether they will be afforded *in practice* the rights they have been guaranteed by Congress. Registrants do not here seek a finding from the ALJ that flubendiamide meets the Registration Standard. Registrants seek only to be afforded the cancellation process they are guaranteed by law. If provided that process, including prior consultation with USDA, independent science review by the SAP, and the right to present evidence and testimony challenging EPA's cancellation determination, Bayer and Nichino are confident they would demonstrate that continued registration of flubendiamide would not cause unreasonable adverse effects and meets the FIFRA Registration Standard.

For these reasons, Bayer and Nichino request that the ALJ issue an accelerated decision denying EPA's proposed cancellation, finding that the forced "voluntary" cancellation condition approach is unlawful and contrary to FIFRA, and ordering EPA to follow the FIFRA § 6(b)

cancellation process if it wishes to cancel the flubendiamide registrations for failure to meet the Registration Standard.

Dated: April 11, 2016

Respectfully Submitted,



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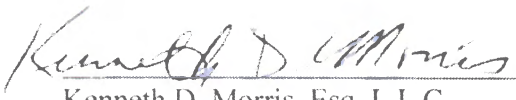

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