UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(e) Notice of Intent to Cancel Flubendiamide Registrations	)))))	**FIFRA Docket No. HQ-2016-0001**

MOTION TO FILE AN AMICUS CURIAE BRIEF AND MEMORANDUM OF AMICUS CROPLIFE AMERICA IN SUPPORT OF BAYER CROPSCIENCE LP'S REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS

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I. Motion to File an Amicus Curiae Brief

Pursuant to the General Rules of Practice Concerning Proceedings,[1] CropLife America ("CropLife") moves that the Administrative Law Judge ("ALJ") accept the amicus memorandum set forth below in support of Bayer CropScience LP's ("Bayer") and Nichino America, Inc.'s ("Nichino") (referred to collectively as "Registrants" or "Bayer" for ease of reference) March 31, 2016, objection to the U.S. Environmental Protection Agency's ("EPA" or "the Agency") proposed cancellation of all registrations issued under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*, for products containing the active ingredient flubendiamide. CropLife is the national not-for-profit trade association representing the companies that develop, manufacture, formulate and distribute crop protection chemicals and plant science solutions for agriculture and pest management in the United States. Its member companies produce, sell and distribute virtually all the crop protection products, including pesticides, used by American farmers.

Registrations under FIFRA are licenses that authorize the distribution and sale of pesticide products. EPA grants a registration for a pesticide product only after extensively analyzing the pesticide's potential effects on human health and the environment, and only if, based on that analysis, the Agency concludes that the product will not cause "unreasonable adverse effects on the environment" (the FIFRA "Registration Standard"). CropLife America members commit substantial financial resources in research, development and testing to support EPA's scientific assessments that are required to approve pesticide product registrations. Each new pesticide registration can require submission to EPA of up to 100 studies or more,

[1] 40 C.F. R. § 164.31.

implicating costs that can exceed $100 million. As a result, pesticide registrations constitute significant property interests that registrants have a strong interest in maintaining.

FIFRA provides EPA with the authority to cancel registrations and, thus, force the removal of pesticide products from the market. This has the effect of terminating the registrant's property interest in its registration and erasing the registrant's substantial investment in its product. In addition, because cancelled products generally can no longer be sold or distributed in the United States, cancellation of a product's registration means that growers lose access to a valuable tool essential to crop production. Because of the seriousness of these impacts, Congress established a carefully prescribed process in FIFRA that EPA must follow if it decides that cancellation of a product's registration is necessary.

The pesticide products at issue here contain the active ingredient flubendiamide, and are registered for use on more than 200 crops. EPA issued a time-limited, five-year conditional registration for flubendiamide on July 31, 2008 under FIFRA § 3(c)(7), 7 U.S.C. § 136a(c)(7). (*See* Exhibit 10).[2] In granting the conditional registration, EPA was required to make a statutory finding that the product did not "cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest." *See* 7 U.S.C. § 136a(c)(7)(C). EPA made this finding when it issued the flubendiamide registration, but the Agency also concluded that it needed additional data to fully evaluate flubendiamide's potential impacts on aquatic environments and organisms, as well as the efficacy of vegetative buffers for flubendiamide use.

[2] The flubendiamide registrations are: Belt® SC Insecticide (EPA Reg. No. 264-1025), Flubendiamide Technical (EPA Reg. No. 71711-26), Vetica® Insecticide (EPA Reg. No. 71711-32), and Tourismo® Insecticide (EPA Reg. No. 71711-33). Nihon Nohyaku Co., Ltd. ("NNC") invented flubendiamide. Bayer has an agreement with NNC and Nichino to license, develop, and market flubendiamide under which Bayer serves as Nichino's regulatory agent for flubendiamide and sells products containing flubendiamide under the Belt® brand name.

Consequently, as a condition of granting the flubendiamide registration, EPA required Bayer to conduct four studies between July 2010 and July 2012 to collect the desired data. (Exhibit 10, Letter from L. Rossi, EPA to D. Larochelle, Bayer CropScience LP (July 31, 2008) ("Preliminary Acceptance Letter")). [3] Bayer satisfied this condition and submitted the required data to EPA in a timely manner. (Exhibit 14, Letter from R. Gebken, EPA to N. Delaney, Bayer CropScience LP (Aug. 26, 2015)).

The instant matter stems from EPA's January 29, 2016 letter to Bayer, in which the Agency ordered Bayer to "voluntarily" request cancellation of its flubendiamide registrations due to EPA's determination that the product poses "unreasonable adverse effects on the environment." (Exhibit 21, Letter from J. Housenger, EPA, to N. Delaney, Bayer CropScience LP (Jan. 29, 2016) ("Cancellation Letter")). After Bayer refused to do so, EPA issued a Notice of Intent to Cancel ("NOIC") for the flubendiamide registrations. (*See* Exhibit 1, *Flubendiamide; Notice of Intent to Cancel Pesticide Registrations*, 81 Fed. Reg. 11,558 (Mar. 4, 2016)). EPA's asserted rationale for issuing the NOIC is that Bayer was required to, but did not, "voluntarily" seek cancellation of its registrations. EPA bases this assertion on an unlawful and overly-broad "condition" that EPA included in the flubendiamide registration, which purports to require Bayer to immediately seek "voluntary" cancellation if, for any reason, the Agency determines that flubendiamide does not meet the FIFRA Registration Standard.

EPA's actions in this matter are unprecedented and have potentially far-reaching and adverse consequences for CropLife America's members and for U.S. agriculture more broadly. Fundamental to the success of modern agriculture is the reliable availability of safe and effective

[3] Exhibits referenced herein correspond to those filed in conjunction with the REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS BY BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

pest control products. Suddenly removing an EPA-approved pest control product from the market can cause severe disruptions for growers as well as registrants. Recognizing this, Congress prescribed in FIFRA very specific procedures that EPA must follow to cancel the registration of a pesticide product if the Agency concludes that the product no longer meets the FIFRA Registration Standard. *See* 7 U.S.C. § 136d(b); 40 C.F.R. Part 164. That process requires (i) that EPA give prior notification to the U.S. Department of Agriculture ("USDA") to allow that agency to weigh in on potential impacts of cancellation on domestic agriculture, *id.*; (ii) that EPA obtain review by the Scientific Advisory Panel ("SAP") to ensure that EPA's risk assessment is scientifically sound, *id.* § 136w(d); and (iii) that EPA provide for a full evidentiary hearing before a neutral ALJ to evaluate the appropriateness of EPA's "unreasonable adverse effects" determination, with the benefit of USDA and SAP input, *id.* § 136d(b), (d); 40 C.F.R. Part 164.

Here, EPA is attempting to short-circuit the carefully designed process set forth in FIFRA Section 6(b), 7 U.S.C. § 136d(b), which Congress specifically intended the Agency to follow in instances where EPA concludes that a pesticide no longer meets the FIFRA Registration Standard. Instead of following the process Congress intended, EPA seeks to invoke the truncated process of FIFRA Section 6(e), 7 U.S.C. § 136d(e), which does not provide for input by USDA, does not require review of EPA's "unreasonable risk" determination by the Scientific Advisory Panel, and does not allow for a full evidentiary hearing before a neutral ALJ to evaluate the appropriateness of EPA's "unreasonable risk" determination. Congress included this pared down process in Section 6(e) for the very specific, and very narrow, purpose of ensuring that registrants make adequate progress toward generating required data or otherwise fulfilling a condition of registration, and ensuring that those data are generated or other

conditions are satisfied within the timeframe set forth in the registration. Congress definitively did not intend the streamlined process of Section 6(e) to be used in instances where EPA proposes cancellation based on a pesticide's purported failure to satisfy the FIFRA Registration Standard.

If EPA's attempt to bypass the procedure that Congress intended is affirmed by this body, it would have significant immediate and long-term negative implications for CropLife's member companies and for agriculture generally. For this reason, CropLife requests that it be permitted to participate as *amicus curiae* in this case to defend this important interest of its member companies. CropLife's *amicus curiae* Memorandum in Support of Registrants follows below.

II. Statutory Background

A. Conditional Registration and FIFRA § 6(e) Proceedings

EPA will register a pesticide product only if it determines that sufficient data are available to conclude that, *inter alia*, the pesticide will "not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). But the registration process—including the generation of voluminous amounts of scientific data by the registrant and review by EPA—can take years to complete, meaning growers are deprived of newer and oftentimes more environmentally-benign products in the meantime. Congress created an alternative pathway called conditional registration that allows new pesticide products to move to market and into the hands of growers in a timeframe that meets grower needs, while also assuring that the FIFRA Registration Standard is satisfied. *See id.* § 136a(c)(7). As is relevant here, conditional registration is appropriate 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)." *Id.* § 136a(c)(7)(C).

As with unconditional registration, EPA must make an initial finding that use of the pesticide product during the conditional registration period "will not cause any unreasonable adverse effect on the environment." In addition, the Agency must also determine that use of the pesticide is "in the public interest." *Id.* But unlike unconditional registration, the conditional registrant assumes continuing obligations over the course of a specified time period, set forth as conditions of registration. While the statute does not expressly restrict the conditions EPA may impose, FIFRA § 3(c)(7)(C) makes clear that Congress' primary concern was with the submission of data to assist EPA in determining whether risk criteria are met. *See id.* § 136a(c)(7)(C).

FIFRA establishes a streamlined process for canceling a conditional registration in limited circumstances. Under Section 6(e), EPA may cancel the registration if (i) the registrant is not making sufficient progress toward satisfying a condition (*e.g.*, not taking the steps necessary to generate data), or (ii) the registrant fails to satisfy a condition (*e.g.*, generate a study) within the time allotted. *Id.* § 136d(e)(1). A cancellation under Section 6(e) shall become final and effective at the end of 30 days from the date EPA issues a notice of intent to cancel, unless the registrant requests a hearing. *Id.* § 136d(e)(2). But the scope of the hearing is narrow, and limited to a determination of whether the registrant has taken the necessary steps to comply with a condition, whether the condition has, in fact, been satisfied, and whether a proposed existing stocks determination is consistent with FIFRA. *Id.* Moreover, a Section 6(e) hearing must be completed within 75 days of the hearing request. *Id.*

In short, a Section 6(e) hearing is not a forum to litigate the merits of a product's safety—*i.e.*, whether it has an "unreasonable adverse effect on the environment"—or whether its registration is otherwise in the public interest. A Section 6(e) hearing is narrowly limited to the evaluation of an existing stocks determination and the resolution of whether the registrant has complied with conditions set forth in the original conditional registration approval.

B. FIFRA § 6(b) Proceedings For Cancelling a Product Registration

While FIFRA § 6(e) does not provide for a procedure to evaluate an EPA decision to cancel a registration due to alleged nonconformance with the FIFRA Registration Standard—*i.e.*, due to a finding of "unreasonable adverse effects on the environment"—Section 6(b) does. Under that provision, Congress established "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). That process involves consultation with other agencies, solicitation of input from expert scientific bodies, and the opportunity for a full administrative hearing on the cancellation. For example, EPA must consult with the Secretary of Agriculture regarding the impact of the cancellation on "production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." 7 U.S.C. § 136d(b). EPA must also grant a request by the registrant for a full administrative hearing on EPA's determination. 40 C.F.R. § 164.20(a). That hearing affords both sides the arsenal of evidentiary tools necessary to defend or challenge the factual and scientific bases for EPA's finding, including the opportunity to conduct discovery, call expert and other witnesses, and introduce all "relevant, competent and material evidence." *Id.* §§ 164.50; 164.51; 164.81. And unlike the truncated procedure set forth under Section 6(e), a Section 6(b) hearing is not time-limited.

Moreover, in recognition of the technical and scientific nature of the inquiry, the Section 6(b) process requires EPA to provide a NOIC to an independent Scientific Advisory Panel, which is comprised of seven scientific experts nominated by the EPA Administrator from a list provided by the National Institutes of Health and by the National Science Foundation. 7 U.S.C. § 136w(d). That panel may issue its expert analysis in the form of published comments "as to the impact on health and the environment of the action proposed." *Id.* § 136w(d)(1). Similarly, the ALJ adjudicating the dispute may refer questions of scientific fact to a committee designated by the National Academy of Sciences. 40 C.F.R. §§ 164.50(e); 164.81(b). That committee then issues an evidentiary report based on its expert findings. *Id.* § 164.81(b). This multi-layered, independent process ensures that EPA's decision to cancel a product registration because the product no longer meets the FIFRA Registration Standard (*i.e.*, because it purportedly causes an "unreasonable adverse effect") is fully vetted through a rigorous, third-party scientific review.

Finally, FIFRA entitles the registrant to additional procedural safeguards should EPA ultimately issue a final cancellation order after a hearing, which order is subject to judicial review in the federal Court of Appeals. 7 U.S.C. § 136n(b).

In short, Congress established a comprehensive procedure under FIFRA § 6(b) to ensure that a registrant receives due process prior to cancellation of a pesticide product's registration based on EPA's finding that the product "causes unreasonable adverse effects on the environment." As discussed below, EPA has failed to satisfy that process or any of its elements here.

III. Factual Background

A. Conditional Registration of Flubendiamide

As set forth in its July 31, 2008 Preliminary Acceptance Letter describing the terms and conditions for registration of flubendiamide, EPA registered flubendiamide in 2008 under FIFRA § 3(c)(7)(C), as a conditional registration of a new active ingredient. As required under FIFRA, EPA found that the registration of flubendiamide was in the public interest and would not cause unreasonable adverse effects on the environment, and therefore granted a registration for five years to allow Registrants sufficient time to generate and submit additional data to address potential persistence. (*See* Exhibit 10, Preliminary Acceptance Letter).

The Preliminary Acceptance Letter also stated that each Registrant "understands and agrees that the time-limited registration of the flubendiamide [products] shall be cancelled if the Agency determines that the continued use of flubendiamide will result in unreasonable adverse effects on the environment." (Exhibit 10, Preliminary Acceptance Letter at ¶ 5). A few paragraphs later, EPA explained that upon its review of the data the Registrants were required to generate, EPA would follow one of three routes:

> (1) Approve the registration of the flubendiamide [products] unconditionally, notwithstanding any restrictions that are deemed necessary; or
>
> (2) The EPA and [Registrant] will mutually agree on a path forward, revising or providing additional data under a conditional registration; or
>
> (3) The Agency will accept the voluntary cancellation of the time-limited registration of the flubendiamide [products].

(Exhibit 10, Preliminary Acceptance Letter at ¶¶ 6(c), 8(c)). The letter then states that:

> If, after EPA's review of the data as set forth . . . above, the Agency makes a determination that further registration of the flubendiamide [products] will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, [Registrant] will

> submit a request for voluntary cancellation of the flubendiamide product registration[s]. That request shall include a statement that [Registrant] recognizes and agrees that the cancellation request is irrevocable.

(Exhibit 10, Preliminary Acceptance Letter at ¶¶ 6(d), 8(d)).

Consistent with the Preliminary Acceptance Letter, Registrants generated the required data and conferred with EPA on all required studies and their results. Registrants consistently submitted the data required by the original conditions, and EPA repeatedly extended the original September 1, 2013 "expiration" date, up until its January 29, 2016 demand for voluntary cancellation of flubendiamide. (*See* Exhibits 12, 14, 16 & 20).

B. EPA's Demand for Voluntary Cancellation

On January 29, 2016, EPA issued a letter attaching a Decision Memorandum notifying Registrants of its unilateral determination that "further registration of the flubendiamide technical and end-use products would result in unreasonable adverse effects to the environment," thereby triggering the "condition" requiring Registrants to now "voluntarily" request cancellation of their flubendiamide registrations. (Exhibit 25, Cancellation Letter at 1). In that same letter, EPA noted that "if the conditions of registration are not complied with, the registration for all flubendiamide products would be subject to cancellation in accordance with section 6(e) of FIFRA." *Id.*

On February 5, 2016, registrants notified EPA that because the voluntary cancellation condition is unlawful, they would not submit such a cancellation request. (Exhibit 22, Letter from D. Sargent, Bayer CropScience LP, to J. Housenger, EPA (Feb. 5, 2016)). Registrants also informed EPA that if the Agency had now for the first time concluded that flubendiamide causes "unreasonable adverse effects," then "EPA must initiate the normal cancellation process under

FIFRA Section 6(b)." *Id.* at 2. Registrants further maintained that flubendiamide does not pose unreasonable adverse effects to the environment. *Id.*

In its March 4, 2016 NOIC, EPA made clear that it was cancelling the flubendiamide registrations for Registrants' failure to meet the condition "obligat[ing] the registrants to expeditiously request voluntary cancellation of the registrations if EPA notified them that EPA determined the registrations did not meet the FIFRA standard for registration." (Exhibit 1, 81 Fed. Reg. at 11,559). While EPA noted that Registrants would be entitled to a hearing under FIFRA § 6(e) to contest this cancellation, it clarified that

> [t]he scope of a hearing under FIFRA § 6(e) is quite narrow; FIFRA provides that the only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided . . . .

Id.

Thus, under the framework noticed by EPA, Registrants would be able to request a hearing to discuss whether they had met the condition in issue—the "condition" to voluntarily cancel the flubendiamide registrations—and nothing more, leaving EPA's determination that flubendiamide has "unreasonable adverse effects" immune from review.

IV. Argument

A. EPA Cannot Invoke FIFRA § 6(e) Proceedings For Cancellation Based on Alleged Unreasonable Adverse Effects on the Environment

1. The Plain Language and Structure of FIFRA Require EPA To Conduct Cancellation Proceedings Based on an "Unreasonable Adverse Effects" Determination Under FIFRA § 6(b), Not § 6(e)

EPA's use of FIFRA § 6(e) to cancel Bayer's registration is unlawful because it bypasses the specific cancellation procedure set forth under FIFRA § 6(b) in favor of the abridged Section 6(e) procedure that is more expedient for EPA. EPA's attempt to force this proceeding through

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

First, as a matter of pure textual interpretation, Congress made clear that cancellation of a product registration due to alleged "unreasonable adverse effects on the environment" must follow the procedure set forth in Section 6(b). That provision states that "[i]f it appears to the Administrator that a pesticide . . . generally causes unreasonable adverse effects on the environment, the Administrator may" either issue a notice of intent to cancel the registration or hold a hearing to determine whether the registration should be canceled. 7 U.S.C. § 136d(b). If the Administrator opts not to hold a hearing, a registrant is nonetheless entitled to one upon request. 40 C.F.R. § 164.20(a). As discussed in Part II.b, *supra*, Section 6(b) "imposes certain obligations on EPA before it may issue a notice of intent to cancel . . . and . . . entitles the registrant to notice, a hearing and other procedural protections before EPA can make a final decision on cancellation." *Reckitt*, 762 F. Supp. 2d at 43 (emphasis added). EPA's action here runs counter to Section 6(b)'s unambiguous text.

Section 6(e)'s language provides EPA no comfort either. To the contrary, Section 6(e)'s plain language makes clear that FIFRA's streamlined cancellation procedure is appropriate only in two limited scenarios: (i) where the registrant has failed to pursue appropriate action toward

fulfilling a condition, or (ii) where a condition has not been met by the end of the period provided. 7 U.S.C. § 136d(e). EPA's determination that a pesticide has "unreasonable adverse effects" qualifies under neither scenario. Nor can EPA square that circle simply by attaching that determination to a "condition" of "voluntary" cancellation upon such a finding, particularly where the statute elsewhere provides for a much more robust process.

In short, FIFRA's plain text belies EPA's attempt to bypass the due process protections ensured under Section 6(b). Because Congress has "directly spoken to the precise question at issue," committing cancellations pursuant to an "unreasonable adverse effects" finding to Section 6(b), EPA acts unlawfully by circumventing that process under Section 6(e). *See Chevron, U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43 (1984).

Second, Congress' use of specific language in Section 6(b) governing cancellations in the event of an "unreasonable adverse effects" determination and its utter silence on the issue under Section 6(e) is strong evidence that Congress intended for Section 6(b) to govern. It is a fundamental canon of statutory construction that "[s]pecific terms prevail over the general in the same or another statute." *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222, 228–29 (1957) (internal quotation marks omitted). EPA therefore cannot ignore the specific procedure laid out in Section 6(b) simply because another statutory provision is written in such general terms that it does not expressly *prohibit* EPA's preferred course of action.

This canon of statutory construction is all the more compelling where, as here, the Agency's preferred approach effectively negates Congress' express and specific command, thereby robbing Section 6(b) of independent meaning. "It is [the court's] duty to give effect, if possible, to every clause and word of a statute, rather than to emasculate an entire section." *United States v. Menasche*, 348 U.S. 528, 538-39 (1955) (internal quotation marks and citations

omitted). Yet EPA has effectively read Section 6(b) right out of the statute. That provision has no independent meaning if EPA can summarily cancel a product registration on the same basis—*i.e.*, with an "unreasonable adverse effects" determination—under Section 6(e). Worse still, under EPA's interpretation, the agency is immunized from any challenge to its determination, an outcome Congress affirmatively rejected by establishing a detailed and multi-tiered independent review process for just such a circumstance.

Third, EPA's construction runs afoul of yet another canon of statutory construction, namely that statutory provisions should be read as part of "a symmetrical and coherent regulatory scheme" that "fit[s] . . . all parts into a harmonious whole." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 133 (2000) (internal quotation marks omitted); *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme."). Before conditionally registering a product EPA must determine that, *inter alia*, it will "not cause any unreasonable adverse effect on the environment." 7 U.S.C. § 136a(c)(7)(C). Section 6(b) uses precisely the same language—"unreasonable adverse effects on the environment"—in establishing the reverse process for canceling a registration. *Id.* § 136d(b). Congress' use of the same language in both provisions indicates that they should be read together, not as siloed directives separate and apart from each other. *Cf. Davis*, 489 U.S. at 809 (reading two parts of a statutory provision together that use the same language). Accordingly, if EPA determines that a pesticide product has "unreasonable adverse effects on the environment," the conditional registration provision directs EPA to the cancellation provision set forth in Section 6(b). EPA's approach here, however, breaks that link, thereby disassembling Congress' coherent statutory design.

In sum, by attempting to shoehorn the flubendiamide cancellation process under Section 6(e), EPA unlawfully seeks to circumvent the due process unambiguously guaranteed by Congress under Section 6(b). Moreover, EPA's unlawful use of the Section 6(e) process is not somehow rendered acceptable because it was included as a "condition" in the flubendiamide registration. *See Sierra Club v. EPA*, 762 F.3d 971, 973-74 (9th Cir. 2014) (an agency's imposition of unlawful requirements in a permit does not render those requirements lawful).

2. Other Evidence of Congressional Intent and Judicial Interpretations Do Not Support EPA's Action

The legislative history is consistent with the plain text of the statute, and reflects Congress's intent to apply the robust cancellation procedures under Section 6(b) to *all* cancellation proceedings based on "unreasonable adverse effects" determinations, including for new products and for conditional registrations.

The cancellation provisions of Section 6(b) are part of the bedrock of FIFRA, and have been embedded in the statute for nearly five decades. Congress gave Section 6(b) extensive consideration when it substantially amended FIFRA in 1972 through its enactment of the Federal Environmental Pesticide Control Act ("FEPCA"). H.R. Rep. No. 92-511, at 22-23 (1971); S. Rep. No. 92-838, pt. 1, at 23-24 (1972); S. Rep. No. 92-970, at 36-38 (1972); and H. R. Rep. No. 92-1540, at 32 (1972) (Conf. Rep.). The 1975 amendments to FIFRA further bolstered Section 6(b) by requiring EPA to consider, among other things, the impact of pesticide cancellations on the production and costs of agricultural commodities, and to report its findings to the Secretary of Agriculture. In 1996, Congress amended Section 6(b) to require the input of the Department of Health and Human Services if the registration subject to cancellation (or change in classification) were to have an impact on public health.

The legislative history of Section 6(b), particularly leading to the 1975 amendments, sheds light on Congress' intent that Section 6(b) serve as the mechanism to cancel a registration based on "unreasonable adverse effects" on the environment, through a process requiring thorough consideration of various factors. By amending the statute over time to require collaboration and input from different agencies, Congress added layers of process to protect the interests of various stakeholders. *See, e.g.*, H. R. Rep. No. 94-497 to Accompany H.R. 8841 (Sept. 19, 1975), at 36-37 (". . . under section 6(b) the Administrator must include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy . . . .").

In 1975 Congress added procedures to Section 6(b) mandating that EPA "provide the Secretary of Agriculture with a copy of such [cancellation] notice and analysis of such impact on the agricultural economy." 7 U.S.C. § 136d(b)(2). As reports from both the Senate and House leading up to them demonstrate, the 1975 Amendments were largely focused on ensuring that EPA's decisions accounted for impacts on the agricultural economy by coordinating with other agencies:

> The provisions in the bill for advance notification of the Secretary of Agriculture of proposed cancellations and changes in classification and of regulations, are in response to the often-stated concern that EPA has not adequately considered the impact of its actions' on agriculture.

S. Rep. No. 94-452, at 8 (1975).

The House Report further emphasized the importance of thoroughly considering the agricultural economy when making cancellation, among other, determinations under FIFRA:

> There was, however, a strong belief among many witnesses that the impact on the agricultural economy of decisions in EPA was not fully developed by EPA and was not given sufficient recognition. The committee amendment meets this concern. It

> seeks to involve the Department of Agriculture in important phases of the decision-making process, in rulemaking and adjudication, and tighten the degree of cooperation between the agencies. By requiring EPA to seek Agriculture's comments, the substitute proposal assures that the impact on the agricultural economy of actions taken by EPA will be fully developed.

H. R. Rep. 94-497, at 6 (1975). Thus, to increase the protection of various stakeholders and sectors of the economy affected by EPA cancellations of pesticides, Congress over time built out Section 6(b) to provide greater and more developed procedural safeguards.

Section 6(b) and its history require a robust cancellation process to address the unique nature of each registration. As representatives of EPA testified during the lead up to the 1975 amendments, a hearing on the merits is central to such a process:

> The very nature of the pesticides regulatory process requires that the Agency decision-making process be collective, applying the several disciplines and areas of expertise to achieve proper evaluation of risks and benefits, and sound implementation of the hearing process. . . . Where effects are suspected but not conclusively proven even after a hearing, an assessment would have to be made concerning the consequences of inaction should the suspected effects be actually demonstrated at a later date.

Federal Insecticide, Fungicide and Rodenticide Act Extension, Hearings Before the Subcomm. on Agric. Res. and Gen. Legis. of the S. Agric. and Forestry Comm. on S. 1629, 94th Cong. 32 (1975).

Public interest groups echoed the seriousness and importance of robust cancellation proceedings during hearings before the House Agriculture Committee in 1975, for example:

> Cancellation is by no means an impetuous or capricious decision. By the time the EPA issues a cancellation order it has collected enough information not only to justify its decision but also on the basis of which to win a prolonged administrative hearing. If the EPA does not feel it has adequate evidence to win the case (as happened with 2,4,5-T) the cancellation order either does not get issued or is later withdrawn. Furthermore, the consumer of

> pesticides assumes that all products allowed to be sold on the market are "safe", as determined by the EPA.

Federal Insecticide, Fungicide and Rodenticide Act Extension, Hearings Before the H. Agric. Comm., 94th Cong. 70 (1975) (statement from Stephanie Harris, Public Citizen's Health Research Group).

Courts and agency decisions have also recognized that FIFRA mandates a robust process for cancellation proceedings that allows for thorough consideration of the impacts of removing an EPA-approved pesticide from the market before the product's registration can be cancelled. For example, in *McGill v. E.P.A.*, the Fifth Circuit recognized that:

> Although the [1972] revisions were aimed at increasing the EPA's ability to protect the environment, ***they were also designed to assure that the economic interests of farmers and other consumers would be fully considered before any pesticide was withdrawn from the market. For this reason, Congress required that any final action taken to cancel or change a registration take into account the impact on the production and prices of agricultural commodities and retail food prices***. In addition, the Administrator of the EPA is required to notify the Secretary of Agriculture before any hearings on particular pesticides are announced, and the Secretary is permitted to comment on the proposed hearings in writing.

593 F.2d 631, 635 (5th Cir. 1979) (citing 7 U.S.C. § 136d(b) and General Explanation of H.R. 10729, S. Rep. No. 92-838, 92d Cong., 2d Sess. (1972)) (emphasis added); *see also In the Matter of Chapman Chem. Co. et al*, 1 E.A.D. 199, at *3 (E.P.A. Feb. 17, 1976) (" . . . before any pesticide can be cancelled under the FIFRA the Administrator must be persuaded that the risks to man or the environment from continued use of the pesticide outweigh the benefits of its continued use.").

Courts have also highlighted the impropriety of circumventing Section 6(b). In 2011, the District Court for the District of Columbia in *Reckitt Benckiser, Inc. v. Jackson* ruled that

Congress did not intend to give EPA the authority under FIFRA to bring a misbranding action in place of a cancellation proceeding. 762 F. Supp. 2d at 42. EPA had issued Plaintiff Reckitt a "Risk Mitigation Decision" (RMD) for its rodenticides, to address concerns about the potential for unreasonable adverse effects associated with Reckitt's registered products. As part of the RMD, EPA required Reckitt to indicate whether it intended to amend its subject registrations to conform to the RMD or, if not, to voluntarily cancel the particular rodenticide. After Reckitt responded that it did not intend to comply with the RMD, it requested EPA to commence the proper process set forth in Section 6(b). EPA declined to do so, and threatened to bring an abbreviated, misbranding action instead. *Id.* at 39.

Reckitt sought declaratory and injunctive relief to prevent EPA from bringing a misbranding action against its products *in lieu* of initiating Section 6(b) cancellation proceedings. On remand (due to jurisdictional issues) from the Court of Appeals, the district court granted Reckitt's motion for summary judgment, and required EPA to undertake the administrative cancellation procedures required by Section 6(b). The Court held that Section 6(b) establishes "a detailed, multi-step process that EPA *must* follow when it wants to cancel or suspend a registration." *Reckitt*, 762 F. Supp. 2d at 42 (emphasis in original). The court admonished EPA for its attempt to "bypass[] cancellation proceedings' and effect[ively] cancel[] the registrations without following the regulatory procedures provided in Section 6. . . . 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." *Id.* at 43 (internal citations omitted).

In the instant case, EPA is again attempting to remove a registered pesticide from the market using a truncated process that may be expedient for the Agency but that circumvents the

very carefully designed process Congress specifically intended EPA to follow when using an "unreasonable adverse effects" determination as the basis for canceling a product's registration. As the legislative history and case law makes plain, Congress never intended the conditional registration provisions of FIFRA to be used in this manner.

B. Congress Did Not Intend Conditional Registrations to Be Used By EPA to Summarily Force "Voluntary" Cancellations Based on Unilateral "Unreasonable Adverse Effects" Determinations

Congress created the conditional registration process for new pesticides to promote innovation while at the same time assuring protection of human health and the environment. Before it can grant conditional registration of a new pesticide under Section 3(c)(7)(C) of FIFRA, EPA must determine that the pesticide will "not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest." 7 U.S.C. § 136a(c)(7)(C). Under the statute, conditional registration is appropriate 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)." *Id.* § 136a(c)(7)(C). Thus, Congress anticipated that conditional registration would be employed as a way of providing registrants with additional time to generate and submit data relevant to the terms of registration, so as to make potentially important new tools available to growers sooner.

In tandem with this provision, Congress created the abbreviated cancellation process of Section 6(e), to address situations in which a registrant was not making adequate progress toward fulfilling its data generation requirements or when a registrant failed entirely to generate the required data within the time allotted as part of the condition of registration. Nowhere did

Congress indicate that the abbreviated process of Section 6(e) is intended to be used when EPA concludes that a registered product causes "unreasonable adverse effects."

Comments made during the Senate debate leading up to the passage of the 1978 amendments to FIFRA confirm that Congress intended the conditional registration process to promote product innovation by permitting a conditional registrant to place on the market a product that meets the FIFRA Registration Standard and provides a public benefit while the registrant continues to develop additional data needed for full evaluation of the product:

> First, a conditional registration can never be granted unless the product has passed every test that was required by EPA except a test requirement imposed too recently to have been met. The Agency does change its data requirements. What provides an appropriate basis on which to reach scientific conclusions about toxicity today, the scientist may wish to augment tomorrow. More reliable testing methods are developed. . . . New requirements do not invalidate conclusions reached before the requirement has been conceived and imposed by EPA. A new pesticide may enter the regulatory process at a time these requirements are changing. This amendment recognizes that in fact some cases the safety of such a product could be more clearly established than that of the existing registered products. Second, as with all other registrations, the Administrator has to find the pesticide would not have an unreasonable adverse effect on the environment. Finally, a more stringent test also applies. The administrator must be shown evidence sufficient to find that this confidential registration is "in the public interest.

123 Cong. Rec. S13,090-92 (1978) (Debate re Senate Passage of S. 1678 as Amended, July 29, 1977).

The legislative history further makes clear that the most significant aspect of conditional registration that sets it apart from unconditional registration is that, with a conditional registration, the registrant is still gathering supporting data for submission to EPA. *See, e.g.,* H. R. Rep. No. 95-343, Part I at 10-11 (1977); S. Rep. 95-343, at 21 (1977); *Federal Pesticide Act of 1978, Comm. on Agric., Nutrition, and Forestry, U.S. Senate*, 95th Cong., 2nd Sess., 181

(Comm. Print 1979) (discussed *infra* in further detail). It follows that the special abbreviated process set aside for cancellation of a conditional registration under Section 6(e) should also apply to that data generation requirement of a conditional registration, to ensure that the data are, in fact, being generated by the registrant and to ensure that the data are submitted within the time allotted by EPA.

The same passages from the legislative history that discuss the data requirements for conditional registration as its distinguishing feature also address the need for an expedited cancellation process, indicating that the expedited cancellation proceedings of Section 6(e) are intended specifically to address the data-driven conditions of conditional registrations, and nothing more. For example, the Committee on Agriculture, Nutrition, and Forestry noted as follows regarding conditional registration:

> The Administrator would be permitted to grant a conditional registration [for a new pesticide] if all data needed for registration are available ***except for data requirements that were imposed after the application was made***. However, to insure that this conditional registration is only extended under safe conditions, the pesticide could not be registered unless: (1) It would not cause undue risks for the environment; (2) its registration was in the public interest; and (3) all data that have historically been required had been submitted. ***The subcommittee further agreed to the provision in S. 1678 that the Administrator could cancel conditional registrations with only limited notice, and any hearings on such cancellation would be limited to the issue of whether the conditions of the registrations have been met.***

Federal Pesticide Act of 1978, Comm. on Agric., Nutrition, and Forestry, U.S. Senate, 95th Cong., 2nd Sess., 181 (Comm. Print 1979) (excerpting the Committee's report on S. 1678, S. Rep. 95-334, 95th Cong., 1st Sess., 5-16 (1977)) (emphasis added). A House Report on a companion bill also links the abbreviated hearing procedures that were enacted in Section 6(e) to the data-driven conditions of conditional registration:

> In general, all new chemicals will have to meet the new data requirements which became effective in August 1975. There may be situations, however, where an applicant has completed most of the tests on a new chemical, ***but because of the imposition of a new testing requirement, he has been unable to complete all required testing***. Moreover, there may be a real need for use of the pesticide to avoid pest outbreaks. It is our opinion that in some of these cases it would be proper to allow conditional registration, if we have on hand most of the data and it indicates no unreasonable adverse effect, and if the public interest would be served by issuance of a conditional registration. . . . ***We strongly believe that the Agency should be required to cancel the registration if the conditions are not met within the appropriate time interval, and that any hearing on such a cancellation should be confined to whether or not the conditions were met*** and how existing stocks should be handled. Public resources should not be devoted to long, drawn-out cancellation procedures for these types of registrations

H. R. Rep. No. 95-343, Part I at 10-11 (1977) (emphasis added).

As the legislative history makes clear, Congress enacted in Section 6(e) an abbreviated process for cancelling conditional registrations—which could be invoked when a registrant either failed to make adequate progress in generating required data, or ultimately failed to submit the required data in a timely manner—to assure that data were generated in a timely manner.

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

- immunize itself against any substantive review of the Agency's "unreasonable adverse effects" determination;

- completely bypass the independent scrutiny that Congress required for such determinations in Section 6(b);
- cloak its unreasonable adverse effects determination as a "condition of registration" that requires the registrant to seek "voluntary" cancellation; and
- invoke Section 6(e) to limit any ALJ review to the artificially narrow question of whether or not the registrant sought "voluntary" cancellation.

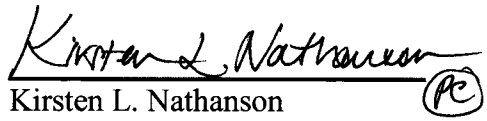
Yet, EPA employed this precise gambit with flubendiamide. The Congressional intent that devised conditional registration demands a dramatically different process and result.

V. CONCLUSION

For the foregoing reasons, CropLife respectfully urges the ALJ to grant Bayer's Request for Hearing, deny EPA's proposed cancellation of flubendiamide, deem EPA's voluntary cancellation condition to flubendiamide's registration unlawful, and require that EPA follow FIFRA's cancellation procedure set forth under FIFRA § 6(b) should it wish to pursue cancellation due to a finding of "unreasonable adverse effects on the environment."

Dated: April 11, 2016

Respectfully submitted,



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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 11th day of April, 2016, a true and correct copy of the foregoing MOTION TO FILE AN AMICUS CURIAE BRIEF AND MEMORANDUM OF AMICUS CROPLIFE AMERICA IN SUPPORT OF BAYER CROPSCIENCE LP'S REQUEST FOR HEARING AND STATEMENT OF OBJECTIONS was filed electronically using the EPA OALJ e-filing system; and served in the following manner to the below addressees:

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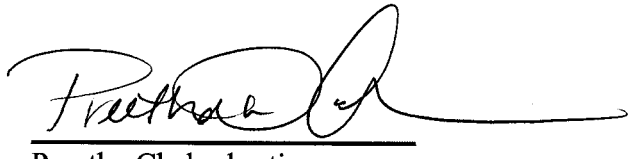

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