

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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In re FIFRA Section 6(e) Notice of Intent to	)	Docket No. FIFRA-HQ-2016-001
Cancel Flubendiamide Conditional Registrations	)	
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**MOTION FOR LEAVE TO FILE AN AMICUS CURIAE BRIEF AND MEMORANDUM OF AMICUS THE CENTER FOR BIOLOGICAL DIVERSITY IN SUPPORT OF DEFENDANT ENVIRONMENTAL PROTECTION AGENCY'S CANCELLATION OF CONDITIONAL REGISTRATIONS FOR PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT FLUBENDIAMIDE**

**I. MOTION FOR LEAVE TO FILE AN AMICUS CURIAE BRIEF**

Pursuant to the General Rules of Practice Concerning Proceedings, 40 C.F. R. § 164.31, the Center for Biological Diversity (Center) moves that the Administrative Law Judge (ALJ) accept the amicus memorandum set forth below in support of the Environmental Protection Agency's (EPA or Agency's) decision to cancel four conditional registrations for pesticide products containing the active ingredient flubendiamide granted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*

**Interest of the Applicant**

The Center is a non-profit organization with 990,000 members and supporters committed to the preservation, protection, and restoration of native species and the ecosystems upon which they depend through science, policy, and environmental law. Based on the understanding that the health and vigor of human societies and the integrity of the natural environment are closely linked, the Center is working to secure a healthy, livable future. The Center's activities include public education, advocacy, and litigation to enforce environmental laws. For more than twenty-

five years, the Center has advocated for the federal government to conserve imperiled species consistent with the Endangered Species Act (ESA) and other applicable laws, such as FIFRA.

As it relates to these proceedings, the Center's Pesticides Reduction Campaign aims to secure programmatic changes in the pesticide registration process and to stop toxic pesticides from contaminating fish and wildlife habitats. The Center advocates that EPA has the duty and the authority to mitigate the adverse effects of pesticides to protect wildlife, human health, and the environment either with strong language in pesticide labels that restricts or prohibits uses or by denying or cancelling registered uses. The Center has worked to ensure that pesticide registrations minimize harms by commenting during the registration process, including submission of at least 100 comments to EPA concerning pesticides in the past year. The Center also develops reports and publications on the harms of pesticides, participates in relevant committees and work groups, and engages the public and other non-profit organizations to lend support to the campaign.

The Center, with others, intervened in the hearing to support of the EPA's Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products, 78 Fed. Reg. 8123 (Feb. 5, 2013). *In the Matter of Reckitt Benckiser LLC, et al.*, EPA FIFRA Docket No. 661. The Center also has initiated a series of lawsuits enforcing EPA's obligation to adhere to the Endangered Species Act in regulating pesticides.<sup>1</sup>

### **Relevance of the Brief to the Proceeding**

This case concerns EPA's decision to cancel four conditionally-granted registrations for pesticide products containing the active ingredient flubendiamide. The facts of the case are

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<sup>1</sup> See, e.g., *Center for Biological Diversity v. Johnson*, Case No. 02-1580-JSW (N.D. Cal.); *Center for Biological Diversity v. EPA*, Case No. 07-2794-JCS (N.D. Cal.); *Center for Biological Diversity v. EPA*, Case No. 11-293 (N.D. Cal.) *on appeal*, No. 14-16977 (9<sup>th</sup> Cir.); *Center for Biological Diversity, et al. v. EPA*, Nos. 14-1036 and 15-5168 (D.C. Cir.).

straightforward: in 2008 and 2009, despite having applied for full registration status, EPA instead granted Bayer Cropscience LP and Nichino America, Inc. (Bayer) a set of time-limited, conditional registrations for flubendiamide and the commercialized products thereof under FIFRA. Bayer was granted only a set of conditional registrations for flubendiamide because of substantial concerns about its mobility; stability and persistence; accumulation in soils, water columns, and sediments; and extremely toxic effects on aquatic invertebrates – concerns which put the pesticide in direct conflict with the minimum registration requirements of FIFRA. These conditional registrations were limited to a period of five years (later extended by agreement with EPA), and included a mandatory set of conditions. The conditional registrations included, among other things, the condition that at the end of the time period if EPA determined that unreasonable adverse effects to the environment continued to persist such that the pesticide could not meet the statutory demands of FIFRA, then Bayer must immediately request from EPA voluntary cancellation of the registrations. Bayer agreed to these terms by accepting the conditional registrations.

At the end of its conditional term, however, Bayer could not show unreasonable adverse effects to the environment did not persist due, in part, to flubendiamide's continuing extreme toxicity. Subject to the terms of the conditional registrations, EPA notified Bayer of its determination that the conditional flubendiamide registrations must be cancelled. Bayer explicitly refused to do so, triggering EPA to initiate the present cancellation proceedings. These proceedings were brought pursuant to section 6(e) of FIFRA, a section reserved expressly for the cancellation of conditional registrations – the category of registration at issue here.

Ignoring these facts, Bayer now comes to the ALJ with the conviction of a faultless victim, damaged by the whims of an administrative agency bent on stripping it of its "right" to

use, sell, and distribute flubendiamide products. Bayer's narrative is incorrect. The conditional registrations at issue granted Bayer no continuing "right" to use, sell, or distribute flubendiamide products. Rather, EPA granted Bayer a temporary authorization to sell flubendiamide, and a chance to prove that these products could meet the registration criteria of FIFRA, under certain conditions and within a certain time period. Bayer failed to do so, and for that there are consequences – statutory consequences prescribed by FIFRA and properly interpreted and applied by EPA.

The Center has a strong interest in this matter, and its knowledge and experience regarding pesticide use, pesticide registration, and the persistent adverse effects of flubendiamide on the environment, put it in a unique position to provide the ALJ with useful contextual information. Further, the Center's legal experience puts it in the position to provide valuable legal opinions regarding EPA's lawful interpretation and application of FIFRA to the facts of this case. *See, infra*, note 1. For these reasons, the Center requests that it be permitted to participate as *amicus curiae* in this case. The Center's *amicus curiae* Memorandum in Support of EPA follows below.

## **II. BACKGROUND**

### **Flubendiamide**

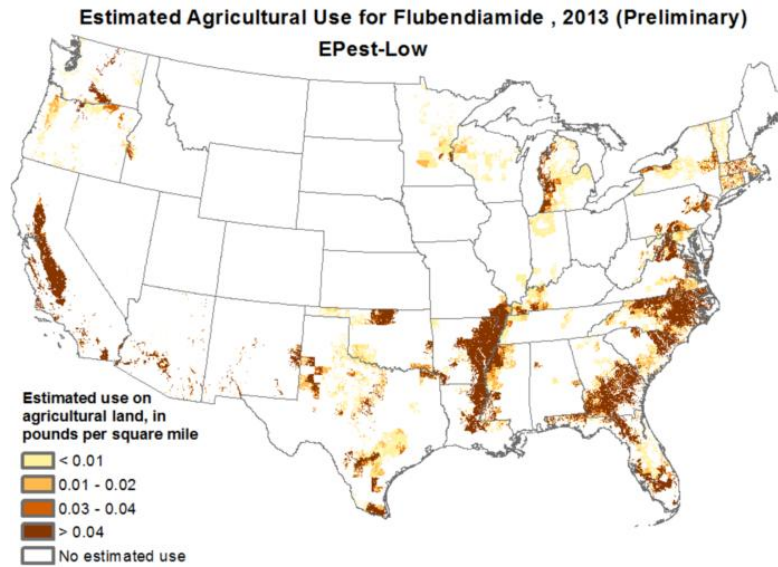
Flubendiamide is a chemical insecticide intended to kill caterpillars. Effects studies show that flubendiamide is chronically toxic to aquatic invertebrates. Exhibit 31, Motion for an Accelerated Decision by Bayer CropScience LP and Nichino America, Inc., *EPA EFED Flubendiamide: Ecological Risk Assessment Addendum* at 1 (Jan. 28, 2016) (hereafter ERA). Flubendiamide slowly converts to its degradate, des-iodo, which is ten times more toxic to aquatic invertebrates than flubendiamide and does not appreciably breakdown. *Id.* at 1-2. In a

series of risk assessments, EPA determined that flubendiamide and des-iodo have the potential for groundwater contamination, are directly introduced to surface waters from spray drift, and are likely to accumulate in soils, water column, and sediments. *Id.* at 2-3. In other words, the chronic toxicity will enter waters and soils and persist and accumulate in the environment. Each time, EPA concluded that the use of flubendiamide is a risk concern to freshwater invertebrates, in particular, benthic invertebrates. *Id.* EPA recently concluded that stream and river monitoring indicates widespread occurrence of flubendiamide and des-iodo, widespread potential for water quality impacts, and “significant effects to aquatic organisms due to the use of flubendiamide could potentially occur in as little as 2 years.” *Id.* at 17.

There are approximately 169 aquatic invertebrate species that are listed as protected under the ESA, 16 U.S.C. §§ 1531-1544. *See* Addendum (listing protected species). Of those 169 species, 143 are “endangered,” meaning that they are in danger of extinction. 16 U.S.C. § 1532(6). The remaining are “threatened,” meaning they are likely to become endangered in the foreseeable future. 16 U.S.C. § 1532(20).

EPA did not have sufficient information to conclude that the adverse effects of flubendiamide would not be unreasonable in order to unconditionally register it when Bayer first requested registration of this new pesticide. Instead, in 2008, EPA allowed a time-limited and conditional registration for aerial and ground applications on certain crops. ERA at 1. In granting this conditional registration, EPA failed to consider the adverse effects of flubendiamide on specific ESA-protected species and their critical habitat, despite the probability that the pesticide was likely to be used near these species and their habitat. EPA allowed a time-limited and conditional registration for aerial and ground applications on certain crops. *Id.*

Use on crops occurs in areas where ESA-protected and other aquatic species and their habitat likely exist.<sup>2</sup>



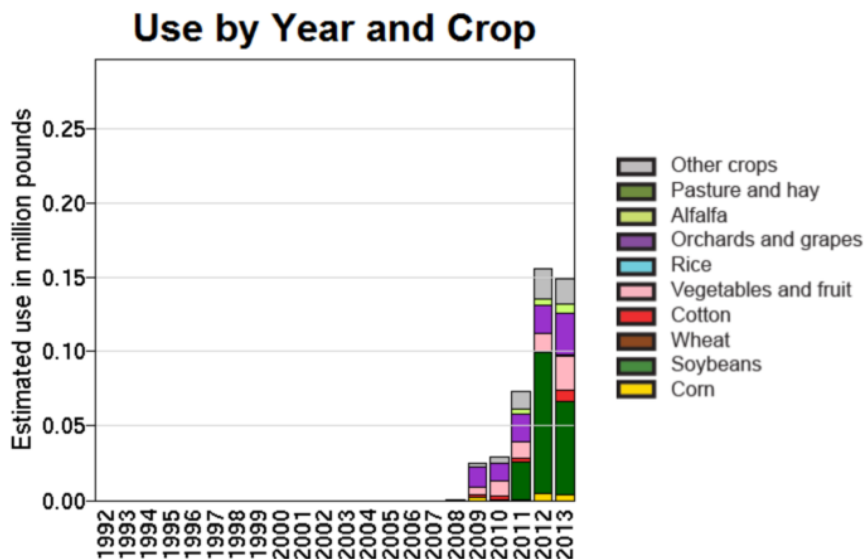
For example, there is substantial use in the Florida panhandle and southwest Georgia where the U.S. Fish & Wildlife Service has designated critical habitat for 15 protected mussel species.<sup>3</sup>



<sup>2</sup> USGS, National Water-Quality Assessment Program, Pesticide National Synthesis Project, [https://water.usgs.gov/nawqa/pnsp/usage/maps/show\\_map.php?year=2013&map=FLUBENDIAMIDE&hilo=L&disp=Flubendiamide](https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2013&map=FLUBENDIAMIDE&hilo=L&disp=Flubendiamide) (last visited Apr. 15, 2016)

<sup>3</sup>U.S. Fish & Wildlife Service, Overview Map of Critical Habitat (all species), [http://www.fws.gov/panamacity/resources/Overview%20Map%20of%20Critical%20Habitat%20\(all%20species\).pdf](http://www.fws.gov/panamacity/resources/Overview%20Map%20of%20Critical%20Habitat%20(all%20species).pdf) (last visited Apr. 15, 2016).

The use of flubendiamide has been steadily increasing since its conditional registration in 2008, doubling between 2010 and 2011, and then again between 2011 and 2012.<sup>4</sup>



The use of flubendiamide is likely to continue to increase the longer it remains conditionally registered and existing stocks are used. Such continued use will result in unreasonable adverse effects to the environment and is very likely to result in harm to protected species, which is prohibited by section 9 of the ESA.

### Legal Framework

Congress enacted FIFRA specifically to provide EPA with the methods and procedures necessary to safely and effectively examine and, as appropriate, approve pesticide chemicals for use, sale, and distribution. In observance of these objectives, and to evaluate the product's toxicity to humans and the environment, prior to its use, sale, or distribution all pesticides must be registered with the Agency. 7 U.S.C. § 136a(a). The registration process is designed to ensure that any pesticide entering the marketplace will, among other things, "perform its intended

<sup>4</sup> USGS, National Water-Quality Assessment Program, Pesticide National Synthesis Project [https://water.usgs.gov/nawqa/pnsp/usage/maps/show\\_map.php?year=2013&map=FLUBENDIAMIDE&hilo=L&disp=Flubendiamide](https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2013&map=FLUBENDIAMIDE&hilo=L&disp=Flubendiamide) (last visited Apr. 15, 2016).

function without unreasonable adverse effects on the environment;" that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment;" and that "its composition is such as to warrant the proposed claims for it." 7 U.S.C. § 136a(c)(5); *see also* 40 C.F.R. § 152.112. The burden of complying with the terms and requirements of this registration process is on the applicant.

In limited circumstances, if an applicant is unable to demonstrate that a new active ingredient meets any one or more of the criteria for registration, rather than denying the application outright, EPA may grant the applicant a conditional license to use, sell, and distribute a pesticide or pesticides. 7 U.S.C. § 136a(c)(7); 40 C.F.R. § 152.114. However, a conditional registration is not unbound.

A conditional registration includes a mandatory set of conditions and is only intended to last for a certain, limited period of time, as provided by the Administrator and incorporated into the terms of the conditional registration. *Id.* Specifically, a conditional registration is allowed under FIFRA only "on the condition" that by the end of the limited time period, the Administrator must receive the lacking data "and the data do not meet or exceed risk criteria." *Id.* In other words, at the close of the limited time period the additional data must show that the product can meet or exceed FIFRA's registration criteria; if it cannot, the pesticide cannot be registered. In addition, the Administrator has generally broad discretion to impose on a conditional registration "such other conditions as the Administrator may prescribe."<sup>5</sup> 7 U.S.C. § 136a(c)(7)(C).

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<sup>5</sup> In contrast, EPA's discretion to conditionally register in the first instance is limited to those circumstances where registrant data is lacking because enough time has not elapsed since EPA first imposed the data requirement. 7 U.S.C. § 136a(c)(7)(C). And, EPA may only allow a conditional registration if it determines that use of the pesticide during the limited time period will not cause any unreasonable adverse effect on the environment and that use of the pesticide is



Finally, if the applicant fails to meet *any* condition imposed in the conditional registration – including but not limited to compliance with FIFRA's registration criteria – by the close of the period the Agency has provided, FIFRA mandates EPA must issue a notice of intent to cancel the conditional registration. 7 U.S.C. § 136d(e)(1) ("The Administrator shall issue a notice of intent to cancel a [conditional] registration ... if ... at the end of the period provided for satisfaction of any condition imposed, that condition has not been met"). In moving forward in cancelling a conditional registration, "[t]he Administrator may [in her discretion] permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection," but the Administrator may only do so if the Administrator determines that such a sale is consistent with FIFRA and "will not have unreasonable adverse effects on the environment." *Id.*

Upon initiation of cancellation proceedings, FIFRA section 6(e) provides the conditional registrant a clear, but limited, route of appeal. Namely, when a person adversely affected by the Agency's notice of cancellation of a conditional registration requests a hearing, the hearing is to narrowly determine "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." 7 U.S.C. § 136d(e)(2). Further, the scope of the hearing may, as is appropriate, include a resolution as to whether the Agency's determination "with respect to the disposition of existing stocks is consistent with" FIFRA. *Id.* The decision issued after the completion of the hearing is final. *Id.*

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in the public interest. *Id.* CropLife America ignores that the latter determination for a conditional registration is confined to use of the pesticide during the limited time period of the conditional registration, 7 U.S.C. § 136a(c)(7)(C), as compared to a finding of no general unreasonable adverse effect from the indefinite use of a pesticide that is unconditionally registered, 7 U.S.C. § 136a(c)(5)(D). Memorandum of Amicus CropLife America in Support at 2.

This route of appeal is particular to conditional registrants. Separately, if EPA believes that an applicant that has already been granted full registration status is thereafter not complying with the provisions of FIFRA or the registered product is causing unreasonable adverse effects on the environment, then the Administrator may act to determine if that registered pesticide should be cancelled or its classification changed pursuant to a different provision of FIFRA, section 6(b). 7 U.S.C. § 136d(b).

### **III. ARGUMENT**

#### **1. The Environmental Protection Agency Properly Interpreted and Applied Section 6(e) of FIFRA in Proceeding with its Cancellation of Four Conditional Flubendiamide Registrations**

EPA granted Bayer a set of time-limited, conditional flubendiamide FIFRA registrations. Now, Bayer alleges that those conditional registrations are without qualification, and that EPA conferred upon it a fixed and absolute set of rights that warrant the more vigorous administrative hearing process statutorily reserved for applicants who have earned full, unconditional registration status. Compare 7 U.S.C. § 136d(e) with 7 U.S.C. § 136d(b). Indeed, Bayer goes to great lengths to describe its entitlement to the registrations, leading the Court down a rabbit hole of dubious legal and scientific analysis.

Bayer's analysis misses the mark in three fundamental ways. First, its analysis relies on the belief that a conditionally-granted registration is functionally equivalent to its unconditional counterpart, and, therefore, that conditional and unconditional registrants maintain the same privileges as they relate to a registration and its cancellation. Second, Bayer attempts to derail the Agency's cancellation proceedings by refuting, in a *post hoc* fashion, the legality and applicability of the conditions of its registrations – conditions that it agreed to and which are anticipated in the plain language of FIFRA. Finally, Bayer erroneously alleges that the

cancellation of a conditionally registered pesticide maintains the same scope of review as the cancellation of a full registered pesticide, which it plainly does not. Each of these issues will be taken in turn.

**A. Conditional Registrations under FIFRA Provide Applicants with Only a Limited Set of Privileges.**

FIFRA makes clear that the registration process is meant to be more than a mere paperwork exercise, but is designed to ensure that any pesticide entering the marketplace will, among other things, "perform its intended function without unreasonable adverse effects on the environment," and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5); *see also* 40 C.F.R. § 152.112. If a pesticide cannot meet these criteria, it cannot be registered.

As FIFRA generously provides, however, in the event an applicant initially fails to fulfill the criteria necessary for immediate registration, EPA may grant them a second chance to meet that criteria. A second chance, though, does not come without strings. Rather, through that secondary process, known as conditional registration, the Agency can grant a limited license for the sale and use of an otherwise rejected pesticide, but only if the applicant can meet certain conditions. *See* 7 U.S.C. § 136a(c)(7).

It is at this point – when the Agency determines that a pesticide did not meet the criteria necessary for registration but could, temporarily, be conditionally registered – there is a fundamental shift in the privileges and statutory options available to the registering party. This shift is rooted in the principle that in granting a conditional registration, the Agency is not providing the applicant with any right to final registration, but is granting the applicant temporary authorization to sell the product and an opportunity to prove that their product can

meet as-yet-unfulfilled underlying statutory requirements (and any additional terms incorporated into that conditional registration).

The cases that Bayer relies upon in claiming that it has acquired a "property right" to the conditional flubendiamide registrations are inapplicable here. *See* Motion for an Accelerated Decision by Bayer Cropsience LP and Nichino America, Inc. at 46; *see also* Request for Hearing and Statement of Objections by Bayer Cropsience LP and Nichino America, Inc. at ¶ 33. Each of those cases relies upon fact situations in which the registrant had a full and final registration.<sup>6</sup> *See Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131 (D.C. Cir. 2011) (concerning reregistration and cancellation of ten actively, fully registered rodenticides); *Ctr. for Biological Diversity v. EPA*, No. 11-CV-00293-JCS, 2013 U.S. Dist. LEXIS 57436 (N.D. Cal. Apr. 22, 2013) (similarly concerning EPA's compliance with the Endangered Species Act in reregistering fully registered pesticides); *see also Woodstream Corp. v. Jackson*, 845 F.Supp.2d 174, 183 n 5 (D.D.C. 2012) (distinguishing the procedures for section 6(e), conditional registration cancellation, from 6(b), unconditional registration cancellation, from the facts of *Reckitt Benckiser* because Reckitt "had an existing, unconditional registration."). Importantly, however, the cases Bayer relies upon do not address what procedure an applicant is entitled to when it only has a conditional registration, and where the Agency is still in full control of *if* and to what capacity a pesticide may be fully registered under FIFRA. The answer: the "rights" granted to applicants are minimal, and are constrained to the terms of the applicant's conditional registration

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<sup>6</sup> Even so, "rights," as they relate to FIFRA registration, are limited to the terms and conditions under which a product has been licensed. *See* 7 U.S.C. § 136a(a), (c)-(e); 5 U.S.C. § 551 (8) ("license' includes the whole or a part of an agency ... registration"); *Reckitt Benckiser*, 613 F.3d at 1133 ("A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used.")

and FIFRA's conditional registration provisions. *See* 7 U.S.C. § 136a(c)(7); *Woodstream Corp.*, 845 F.Supp.ed at 181-182.

Here, when Bayer originally applied for the flubendiamide registrations at issue, it was unable to fulfill the criteria necessary for immediate registration. Rather than withdrawing its application at that time and reformulating a pesticide that could meet the FIFRA registration criteria, Bayer opted to forge ahead, and availed itself of the qualified, conditional registration process. Bayer did so knowing that EPA's issuance of a conditional registration did not come with a guarantee of final approval, but, instead, with a list of conditions that, if not complied with, would make the conditional registration immediately subject to review and cancellation pursuant to section 6(e) of FIFRA. *See, e.g., Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984) ("Monsanto has not challenged the ability of the Federal Government to regulate the marketing and use of pesticides. Nor could Monsanto successfully make such a challenge, for such restrictions are the burdens we all must bear in exchange for "the advantage of living and doing business in a civilized community.") (internal citations omitted).

Bayer cannot ignore the circumstances that kept its products from originally being registered, and it is erroneous for it to now attempt to gloss over the resultant conditions and limitations on their temporary flubendiamide registrations. As discussed further below, the conditional status of these registrations, coupled with the limited set of privileges that they grant, controls how the ALJ should review EPA's cancellation decision, and supports that EPA proceeded properly in moving to cancel Bayer's conditional flubendiamide registrations pursuant to Section 6(e) of FIFRA.

**B. Applicants' Limited Set of Privileges are Restricted to the Terms of their Time Limited, Conditional Flubendiamide Registrations**

All of the registrations at issue in these proceedings were conditionally granted to Bayer by EPA. *See* Exhibit 1, *Flubendiamide; Notice of Intent to Cancel Pesticide Registrations*, 43 Fed. Reg. 11558, 11558 (Mar. 4, 2016) ("The flubendiamide products at issue in this proceeding were conditionally registered pursuant to FIFRA section 3(c)(7)(C) and EPA's regulations at 40 CFR 152.114 and 152.115.") ("Flubendiamide NOIC"); Exhibit 21, Letter from Jack Housenger (EPA Office of Pesticide Programs) to Bayer Requesting Voluntary Cancellation of Flubendiamide Conditional Registrations, 1 (Jan. 29, 2016) (same); Exhibit 11, EPA Notices of Registration for Flubendiamide Technical (EPA Reg. No. 71711-26) and Belt® SC Insecticide (EPA Reg. No. 264-1025) (Aug. 1, 2008) (same); Exhibit 10, EPA Preliminary Acceptance of Flubendiamide Registrations (July 31, 2008) (same).<sup>7</sup> FIFRA grants EPA broad discretion to include conditions and limitations on any conditional approval, including a condition obligating Bayer to promptly request voluntary cancellation of the registrations if and when EPA provides notice of its determination that the pesticide flubendiamide "did not meet the FIFRA standard for registrations." Flubendiamide NOIC at 11559; 7 U.S.C. § 136a(c)(7)(C) (A conditional registration can include any other "such ... conditions as the Administrator may prescribe."). As EPA rightly summarizes, and as common sense dictates, without conditions, a conditional registration is unlikely to be granted. Flubendiamide NOIC at 11559 ("Without [the voluntary cancellation] condition, the registration would likely not have been approved by EPA.")

Bayer knew of and accepted the mandatory nature of these conditions in advance of agreeing to proceed with the conditional registrations. Since agreeing to those terms, Bayer has consistently benefited from these conditional registrations, including through the sale of its

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<sup>7</sup> Exhibits referenced from this point on correspond to those filed in conjunction with the Request for Hearing and Statement of Objection by Bayer CropScience LP and Nichino America, Inc.

flubendiamide products – benefits that it otherwise would not have enjoyed if EPA had opted, instead, to wholly reject its original, deficient application for registration. In exchange for that benefit, Bayer was to provide EPA within five years with information sufficient to meet or exceed the registration requirements of FIFRA, and to show that its product would not result in unreasonable adverse effects on the environment. Flubendiamide NOIC at 11559. Bayer was unable to do so. *Id.*; Exhibit 21, Letter from Jack Housenger (EPA Office of Pesticide Programs) to Bayer Requesting Voluntary Cancellation of Flubendiamide Conditional Registrations, 1 (Jan. 29, 2016).

As a result, under the conditional terms of its registrations, Bayer was to expeditiously request the voluntary cancellation of its flubendiamide registrations. Flubendiamide NOIC at 11559 (Mar. 4, 2016). Despite the mandatory nature of this condition, Bayer refused to do so. *Id.* Bayer now contests the legality of this voluntary cancellation term.

However, earlier in these very proceedings Bayer demonstrated not only its understanding of the effect of the voluntary cancellation term of its conditional registration, it complied with it. In the very same letter in which EPA notified Bayer of its determination that the four flubendiamide pesticides at issue would result in unreasonable adverse effects on the environment, and, therefore, could not be registered (thereby triggering the voluntary cancellation provision), it also notified Bayer that a fifth flubendiamide registration - SYNAPSE WG Insecticide, EPA Reg. No. 264-1026 - likewise did not meet FIFRA's registration criteria and must be cancelled. Exhibit 21, Letter from Jack Housenger (EPA Office of Pesticide Programs) to Bayer Requesting Voluntary Cancellation of Flubendiamide Conditional Registrations, 1 (Jan. 29, 2016). Unlike with the present four registrations, however, Bayer complied with EPA's request and did with SYNAPSE just what it is now alleging is unlawful: it

voluntarily withdrew the conditional registration for that pesticide. *Flubendiamide; Notice of Receipt of Request to Voluntarily Cancel a Pesticide Product Registration*, 69 Fed. Reg. 21344, 21344 (Apr. 11, 2016).

There is also a practical consideration here. The Agency includes conditions such as voluntary cancellation in FIFRA conditional registrations for the purpose of administrative (and judicial) economy and environmental health. If a pesticide is unable to meet the criteria of FIFRA, as EPA has demonstrated with these flubendiamide pesticides, it cannot be registered, and any use of that conditionally approved pesticide should promptly be discontinued. *See* 7 U.S.C. § 136d(e). Indeed, environmental health and safety require such immediate action. *Id.* In recognition of these significant interests, the requirement for voluntary cancellation supports the Agency in meeting its obligations under FIFRA, while also efficiently utilizing not only its own administrative resources, but also the resources of the ALJ.

Bayer unmistakably agreed to the voluntary cancellation terms when it accepted these conditionally-granted registrations for pesticide products containing the active ingredient flubendiamide, and it has demonstrated its understanding and willingness to comply with an exact carbon copy of these terms. The conditions contained in these registrations are binding, and Bayer's failure to comply with those conditions supports that EPA proceeded properly in moving to cancel Bayer's conditional flubendiamide registrations.

### **C. Conditional Registrations under FIFRA Provide Applicants with Only a Limited Scope of Review.**

Despite its direct violation of the terms of the flubendiamide conditional registrations, Bayer is contending that the privileges afforded to it through a conditional registration are equivalent to those afforded to a party who has been granted full registration, and, therefore, that any cancellation of their conditional registrations should proceed under the more robust analysis



made available for final registrations under FIFRA section 6(b). Motion for an Accelerated Decision by Bayer Cropscience LP and Nichino America, Inc. at 46-47. That is, however, not the case.

As discussed previously, during its initial application process Bayer was unable to meet the criteria necessary for FIFRA registration for any of the flubendiamide products presently at issue. Despite that failure, EPA offered Bayer a second, conditional chance to show that its products could meet FIFRA's registration criteria. However, that second chance was not final; it was conditioned and time-limited pursuant to FIFRA section 3(c)(7)(C). As a result, Bayer simply does not have the "property right" that it claims. Rather, as FIFRA plainly provides, the cancellation of conditional registrations, those issued under section 3(c)(7), must proceed pursuant to the procedural provisions provided in section 6(e). *See* 16 U.S.C. § 136d(e)(1); *Woodstream Corp.*, 845 F.Supp.2d at 177 ("Cancellations of *conditioned* registrations fall under Section 6(e).").

In arguing that EPA must proceed under a separate subsection of FIFRA, section 6(b), in initiating cancellation procedures, Bayer glosses over the significant distinction between conditional and unconditional registrations. Section 6(b) of FIFRA is only appropriate for an applicant that has already been granted full registration status, and is, thereafter, found not to be complying with the provisions of FIFRA or the registered product is causing unreasonable adverse effects on the environment. 7 U.S.C. § 136d(b). In contrast, use of the hearing procedures described in section 6(b) is not proper for "registration issued under section 3(c)(7) of this Act." 7 U.S.C. § 136d(e)(1); *Woodstream Corp.*, 845 F.Supp.2d at 177 (providing that a hearing held pursuant to section 6(e) has a narrower scope than a hearing held pursuant to 6(b)). The flubendiamide registrations were issued under section 3(c)(7) of the Act. *See, e.g.,*

Flubendiamide NOIC at 11558 ("The flubendiamide products at issue in this proceeding were conditionally registered pursuant to FIFRA section 3(c)(7)(C) and EPA's regulations at 40 CFR 152.114 and 152.115.") Therefore, EPA is not seeking to "force the cancellation process down a different and inappropriate path . . . ." Motion for an Accelerated Decision by Bayer CropScience LP and Nichino America, Inc. at 47. EPA is merely adhering to the path FIFRA provides for cancelling a conditional registration, which is cancellation as provided under section 6(e).

Pursuant to section 6(e), review of an Agency decision on cancellation of a conditional registration is reviewable by the ALJ, but is limited to "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."<sup>8</sup> 7 U.S.C. § 136d(e)(2). Under this analysis, the ALJ is left with two questions: did Bayer comply with the conditions of its registration and did it do so within the time limit provided by the Agency. If those terms are not met, then EPA must issue a notice of intent to cancel the registration. 7 U.S.C. § 136d(e)(1) ("The Administrator shall issue a notice of intent to cancel a registration ... if ... at the end of the period provided for satisfaction of any condition imposed, that condition has not been met"). As EPA has determined, Bayer has failed to meet both steps of this analysis for any of its four conditionally registered flubendiamide pesticides. *See* Flubendiamide NOIC at 11559-11560. For that reason, cancellation of the flubendiamide registrations is appropriate.

## **2. The Environmental Protection Agency's Limitation on Bayer's Sale of Flubendiamide Stocks is Consistent with FIFRA**

Once a pesticide is cancelled, no one has a license to sell or use it. Pursuant to section 6(e), the Administrator has limited discretion, but is not required, to permit the continued sale

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<sup>8</sup> As discussed further below, the scope of the hearing may, as is appropriate, include a resolution as to whether the Agency's determination "with respect to the disposition of existing stocks is consistent with" FIFRA. 7 U.S.C. § 136d(e)(2).

and use of existing stocks of a pesticide whose conditional registration has been cancelled. 7 U.S.C. § 136d(e)(1). If the Administrator permits it, the sale or use is “to such extent, under such conditions, and for such uses as the Administrator may specify.” *Id.* Accordingly, FIFRA provides EPA authority to require the immediate cessation of sale and use of existing stocks that were conditionally registered, and Bayer has no right to continue to sell or use flubendiamide once it is cancelled.

Moreover, the Administrator is limited to allowing continued sale or use of a cancelled pesticide only “if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment.” 7 U.S.C. § 136d(e)(1). EPA has concluded that stream and river monitoring indicates widespread occurrence of flubendiamide and des-iodo, widespread potential for water quality impacts, and “significant effects to aquatic organisms due to the use of flubendiamide could potentially occur in as little as 2 years.” ERA at 17. This finding provides additional support to EPA’s refusal to allow continued sale of existing stocks of flubendiamide.

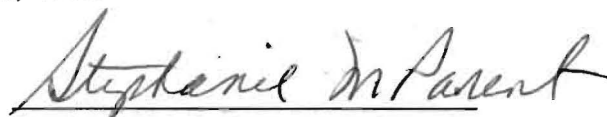
Additional delay caused by the procedure to cancel also supports EPA’s decision not to allow continued sale of existing stocks of flubendiamide, in particular because it is likely to have adverse effects on endangered species. EPA had anticipated that Bayer would comply with the mandatory condition to seek voluntary cancellation within one week, which it has refused to do. The section 6(e) process adds an additional three to four months or more before cancellation. And, Bayer is arguing for the inapplicable 6(b) process, which will entail additional delay before flubendiamide is cancelled and harmful use stops. This delay is going to result in additional exposure and accumulation in the environment of a persistent chemical that is chronically toxic to aquatic invertebrates, many of which are protected under the ESA. Adverse effects on aquatic

invertebrates have cascading effects on the entire stream food web. For example, freshwater mussels “excrete nutrients, aiding the growth of micro-organisms that feed fish and larger invertebrates” in addition to providing essential water filtering.<sup>9</sup> Thus, any further delay in the cancellation proceeding, or in allowing continued sale of existing stocks, will result in additional harm to protected endangered species that is not allowed under FIFRA and is prohibited conduct under the ESA.

#### IV. CONCLUSION

For the forgoing reasons, Bayer's conditional registrations for pesticide products containing the active ingredient flubendiamide must be cancelled, and its sale of flubendiamide stocks must be prohibited.

Respectfully submitted this 15th day of April, 2016.



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<sup>9</sup> USGS, *The Secret Lives of Mussels: America's Most Endangered Species!* (Apr. 4, 2013), available at [http://www.usgs.gov/blogs/features/usgs\\_top\\_story/the-secret-lives-of-mussels-americas-most-endangered-species/](http://www.usgs.gov/blogs/features/usgs_top_story/the-secret-lives-of-mussels-americas-most-endangered-species/)

<b>Scientific Name</b>	<b>Common Name</b>	<b>Status</b>
<i>Alasmidonta atropurpurea</i>	Cumberland elktoe	Endangered
<i>Alasmidonta heterodon</i>	Dwarf wedgemussel	Endangered
<i>Alasmidonta raveneliana</i>	Appalachian elktoe	Endangered
<i>Amblema neislerii</i>	Fat threeridge (mussel)	Endangered
<i>Ambrysus amargosus</i>	Ash Meadows naucorid	Threatened
<i>Antrobia culveri</i>	Tumbling Creek cavesnail	Endangered
<i>Antrolana lira</i>	Madison Cave isopod	Threatened
<i>Arkansia wheeleri</i>	Ouachita rock pocketbook	Endangered
<i>Assimineia pecos</i>	Pecos assiminea snail	Endangered
<i>Athearnia anthonyi</i>	Anthony's riversnail	Endangered
<i>Batrisodes texanus</i>	Coffin Cave mold beetle	Endangered
<i>Batrisodes venyivi</i>	Helotes mold beetle	Endangered
<i>Branchinecta conservatio</i>	Conservancy fairy shrimp	Endangered
<i>Branchinecta longiantenna</i>	Longhorn fairy shrimp	Endangered
<i>Branchinecta lynchi</i>	Vernal pool fairy shrimp	Threatened
<i>Branchinecta sandiegonensis</i>	San Diego fairy shrimp	Endangered
<i>Brychius hungerfordi</i>	Hungerford's crawling water Beetle	Endangered
<i>Cambarus aculabrum</i>	Cave crayfish	Endangered
<i>Cambarus veteranus</i>	Guyandotte River crayfish	Endangered
<i>Cambarus zophonastes</i>	Cave crayfish	Endangered
<i>Campeloma decampi</i>	Slender campeloma	Endangered
<i>Cicindela nevadica lincolniana</i>	Salt Creek Tiger beetle	Endangered
<i>Cicindela ohlone</i>	Ohlonge tiger beetle	Endangered
<i>Cicindela puritana</i>	Puritan tiger beetle	Threatened
<i>Cicurina baronia</i>	Robber Baron Cave Meshweaver	Endangered
<i>Cicurina madla</i>	Madla's Cave Meshweaver	Endangered
<i>Cicurina venii</i>	Braken Bat Cave Meshweaver	Endangered
<i>Cicurina vespera</i>	Government Canyon Bat Cave Meshweaver	Endangered
<i>Cumberlandia monodonta</i>	Spectaclecase (mussel)	Endangered
<i>Cyprogenia stegaria</i>	Fanshell	Endangered
<i>Desmocerus californicus dimorphus</i>	Valley elderberry longhorn beetle	Threatened
<i>Dinacoma caseyi</i>	Casey's June Beetle	Endangered
<i>Discus macclintocki</i>	Iowa Pleistocene snail	Endangered
<i>Dromus dromas</i>	Dromedary pearlymussel	Endangered
<i>Elaphrus viridis</i>	Delta green ground beetle	Threatened
<i>Elimia crenatella</i>	Lacy elimia (snail)	Threatened
<i>Elliptio chipolaensis</i>	Chipola slabshell	Threatened
<i>Elliptio spinosa</i>	Altamaha Spiny mussel	Endangered
<i>Elliptio steinstansana</i>	Tar River spiny mussel	Endangered
<i>Elliptoideus sloatianus</i>	Purple bankclimber (mussel)	Threatened
<i>Epioblasma brevidens</i>	Cumberlandian combshell	Endangered
<i>Epioblasma capsaeformis</i>	Oyster mussel	Endangered
<i>Epioblasma florentina curtisii</i>	Curtis pearlymussel	Endangered
<i>Epioblasma florentina florentina</i>	Yellow blossom (pearlymussel)	Endangered
<i>Epioblasma florentina walkeri</i> (=E. walkeri)	Tan riffleshell	Endangered
<i>Epioblasma metastriata</i>	Upland combshell	Endangered

<i>Epioblasma obliquata obliquata</i>	Purple Cat's paw (=Purple Cat's paw pearlymussel)	Endangered
<i>Epioblasma obliquata perobliqua</i>	White catspaw (pearlymussel)	Endangered
<i>Epioblasma othcaloogensis</i>	Southern acornshell	Endangered
<i>Epioblasma penita</i>	Southern combshell	Endangered
<i>Epioblasma torulosa gubernaculum</i>	Green blossom (pearlymussel)	Endangered
<i>Epioblasma torulosa rangiana</i>	Northern riffleshell	Endangered
<i>Epioblasma torulosa torulosa</i>	Tubercled blossom (pearlymussel)	Endangered
<i>Epioblasma triquetra</i>	Snuffbox mussel	Endangered
<i>Epioblasma turgidula</i>	Turgid blossom (pearlymussel)	Endangered
<i>Fusconaia burkei</i>	Tapered pigtoe	Threatened
<i>Fusconaia cor</i>	Shiny pigtoe	Endangered
<i>Fusconaia cuneolus</i>	Finerayed pigtoe	Endangered
<i>Fusconaia escambia</i>	Narrow pigtoe	Threatened
<i>Fusconaia rotulata</i>	Round Ebonyshell	Endangered
<i>Gammarus acherondytes</i>	Illinois cave amphipod	Endangered
<i>Gammarus desperatus</i>	Noel's Amphipod	Endangered
<i>Gammarus hyalleloides</i>	Diminutive Amphipod	Endangered
<i>Gammarus pecos</i>	Pecos amphipod	Endangered
<i>Hamiota australis</i>	Southern sandshell	Threatened
<i>Hemistena lata</i>	Cracking pearlymussel	Endangered
<i>Heterelmis comalensis</i>	Comal Springs riffle beetle	Endangered
<i>Ischnura luta</i>	Rota blue damselfly	Endangered
<i>Juturnia kosteri</i>	Koster's springsnail	Endangered
<i>Lampsilis abrupta</i>	Pink mucket (pearlymussel)	Endangered
<i>Lampsilis altilis</i>	Finelined pocketbook	Threatened
<i>Lampsilis higginsii</i>	Higgins eye (pearlymussel)	Endangered
<i>Lampsilis perovalis</i>	Orangenacre mucket	Threatened
<i>Lampsilis powellii</i>	Arkansas fatmucket	Threatened
<i>Lampsilis rafinesqueana</i>	Neosho Mucket	Endangered
<i>Lampsilis streckeri</i>	Speckled pocketbook	Endangered
<i>Lampsilis subangulata</i>	Shinyrayed pocketbook	Endangered
<i>Lampsilis virescens</i>	Alabama lampmussel	Endangered
<i>Lasmigona decorata</i>	Carolina heelsplitter	Endangered
<i>Lemiox rimosus</i>	Birdwing pearlymussel	Endangered
<i>Lepidurus packardi</i>	Vernal pool tadpole shrimp	Endangered
<i>Leptodea leptodon</i>	Scaleshell mussel	Endangered
<i>Leptoxis ampla</i>	Round rocksnail	Threatened
<i>Leptoxis foremani</i>	Interrupted (=Georgia) Rocksnail	Endangered
<i>Leptoxis plicata</i>	Plicate rocksnail	Endangered
<i>Leptoxis taeniata</i>	Painted rocksnail	Threatened
<i>Lepyrium showalteri</i>	Flat pebblesnail	Endangered
<i>Lirceus usdagalun</i>	Lee County cave isopod	Endangered
<i>Margaritifera hembeli</i>	Louisiana pearlshell	Threatened
<i>Margaritifera marrianae</i>	Alabama pearlshell	Endangered
<i>Medionidus acutissimus</i>	Alabama moccasinshell	Threatened
<i>Medionidus parvulus</i>	Coosa moccasinshell	Endangered
<i>Medionidus penicillatus</i>	Gulf moccasinshell	Endangered

<i>Medionidus simpsonianus</i>	Ochlockonee moccasinshell	Endangered
<i>Microhexura montivaga</i>	Spruce-fir moss spider	Endangered
<i>Neoleptoneta microps</i>	Government Canyon Bat Cave Spider	Endangered
<i>Neoleptoneta myopica</i>	Tooth Cave Spider	Endangered
<i>Obovaria retusa</i>	Ring pink (mussel)	Endangered
<i>Orconectes shoupi</i>	Nashville crayfish	Endangered
<i>Pacifastacus fortis</i>	Shasta crayfish	Endangered
<i>Palaemonetes cummingi</i>	Squirrel Chimney Cave shrimp	Threatened
<i>Palaemonias alabamiae</i>	Alabama cave shrimp	Endangered
<i>Palaemonias ganteri</i>	Kentucky cave shrimp	Endangered
<i>Pegias fabula</i>	Littlewing pearlymussel	Endangered
<i>Physa natricina</i>	Snake River physa snail	Endangered
<i>Plethobasus cicatricosus</i>	White wartyback (pearlymussel)	Endangered
<i>Plethobasus cooperianus</i>	Orangefoot pimpleback (pearlymussel)	Endangered
<i>Plethobasus cyphus</i>	Sheepnose Mussel	Endangered
<i>Pleurobema clava</i>	Clubshell	Endangered
<i>Pleurobema collina</i>	James spiny mussel	Endangered
<i>Pleurobema curtum</i>	Black clubshell	Endangered
<i>Pleurobema decisum</i>	Southern clubshell	Endangered
<i>Pleurobema furvum</i>	Dark pigtoe	Endangered
<i>Pleurobema georgianum</i>	Southern pigtoe	Endangered
<i>Pleurobema gibberum</i>	Cumberland pigtoe	Endangered
<i>Pleurobema hanleyianum</i>	Georgia pigtoe	Endangered
<i>Pleurobema marshalli</i>	Flat pigtoe	Endangered
<i>Pleurobema perovatum</i>	Ovate clubshell	Endangered
<i>Pleurobema plenum</i>	Rough pigtoe	Endangered
<i>Pleurobema pyriforme</i>	Oval pigtoe	Endangered
<i>Pleurobema strodeanum</i>	Fuzzy pigtoe	Threatened
<i>Pleurobema taitianum</i>	Heavy pigtoe	Endangered
<i>Pleurocera foremani</i>	Rough hornsnail	Endangered
<i>Pleuronaia dolabelloides</i>	Slabside Pearlymussel	Endangered
<i>Potamilus capax</i>	Fat pocketbook	Endangered
<i>Potamilus inflatus</i>	Alabama (=inflated) heelsplitter	Threatened
<i>Pseudocopaedodes eunus obscurus</i>	Carson wandering skipper	Endangered
<i>Pseudotryonia adamantina</i>	Diamond Tryonia	Endangered
<i>Ptychobranthus greenii</i>	Triangular Kidneyshell	Endangered
<i>Ptychobranthus jonesi</i>	Southern kidneyshell	Endangered
<i>Ptychobranthus subtentum</i>	Fluted kidneyshell	Endangered
<i>Pyrgulopsis (=Marstonia) pachyta</i>	Armored snail	Endangered
<i>Pyrgulopsis bernardina</i>	San Bernardino springsnail	Threatened
<i>Pyrgulopsis bruneauensis</i>	Bruneau Hot springsnail	Endangered
<i>Pyrgulopsis chupaderae</i>	Chupadera springsnail	Endangered
<i>Pyrgulopsis neomexicana</i>	Socorro springsnail	Endangered
<i>Pyrgulopsis ogmorhaphae</i>	Royal marstonia (snail)	Endangered
<i>Pyrgulopsis roswellensis</i>	Roswell springsnail	Endangered
<i>Pyrgulopsis texana</i>	Phantom Springsnail	Endangered
<i>Pyrgulopsis trivialis</i>	Three Forks Springsnail	Endangered

Quadrula cylindrica cylindrica	Rabbitsfoot	Threatened
Quadrula cylindrica strigillata	Rough rabbitsfoot	Endangered
Quadrula fragosa	Winged Mapleleaf	Endangered
Quadrula intermedia	Cumberland monkeyface (pearlymussel)	Endangered
Quadrula sparsa	Appalachian monkeyface (pearlymussel)	Endangered
Quadrula stapes	Stirrupshell	Endangered
Somatochlora hineana	Hine's emerald dragonfly	Endangered
Spelaeorchestia koloana	Kauai cave amphipod	Endangered
Streptocephalus woottoni	Riverside fairy shrimp	Endangered
Stygobromus (=Stygonectes) pecki	Peck's cave amphipod	Endangered
Stygobromus hayi	Hay's Spring amphipod	Endangered
Stygoparnus comalensis	Comal Springs dryopid beetle	Endangered
Syncaris pacifica	California freshwater shrimp	Endangered
Tartarocreagris texana	Tooth Cave pseudoscorpion	Endangered
Taylorconcha serpenticola	Bliss Rapids snail	Threatened
Texamaurops reddelli	Kretschmarr Cave mold beetle	Endangered
Texella cokendolpheri	Cokendolpher Cave Harvestman	Endangered
Texella reddelli	Bee Creek Cave harvestman	Endangered
Texella reyesi	Bone Cave harvestman	Endangered
Thermosphaeroma thermophilus	Socorro isopod	Endangered
Toxolasma cylindrellus	Pale lilliput (pearlymussel)	Endangered
Tryonia alamosae	Alamosa springsnail	Endangered
Tryonia cheatumi	Phantom Tryonia	Endangered
Tryonia circumstriata (=stocktonensis)	Gonzales tryonia	Endangered
Tulotoma magnifica	Tulotoma snail	Threatened
Villosa choctawensis	Choctaw bean	Endangered
Villosa fabalis	Rayed Bean	Endangered
Villosa perpurpurea	Purple bean	Endangered
Villosa trabalis	Cumberland bean (pearlymussel)	Endangered



## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 15th day of April, 2016, a true and correct copy of the foregoing MOTION FOR LEAVE TO FILE AN AMICUS CURIAE BRIEF AND MEMORANDUM OF AMICUS THE CENTER FOR BIOLOGICAL DIVERSITY IN SUPPORT OF DEFENDANT ENVIRONMENTAL PROTECTION AGENCY'S CANCELLATION OF CONDITIONAL REGISTRATIONS FOR PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT FLUBENDIAMIDE was filed electronically using the EPA OALJ e-filing system, and served in the following manner to the below addresses:

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