

**ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.**

In re:)
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Bayer CropScience LP and) FIFRA Appeal No. 16-(01)
Nichino America, Inc.)
)
Docket No. FIFRA-HQ-2016-001)

**AMICUS BRIEF OF
THE CENTER FOR BIOLOGICAL DIVERSITY**

I. INTRODUCTION

This matter is straightforward. Bayer CropScience LP and Nichino America, Inc. (Bayer) were unable to demonstrate that their flubendiamide products met the criteria for registration pursuant to Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Rather than a registration denial, Bayer negotiated for time-limited, conditional registrations under Section 3(c)(7)(C), including the condition that it would request voluntary cancellation if the Environmental Protection Agency (EPA) determined that Bayer could not resolve EPA’s concerns about flubendiamide’s adverse effects on the environment. When the EPA so determined, Bayer refused to request voluntary cancellation; meaning, it failed to satisfy an express condition of its conditional registrations. EPA appropriately pursued cancellation based on Bayer’s failure to satisfy this condition pursuant to Section 6(e), and the Administrative Law Judge (ALJ) appropriately limited the scope of the hearing to whether Bayer satisfied the voluntary cancellation decision.

For the last eight years, Bayer has had the benefit of its business decision to sell flubendiamide pursuant to conditional registrations. These eight years were borrowed time,

dependent on Bayer showing that its product could meet the express conditions of its conditional registrations. As the record shows, Bayer failed to do so.

Bayer is attempting extend the time it can sell flubendiamide by arguing for a Section 6(b) hearing and evidentiary battle concerning whether the use and sale of flubendiamide creates an unreasonable risk to the environment. As EPA's risk analysis clearly shows, flubendiamide creates a risk so severe that it should never have been granted conditional registration in the first instance, let alone be allowed to continue on the market. Cancellation is necessary to prevent further accumulation of this persistent and extremely toxic pesticide in the environment to prevent further direct harm to species, including endangered and threatened species, and the aquatic habitats on which they rely. However, that risk analysis is outside of the scope of these proceedings. Rather, the question before the Board is a narrow one: whether Bayer complied with the express condition of its conditional registrations for flubendiamide—the condition that it negotiated—requiring voluntary cancellation. As the facts clearly bear out, Bayer did not comply with the terms of its conditional registrations; therefore, cancellation is proper and the ALJ's decision should be upheld.

II. INTERESTS OF THE AMICUS

The Center for Biological Diversity (Center) is a non-profit organization with over one million 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.

A. Interest in the FIFRA Pesticide Registration Process

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 with strong language in pesticide labels that restricts or prohibits uses and 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 over 100 comments to EPA concerning pesticides in the past year. The Center 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 also has initiated a series of lawsuits enforcing EPA's obligation to adhere to the Endangered Species Act when it authorizes the use of pesticides.¹

B. Interest in the Cancellation of the Conditional Registration of Flubendiamide

The Center has a strong interest in expeditious cancellation of flubendiamide to protect imperiled species, such as butterflies and mussels, that are already at risk of extinction and are at risk from direct and chronic exposure to flubendiamide and its degradate, des-iodo. Cancellation should already have occurred voluntarily on February 5, 2016, if Bayer had complied with the condition it agreed to when it accepted the conditional registrations. Respondent's Exhibit

¹ 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 (9th Cir.); *Center for Biological Diversity, et al. v. EPA*, Nos. 14-1036 and 15-5168 (D.C. Cir.).

(“RE”) 2 at 200011-200012. Now that Bayer has refused, EPA appropriately pursued cancellation pursuant to FIFRA Section 6(e), which, by its plain terms, is the procedure for cancellation of conditional registrations for failure to meet a condition. 7 U.S.C. § 136d(e). Flubendiamide has never met FIFRA’s minimal requirements for unconditional registration, nor has EPA ever ensured that its use will not cause jeopardy to species protected under the ESA or adversely modify their critical habitat. *See* 16 U.S.C. § 1536. The Center’s interest is in removal of this pesticide from the market to cease its harmful accumulation in the environment.

Flubendiamide is a chemical insecticide intended to kill caterpillars. In its decision that it could only conditionally register flubendiamide for five years, EPA identified “potential direct risk to non-target lepidopterous species, including endangered species.” RE 1 at 200007 (explaining lepidoptera may be in and adjacent to treated fields and that those larvae that are aquatic will be exposed to flubendiamide and its degradate, des-iodo). Lepidoptera include butterflies. There are 27 species of butterfly listed as “endangered” under the ESA,² meaning that they are in danger of extinction. 16 U.S.C. § 1532(6).

EPA’s primary concern was, and is, the potential for flubendiamide and its degradate, des-iodo, to accumulate in aquatic sediments and the adverse effects this would have on aquatic benthic invertebrates due to chronic exposure. RE 1 at 200007; RE 5 at 200068. Flubendiamide and des-iodo are likely to accumulate in soils, water column, and sediments with each successive application. RE 1 at 200006. Their persistence will subject species that rely on these habitats to chronic exposure of increasing toxicity over time. RE 1 at 200007 (accumulation and risk would multiply exponentially with each application, especially des-iodo). Subsequent U.S. Geological

² Species search for “butterfly” at <https://www.fws.gov/endangered/> (last visited June 16, 2016) shows 27 species of butterfly are endangered.

Service stream and river monitoring (2012-2014) indicates widespread occurrence of flubendiamide and des-iodo in the environment. RE 5 at 200074.

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,” and the remaining are “threatened,” meaning they are likely to become endangered in the foreseeable future. 16 U.S.C. § 1532(20). Use on crops occurs in areas where ESA-protected and other aquatic species and their habitat likely exist.³ 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.^{4,5}

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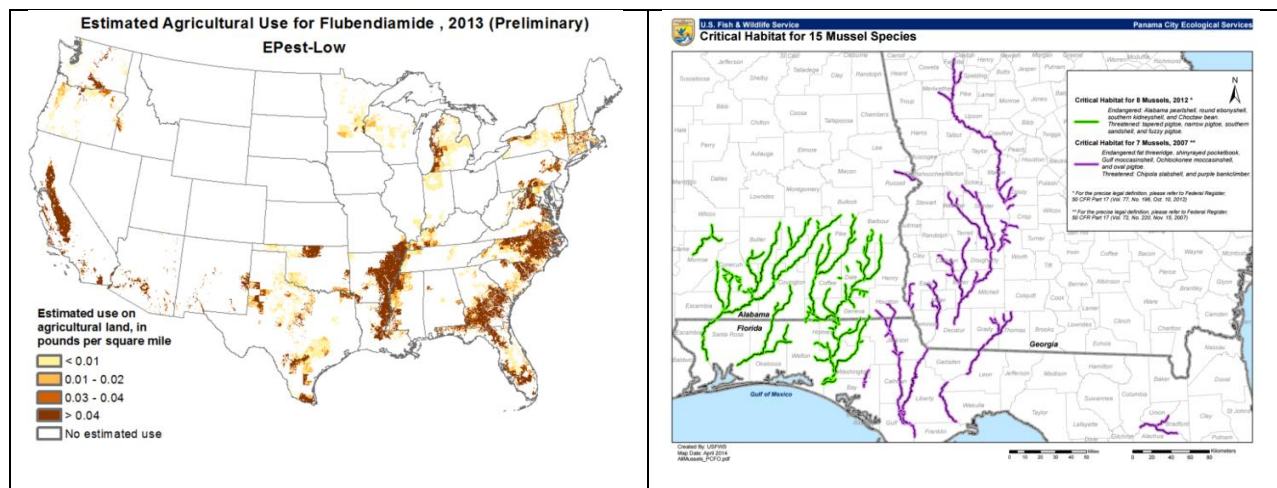
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³ USGS, National Water-Quality Assessment Program, Pesticide National Synthesis Project, https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2013&map=FLUBENDIAMIDE&hilo=L&disp=Flubendiamide (last visited June 19, 2016).

⁴ 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 June 19, 2016).

⁵ Concerning freshwater mussels, Bayer responded that EPA “repeatedly concluded there are no risks of concern to estuarine and marine mollusks, and acute toxicity testing on oysters showed no risks of concern.” Bayer Response to Center Amicus at 5, ALJ Dkt. #23. This ignores the concern for adverse effects on freshwater invertebrates, moreover, it is incorrect. For example, in 2010, EPA repeated that the chronic level of concern for benthic invertebrates was exceeded for flubendiamide and its des-iodo degradate. PBNX 28 at 4-5 (EPA EFED Risk Assessment for Legume Vegetable and Christmas Tree New Uses for the Insecticide Flubendiamide (May 17, 2010), EPA Docket # EPA-HQ-OPP-2007-0099-0023 (admitted but not for substance)). For aquatic invertebrates, the formulated products were found to be more toxic than the technical grade material and exceeded the acute level of concern for endangered species. *Id.* No toxicity data was provided for the formulated products for marine/estuarine invertebrates, therefore, EPA presumed direct effects on listed marine/estuarine mollusks and crustaceans. *Id.* Bayer confuses acute toxicity testing with the problem here: the chronic exposure aquatic invertebrates will suffer as flubendiamide and the more toxic des-iodo persist and accumulate in their habitat.



Continued use of flubendiamide is very likely to result in harm to protected species, which is prohibited by section 9 of the ESA. In granting this conditional registration, EPA never consulted with the expert wildlife agencies to ensure its conditional registration of flubendiamide would not cause jeopardy to listed species. 16 U.S.C. § 1536(a)(2). For these reasons, the Center is interested in the expeditious cancellation of flubendiamide through the appropriate Section 6(e) process.

III. LEGAL FRAMEWORK

In FIFRA, Congress prohibits the sale or distribution of any pesticide unless EPA registers it. 7 U.S.C. § 136a(a). The procedure for registration is set forth in Section 3(c) of FIFRA. An applicant for registration must provide an application to EPA, which consists of a statement containing certain information and data in support of registration. 7 U.S.C. § 136a(c)(1),(2). The EPA then reviews the application and data and may either fully register the pesticide if it meets the registration criteria in Section 3(c)(5) or deny registration if the applicant does not meet the registration criteria in accordance with Section 3(c)(6). 7 U.S.C. § 136a(c)(3). The burden of complying with the terms and requirements for registration is on the applicant.

EPA may only fully register a pesticide under Section 3(c)(5) if it will, among other things, “perform its intended 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. If EPA denies registration because the applicant does not satisfy the Section 3(c)(5) registration criteria, the applicant is entitled to the remedies provided in Section 6. 7 U.S.C. §§ 136a(c)(6), 136d.

“Notwithstanding the provisions of” Section 3(c)(5), under three limited, “special” circumstances, EPA may grant an applicant a conditional license to sell and distribute a pesticide or pesticides. 7 U.S.C. § 136a(c)(7); 40 C.F.R. § 152.114. The third special circumstance is at issue in this appeal, which provides that EPA has limited discretion to conditionally register a pesticide containing a new active ingredient only 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). The time period of conditional registration must be limited to the time reasonably sufficient to generate the data. *Id.* 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 in the public interest. *Id.* A conditional registration must be limited in time and the EPA must receive any missing data, which demonstrates the pesticide meets or exceeds certain risk criteria. 7 U.S.C. § 136a(c)(7)(C). 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 fully registered under Section 3(c)(5). In addition, EPA has generally broad discretion to impose on a

conditional registration “such other conditions as the Administrator may prescribe.” 7 U.S.C. § 136a(c)(7)(C).

If the applicant fails to meet *any* condition imposed in the conditional registration by the close of the period the Agency has provided, FIFRA mandates EPA must issue a notice of intent to cancel the conditional registration pursuant to Section 6(e). 7 U.S.C. § 136d(e)(1) (Section 6(e) expressly applies to conditional registrations, providing “[t]he 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 she 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 for failure to satisfy a condition of a conditional registration, 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.* 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).

IV. BACKGROUND

EPA only granted Bayer a set of time-limited, conditional registrations for flubendiamide products under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). EPA did not register the flubendiamide products under Section 3(c)(5) because they did not satisfy the minimum criteria for such registration due to substantial concerns about the mobility; stability and persistence; accumulation in soils, water columns, and sediments; and extremely toxic effects on aquatic invertebrates of flubendiamide and its degradate, des-iodo. These conditional registrations were limited to a period of five years (later extended by agreement with EPA), and included a mandatory set of conditions, including risk mitigation measures, a run-off/vegetative buffer strip study, monitoring, and voluntary cancellation if EPA's risk concerns were not resolved. RE 1 at 20007-08. These conditions would allow EPA to evaluate, at the end of the 5-year conditional registration, whether its concerns of unreasonable adverse effects to the environment continued to persist such that the pesticide could not satisfy the Section 3(c)(5) criteria for full registration. If not, 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. 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 when a condition of the registration has not been met.

V. ARGUMENT

Bayer made a calculated business decision to accept all conditions, including voluntary cancellation, in order to obtain a conditional registration that allowed it to begin selling its flubendiamide products in 2008. EPA would not have granted the time-limited conditional registration pursuant to Section 3(c)(7)(C) without the voluntary cancellation condition. When Bayer refused to comply with the condition of voluntary cancellation, EPA appropriately noticed cancellation pursuant to Section 6(e). Bayer is not entitled to anything further simply because its gamble that it would eventually convince EPA that it should fully register flubendiamide products under Section 3(c)(5) didn't pan out. In addition, EPA's existing stocks determination is appropriate.

A. Bayer Made a Calculated Choice to Forgo a Section 6(b) Hearing by Accepting Conditional Registrations.

Bayer does not dispute that, by law, it does not have a right to sell or distribute pesticides unless EPA registers them, regardless of how much money it has invested,⁶ nor could it. *See,*

⁶ How much Bayer invested is not relevant to whether a voluntary cancellation condition is lawful. Moreover, every company that expends funds to develop a product that requires federal agency permission by law is taking a risk that it will not obtain such permission and lose its investment. Otherwise, the criteria for registration would be converted to the amount of money expended on the development of a pesticide. For context, Bayer publicly states that it invests 10% of its annual sales in Research & Development (roughly 850 million Euro in 2012, or about \$1 billion U.S. dollars in 2012) <http://www.cropscience.bayer.com/en/About-Crop-Science.aspx> (last visited June 16, 2016). Bayer's crop science business is reported to be valued at \$45 billion

e.g., Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1007 (1984) (federal restrictions on the marketing and use of pesticides “are the burdens we all must bear in exchange for ‘the advantage of living and doing business in a civilized community.’”) (citations omitted). Instead, Bayer took full advantage of conditional registrations to begin selling its products in 2008, rather than be denied registration for failure to meet the registration criteria, which would have entitled it to a Section 6(b) hearing on the denial at that time.

The FIFRA registration process has three potential outcomes: full registration if the applicant meets the registration criteria in Section 3(c)(5); denial of registration if the applicant cannot meet those criteria; or conditional registration in special circumstances. 7 U.S.C. § 136a(c)(5),(6) and (7). If EPA denies registration, the applicant is entitled to the remedies provided in Section 6. 7 U.S.C. § 136a(c)(6) (referencing 7 U.S.C. § 136d). If EPA grants conditional registration, and the registrant fails to satisfy a condition, cancellation is pursuant to Section 6(e). 7 U.S.C. § 136d(e).

Bayer has wrongly argued that “[t]he registration criteria established under FIFRA for both conditional and unconditional registration are identical” Response to Center Amicus at 2, ALJ Dkt. #23. By its plain terms, a conditional registration is granted “[n]otwithstanding the provisions of paragraph (5)” 7 U.S.C. § 136a(c)(7). “Notwithstanding” means “despite” the thing mentioned.⁷ In other words, despite the criteria required for full registration of an indefinite length of time in Section 3(c)(5), EPA may, under certain, limited circumstances, conditionally register a pesticide containing a new active ingredient pending the generation and submission of data that the applicant has not had sufficient time to develop since EPA imposed

<http://www.reuters.com/article/us-bayercropscience-m-a-monsanto-idUSKCN0WN1DH> (last visited June 16, 2016).

⁷ See, e.g., <http://dictionary.cambridge.org/us/dictionary/english/notwithstanding>

the requirement. 7 U.S.C. § 136a(c)(7)(C). To do so, EPA must ensure that that use of the pesticide “during such period” of the time-limited, conditional registration will not cause any unreasonable adverse effect on the environment; however, this finding is not identical to the criteria for registration under Section 3(c)(5), which requires EPA to find the pesticide will not generally cause unreasonable adverse effects on the environment for an indefinite period of time, decades into the future. *Compare* 7 U.S.C. § 136a(c)(7)(C) and 7 U.S.C. § 136a(c)(5).

Here, Bayer was unable to demonstrate its flubendiamide products met the registration criteria for full registration pursuant to Section 3(c)(5).⁸ EPA had substantial concerns about the mobility; stability and persistence; accumulation in soils, water columns, and sediments; and extremely toxic effects on aquatic invertebrates from chronic exposure to flubendiamide and its degradate, des-iodo that precluded it from concluding that the use of these pesticides would not generally cause unreasonable adverse effects on the environment. RE 1 at 200007-08. Therefore, EPA could have denied registration pursuant to Section 3(c)(6). If EPA had done so, Bayer would have been entitled to remedies provided in Section 6. 7 U.S.C. § 136a(c)(6) (referencing 7 U.S.C. § 136d). Presumably, Bayer would have requested a hearing to challenge EPA’s registration denial and attempted to demonstrate flubendiamide would not generally cause unreasonable adverse effects on the environment. *See* 7 U.S.C. § 136d(b) (hearing concerning pesticides that do not comply with registration criteria) and 7 U.S.C. § 136d(d) (setting forth hearing procedures when a hearing is requested pursuant to Section 6(b)); *see also* Bayer Appeal Brief at 17 (recognizing that Bayer could have sought a denial hearing).

⁸ Further, it is not evident in EPA’s Decision Memorandum that it determined the use during the 5-year period of conditional registration would not cause any unreasonable adverse effect on the environment. Instead, EPA expresses concerns about the risks of flubendiamide to aquatic benthic invertebrates and uncertainties about the modeling and the mitigation. RE 1 at 200007-08.

Rather than pursue a 6(b) hearing on the merits of whether its flubendiamide products met the criteria for full registration, Bayer opted to negotiate with EPA and avail 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.

FIFRA grants EPA broad discretion to include conditions and limitations on any conditional approval. 7 U.S.C. § 136a(c)(7)(C) (A conditional registration can include "such ... conditions as the Administrator may prescribe."). Here, EPA proposed a condition that the conditional registrations would expire, but Bayer negotiated for the voluntary cancellation condition. RE 4 at 200036 (Bayer agreeing to "fast death" approach of voluntary cancellation without cancellation hearing). Now Bayer attempts to argue that the same condition it sought is unlawful. A condition requiring voluntary cancellation is consistent with FIFRA, which provides that a registrant "may, at any time, request that a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses." 7 U.S.C. § 136d(f)(1)(A). This is different than a condition that would directly conflict with a provision of FIFRA, such as a condition requiring an applicant to pay twice the fees specified by Congress. *See* Bayer Appeal Brief at 10. While EPA does not have discretion to require a condition that is inconsistent with FIFRA or other applicable laws, it does have discretion to condition registration upon voluntary cancellation, where voluntary cancellation is expressly provided for in FIFRA.

Bayer's argument that the voluntary cancellation condition is unlawful because it deprives Bayer of a hearing pursuant to Section 6(b) is unavailing. Bayer itself chose to avoid registration denial and forgo the Section 6 remedies that such a denial provides. EPA would not

have granted the conditional registrations without the condition obligating Bayer to promptly request voluntary cancellation. RE 8 at 200083. (“Without [the voluntary cancellation] condition, the registration would likely not have been approved by EPA”). The condition was necessary because EPA already had information that flubendiamide and des-iodo were persistent and likely to accumulate in the environment, increasing toxicity with each application. The alternative for Bayer was the outcome that each applicant who cannot meet the registration criteria faces—registration denial and the opportunity to request a 6(b) hearing on the “merits” of its products.

Of course, there is a significant difference between a 6(b) hearing that Bayer would have had on a registration denial and the 6(b) hearing Bayer wants now. The former would occur before Bayer could sell flubendiamide, while the latter allows Bayer to continue to sell its products during the time it takes for the hearing. Bayer cannot have it both ways and argue it was deprived of a hearing that it chose not to pursue in exchange for the ability to sell its products pursuant to a conditional registration that had a mandatory condition to request voluntary cancellation if EPA determined certain circumstances warranted it.

B. Section 6(e) Is the Appropriate Procedure to Cancel Conditional Registrations When a Condition Has Not Been Met.

FIFRA Section 6(e) is the appropriate procedure to cancel Bayer’s conditional registrations because it failed to meet the condition requiring it to seek voluntary cancellation. Bayer has received all the process to which the terms of its conditional registrations entitle it. The flubendiamide conditional registrations are similar to those at issue in *Woodstream Corp.*, and different than those at issue in the *Reckitt Benckiser*, because these registrations contain a lawful condition—voluntary cancellation—that Bayer has not met. Therefore, the EPA correctly provided notice of cancellation pursuant to Section 6(e) and the ALJ properly limited the scope of the hearing.

Bayer's assertion that it has a property right that entitles it to a Section 6(b) hearing is incorrect. FIFRA registrations are limited to the terms and conditions under which a product has been licensed. *See* 7 U.S.C. § 136a(a), (c)-(e); *see Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2011) ("A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used"). Here, Bayer only has conditional registrations, which contain the condition that Bayer must request voluntary cancellation if EPA determines that Bayer cannot meet the registration criteria.

Bayer knew of and accepted the mandatory nature of the conditions in advance of agreeing to proceed with the conditional registrations. Since agreeing to those terms, Bayer has consistently benefited from these conditional registrations— 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 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, or request voluntary cancellation. RE 1 at 200008 ("If there are risk concerns at that time [end of 5-year condition registration] . . . the registrants have agreed that the pesticide will be voluntarily cancelled"); RE 2 at 200012 (paragraphs 6(d) and 8(d) include explicit agreement to request voluntary cancellation). Despite the mandatory nature of the condition to request voluntary cancellation, Bayer refused to do so. *Id.*

Section 6(e) plainly provides that the EPA "shall issue a notice of intent to cancel a registration issued under section 136a(c)(7) of this title [Section 3(c)(7)] if . . . at the end of the period provided for satisfaction of any condition imposed, that condition has not been met." 7 U.S.C. § 136d(e). Here, Bayer has not met the condition to request voluntary cancellation.

Making the determination that Bayer did not meet a condition of its conditional registrations is amenable to the streamlined review of Section 6(e). *See* Bayer Appeal Brief at 13. For the same reason, EPA is not required to seek suspension pursuant to Section 6(c) because Section 6(e) is the appropriate procedure for review of Bayer's failure to meet the mandatory condition to which it had agreed. *See* Bayer Appeal Brief at 8.

The condition to request voluntary cancellation is analogous to the expiration condition in the conditional registrations that were upheld in *Woodstream Corp. v. Jackson*, 845 F.Supp.2d 174 (D.D.C. 2012). Woodstream's application for amended registrations of rodenticide products did not comply with a 2008 Risk Mitigation Decision (RMD); therefore, the registrations were approved "only subject to the condition that the registration shall expire by June 4, 2011." *Id.* at 178 and 182. Woodstream had the opportunity to eliminate the expiration condition if it requested amended registrations that conformed to the RMD. But, if it did not, any product release after June 4, 2011 would no longer be registered and in violation of FIFRA. *Id.* at 178. Like Bayer here, Woodstream argued that EPA abused its discretion because the expiration condition would allow EPA to "bypass" the important procedural protections provided by Section 6(b). *Id.* at 182-83. The court held that Woodstream could have applied for an amended registration that did not have the expiration condition, which EPA presumably would have denied, thereby affording Woodstream remedies under Section 6. *Id.* Woodstream also argued that it had to accept the conditional amended registrations for bromethalin because it needed them to stay competitive in the marketplace. *Id.* at 183. The court found the fact that Woodstream was "forced to make a business choice" did not render the expiration condition unlawful. *Id.*

Likewise, Bayer could have sought review of the decision if it thought the cancellation condition was unlawful or sought an amended registration that did not contain the voluntary cancellation decision, but it did not. That is likely because Bayer had made a business decision to accept the registration with conditions and avoid a Section 6(b) hearing so that it could immediately, and for the next eight years, sell flubendiamide products pursuant to the conditional registration.

The registrations at issue in *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131 (D.C. Cir. 2011) are distinguishable. Reckitt Benckiser also held registrations of rodenticide products that did not comply with the 2008 RMD. However, these registrations did not contain an expiration condition, as in *Woodstream*, nor a voluntary cancellation condition, as in Bayer's conditional registrations of flubendiamide products.⁹ Instead, the RMD directed registrants to inform EPA whether they intended to amend their registrations to conform to the RMD, and, if not, any products released after June 4, 2011 that did not conform to the RMD would be considered misbranded. *Id.* at 39. Reckitt Benckiser declined to amend its registrations to conform to the RMD and brought suit for declaratory and injunctive relief to prevent EPA from initiating misbranding or other enforcement. The court held that EPA could not use its misbranding enforcement authority instead of cancellation pursuant to Section 6(b) when it found that a pesticide "no longer" met the registration criteria. *Id.* at 43-44. Here, EPA is not trying to cancel flubendiamide pursuant to an enforcement action; EPA is holding Bayer to a mandatory term of its conditional registration.

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

⁹ Even if Bayer is correct that some of the registrations at issue in *Reckitt* were conditional registrations, the relevant inquiry concerns the voluntary cancellation condition.

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."¹⁰ 7 U.S.C. § 136d(e)(2). Under this analysis, the ALJ is left with two questions: did Bayer comply with the condition of its registration to request cancellation and did it do so within the time limit provided by EPA. Bayer has failed to do so for any of its four conditionally registered flubendiamide pesticides. For that reason, cancellation of the flubendiamide registrations is appropriate.

C. 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 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 that “significant effects to aquatic organisms due to the use of flubendiamide could potentially

¹⁰ 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).

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. 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.¹¹ 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.

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¹¹ 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-america-s-most-endangered-species/

VI. 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 20th day of June, 2016.



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ADDENDUM

Aquatic Invertebrates Listed under the Endangered Species Act

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

STATEMENT OF COMPLIANCE WITH WORD LIMITATION

I hereby certify that this Amicus Brief, including all relevant portions, contains fewer than 14,000 words.


Stephanie M. Parent

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 20th day of June, 2016, a true and correct copy of the foregoing AMICUS BRIEF OF THE CENTER FOR BIOLOGICAL DIVERSITY was filed electronically using the EPA Environmental Appeals Board e-filing system, and served in the following manner to the below addresses:

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