ORAL ARGUMENT NOT YET SCHEDULED
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioner*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *Respondent*, DOW AGROSCIENCES LLC, *Respondent-Intervenor.*	No. 14-73353
CENTER FOR FOOD SAFETY, *et al.* *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and GINA MCCARTHY, in her official capacity as Administrator, *Respondents*, DOW AGROSCIENCES LLC, *Respondent-Intervenor.*	No. 14-73359

RESPONDENTS' MOTION FOR VOLUNTARY VACATUR AND REMAND

Respondent United States Environmental Protection Agency ("EPA") hereby moves for voluntary vacatur and remand of EPA's registration, as amended, of Dow AgroSciences' ("Dow") "Enlist Duo" herbicide under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Enlist Duo is an herbicide developed for use on corn and soybean crops that are genetically engineered to be resistant to the two active ingredients in Enlist Duo. As explained below, because EPA is in receipt of new information regarding potential synergistic effects between the two ingredients on non-target plants, EPA seeks a voluntary remand in order to reconsider the Enlist Duo registration in light of the new information. EPA also seeks vacatur of the registration because EPA cannot be sure, without a full analysis of the new information, that the current registration does not cause unreasonable effects to the environment, which is a requirement of the registration standard under FIFRA.

On November 24, 2015, Counsel for EPA informed counsel for all parties of EPA's intention to file this motion. Counsel for Petitioners in these consolidated Petitions have indicated that their respective clients do not oppose this motion. Counsel for Dow has indicated that Dow intends to file a response to this motion.

BACKGROUND

FIFRA generally governs pesticide regulation in the United States. *See generally* 7 U.S.C. §§ 136-136y. It regulates the sale, distribution, labeling, and use of pesticides while protecting human health and the environment from associated unreasonable

adverse effects. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991-92 (1984). To that end, FIFRA establishes a federal registration scheme that generally precludes distributing or selling any pesticide that has not been "registered" by EPA. 7 U.S.C. § 136a(a); *Fairhurst v. Hagener*, 422 F.3d 1146, 1151 (9th Cir. 2005). A FIFRA registration is a license that establishes the terms and conditions under which a pesticide may be lawfully sold, distributed, and used. *See* 7 U.S.C. §§ 136a(c)(1)(A)-(F), 136a(d)(1). Applicants for pesticide registrations must submit proposed label language addressing a number of different topics, including ingredients, directions for use, and adverse effects of the products. *See* 7 U.S.C. § 136a(c); 40 C.F.R. § 152.50 & Part 156. *Welchert v. Am. Cyanamid, Inc.*, 59 F.3d 69, 71 (8th Cir. 1995).

FIFRA authorizes EPA to issue registrations for new active ingredients under section 3(c)(5) or "conditional" registrations under section 3(c)(7). 7 U.S.C. §§ 136a(c)(5), (c)(7). To support either type of registration, applicants must submit or cite studies intended to identify potential effects on human health and the environment. 7 U.S.C. § 136a(c); 40 C.F.R. Part 158. EPA approves each registration only after a careful review of the submitted product data and label. *See Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 560 (9th Cir. 1995). To register a pesticide under section 3(c)(5), as EPA did here, EPA must determine that (1) the pesticide's composition warrants the proposed claims for it, (2) the pesticide's labeling complies with the requirements of FIFRA, (3) the pesticide will perform its intended function

"without unreasonable adverse effects on the environment," and (4) when used in accordance with widespread and commonly recognized practice, the pesticide "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). As relevant here, the phrase "unreasonable adverse effects on the environment" is defined within FIFRA to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide." 7 U.S.C. § 136(bb)(1).

In November 2011, Dow applied to EPA for registration of Enlist Duo under FIFRA. ER 8. On October 15, 2014, EPA granted Dow's request and issued a registration for Enlist Duo for use in Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin. *See* ER 7-8. Additionally, on March 31, 2015, EPA issued a final decision amending the registration to allow Enlist Duo use in Arkansas, Kansas, Louisiana, Minnesota, Missouri, Mississippi, Nebraska, Oklahoma, and North Dakota. *See* ER 1-2. As part of the registration, EPA required certain drift reduction measures, including a 30-foot downwind in-field buffer from "sensitive areas" in order to avoid effects on non-target organisms, including endangered plant species, located off the field. ER 34-35. "Sensitive Areas" are defined by the label as any areas other than roads, paved, or gravel surfaces; planted agricultural fields (with the exception of certain crops susceptible to the herbicide); agricultural fields that have been prepared for planting; and areas covered by the footprint of a building, shade house, green

house, silo, feed crib, or other man-made structure with walls and or roof. *See* ER 498.

In response to comments contending that EPA did not address the potential synergistic effects of Enlist Duo's two active ingredients, EPA stated that it "adequately addressed the issue of synergism between [the two Enlist Duo ingredients] by evaluating data on the chemicals individually as well as with formulation-specific information." ER 19. After reviewing that information, EPA concluded that "[g]iven that there is no indication of synergism between [the two Enlist Duo ingredients] for mammals, freshwater fish, and freshwater invertebrates, EPA believes it is reasonable to assume that there are no synergistic interactions for the taxonomic groups that were not tested, including plants." *Id.* EPA also stated that "[t]he mixture [of the two ingredients] does not show a greater toxicity compared to either parent compound alone." ER 561.

Recently, however, EPA discovered that Dow made claims of "synergistic herbicidal weed control" in its Provisional and Non-provisional patent applications for Enlist Duo. The Provisional application was filed on December 20, 2013, and the final application was filed on December 11, 2014. *See* http://portal.uspto.gov/pair/PublicPair (Provisional App. No. 61919135; Non-provisional App. No. 14567574); Ex. 1 (October 13, 2015, Letter from EPA to Dow). On October 13, 2015, after reviewing the patent application, EPA sent Dow a letter

pursuant to 40 CFR §159.195(c) (implementing FIFRA section 6(a)(2), 7 U.S.C. § 136d(a)(2)), advising Dow that the claimed "synergism" could affect the Agency's assessment of drift reduction measures for avoiding impacts to non-target organisms, including those listed as endangered, and requesting all available information within 30 days of the letter. *Id.* EPA received Dow's response on November 9, 2015. EPA is still evaluating the extensive information contained in Dow's response, but an initial review indicates that the 30-foot buffer included in the registration may not be adequate. Ex. 2 (Declaration of Donald Brady, Ph.D. ¶¶ 11-12.) Accordingly, in light of the new information regarding the potential synergism of the two Enlist Duo ingredients, EPA seeks a voluntary remand with vacatur to reconsider the Enlist Duo registration.

ARGUMENT

Agency decisions are not carved in stone. Instead, an agency must consider the "wisdom of its policy on a continuing basis," for example, "in response to changed factual circumstances." *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (citations omitted). "[W]hen an agency action is reviewed by the courts . . . . the agency may take one of five positions," one of which is "seek[ing] a remand to reconsider its decision because of intervening events outside of the agency's control . . . ." *SKF USA, Inc. v. United States*, 254 F.3d 1022, 1027-28 (Fed. Cir. 2001); *see also California Communities Against Toxics v. EPA*, 688 F.3d 989 (9th Cir.

2012) (citing *SKF*, 254 F.3d at 1029). Indeed, courts generally only "refuse voluntarily requested remand when the agency's request is frivolous or made in bad faith." *California Communities*, 688 F.3d at 992. "Administrative reconsideration is a more expeditious and efficient means of achieving an adjustment of agency policy than is resort to the federal courts." *B.J. Alan Co. v. ICC*, 897 F.2d 561, 562 n.1 (D.C. Cir. 1990) (quoting *Commonwealth of Pennsylvania v. ICC*, 590 F.2d 1187, 1194 (D.C. Cir. 1978)).

Here, EPA has learned that it did not have all relevant information at the time it made its registration decision. Specifically, Dow did not submit to EPA during the registration process the extensive information relating to potential synergism it cited to the Patent Office; EPA only learned of the existence of that information after the registrations were issued and only recently obtained the information. Ex. 2 (Brady Declaration ¶¶ 4, 5, 8). EPA's scientists have preliminarily reviewed this data over the last two weeks, and believe, based on that review, that the data indicate that the 30-foot buffer on the approved label may not be adequate to protect non-target plant species located outside the treated fields. *Id.* ¶ 11. EPA requires additional time in which to fully assess the new information. *Id.* ¶ 12.

Because EPA has become aware of previously-existing information about possible synergistic effects that it did not consider, the Agency can no longer represent to the Court that it its conclusions were correct regarding whether issuance

of the registration met the standard in FIFRA and whether the buffer zones included in the registration support the finding that the registration will have no effect upon threatened or endangered plant species. EPA therefore consents to vacatur as well as remand of the Enlist Duo registration. Following remand and vacatur of the Enlist Duo registration, EPA would fully evaluate the new information and determine whether a new registration could be issued and, if so, whether additional terms and conditions would be necessary for the new registration.[1] To the extent that any interested party is not satisfied with any final action on remand, that party may obtain review of that agency action in this Court in accordance with FIFRA section 16, 7 U.S.C. § 136n.

In environmental cases, to decide whether remand with or without vacatur is the appropriate remedy, a factor this Court considers is the extent to which vacatur would cause or prevent possible environmental harm. *See Pollinator Stewardship Council v. EPA*, __ F.3d __, 2015 WL 7003600 at *12 (9th Cir. Nov. 12, 2015) (collecting cases). In *Pollinator Stewardship*, for example, this Court concluded that because of possible adverse effects on bee populations from the pesticide at issue in the

[1] In addition to its FIFRA-related concerns, EPA seeks vacatur and remand in light of the new information that came to light in Dow's patent application in order to review its determination that Enlist Duo would have no effect on species listed as endangered or threatened under the Endangered Species Act. In particular, EPA is concerned about the potential effects of Enlist Duo on certain plant species.

registration under review, "leaving the EPA's registration . . . in place risks more potential environmental harm than vacating it." *Id.* In light of that consideration, and because EPA could reach a different result on remand after obtaining the studies that the Court found were lacking, this Court vacated the registration. *Id.* A similar analysis applies here in that EPA may determine that changes to the registration are necessary to adequately protect non-target plant species, including those listed as endangered.

Specifically, before EPA can register a pesticide under FIFRA, FIFRA section 3(c)(5) requires that EPA determine, in part, that the pesticide "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). EPA made such a finding here, supported by the 30-foot in-field buffer requirement. *See* ER 1, 8, 30, 34. However, the new information obtained from Dow calls that finding into question—the information suggests that EPA's analysis may have understated the phytotoxicity of the product, therefore EPA can no longer be confident that Enlist Duo will not cause risks of concern to non-target organisms, including those listed as endangered, when used according to the approved label. Ex. 2 (Brady Declaration ¶¶ 10-12). And, based on the initial review of the new information, EPA believes that the 30-foot in-field buffer may not be adequate, thereby allowing a registration only on terms potentially different from those of the registration currently in effect. *Id.* Accordingly, keeping the registration in effect may

risk more environmental harm than vacating it, and it is possible that EPA's action on remand will result in a change to the registration.

A second factor courts consider in determining whether vacatur is appropriate is whether such relief (which constitutes an "'interim change that may itself be changed"') would cause "'disruptive consequences."' *California Communities*, 688 F.3d at 992 (quoting *Allied–Signal, Inc. v. U.S. Nuclear Regulatory Comm'n,* 988 F.2d 146, 150–51 (D.C.Cir. 1993)). While there may be some economic impacts to Dow from a vacutur, the extent of such impacts is unclear, and EPA believes that vacatur is appropriate in light of the potential environmental impacts and the fact that EPA's action on remand may result in a change to the registration. *See Pollinator Stewardship*, __ F.3d __, 2015 WL 7003600 at *12 (determining that vacatur is appropriate in light of potential environmental harm and fact that EPA may change registration on remand).

Thus, remand with vacatur is appropriate here. If this Court vacates this registration, EPA will then issue a cancellation order to regulate the sale, distribution, and use of existing stocks of Enlist Duo pursuant to FIFRA. *See* 7 U.S.C. § 136d(a)(1).

CONCLUSION

In summary, EPA has provided a reasonable basis for seeking voluntary remand. As the supporting EPA Declaration explains, the new information cited

above has called into question the validity of the Agency's earlier conclusion that use of Enlist Duo will not cause "unreasonable adverse effects on the environment." Because remand with vacatur will be more protective of the environment and because EPA might not have issued the existing registration had it been aware of the potential synergy information at the time the initial registration was issued, vacatur is appropriate in this case. Thus, EPA respectfully requests that the Court vacate the Enlist Duo registration and to remand it to the Agency for further consideration.

DATED: November 24, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I served a copy of RESPONDENT'S MOTION FOR VOLUNTARY VACATUR AND REMAND via Notice of Docket Activity by the Court's CM/ECF system, on November 24, 2015, on all counsel of record:

/s/David A. Carson
David A. Carson

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVETION

October 13, 2015

Diego Fonseca
Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

Re: Enlist Duo and Reporting Obligations Under FIFRA section 6(a)(2)

Dear Mr. Fonseca:

The Environmental Protection Agency (EPA or the Agency) is concerned about the claims of "synergistic herbicidal weed control" when using "a mixture comprising (a) a 2,4-D-choline salt and (b) a salt of N-(phosphonomethyl)glycerine (glyphosate)" made in Dow AgroSciences LLC's (DAS) United States Patent Application, filed Dec. 11, 2014, Pub. No. US 2015/0173371 A1, Pub. Date June 25, 2015 (Patent Application), and the supporting data underlying those claims of "synergy" summarized on pages 7 through 10 of the Patent Application. The Patent Application claims and defines "synergism" as follows:

> [I]n some embodiments, the combination of 2,4-D-choline and a salt of glyphosate exhibit synergism, i.e., the herbicidal active ingredients are more effective in combination than when applied individually. Synergism has been defined as "an interaction of two or more factors such that the effect when combined is greater than the predicted effect based on the response of each factor applied separately." Shaner, D. L., Ed. *Herbicide Handbook,* 10th ed. Lawrence: Weed Science Society of America, 2014. In certain embodiments, the compositions exhibit synergy as determined by Colby's equation (Colby, S. R. Calculation of the synergistic and antagonistic response of herbicide combinations. Weeds 1967, 15, 20-22).

Patent Application at 2, paragraph [0020]. Empirical demonstration of the "synergism" claimed in the Patent Application would have the potential to impact the assessment of drift reduction measures (including spray drift buffers) for avoiding effects to non-target organisms. Consequently, the Agency needs to fully understand the claims to "synergism" made in the Patent Application by DAS, the supporting studies discussed in the Patent Application regarding the claims to "synergism," and any other studies conducted or possessed by DAS that test the combined effects of Enlist Duo product co-formulants, including the entire product formulation, and that indicate potential "synergism," as defined in the Patent Application. As a registrant of pesticide products registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), you are required to notify the EPA pursuant to FIFRA section 6(a)(2), 7 U.S.C. § 136d(a)(2), of any "additional factual information regarding unreasonable adverse effects on the environment [in your possession]."

EPA's implementing regulations at 40 CFR Part 159 identify the types of information that registrants must submit to the Agency pursuant to FIFRA section 6(a)(2). Those regulations include a provision that requires registrants to submit information that "the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a pesticide or about the appropriate terms and conditions of registration of a product" (40 CFR 159.195(a)), and a provision requiring that information be submitted if "the registrant has been informed by EPA that such additional information has the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product." 40 CFR 159.195(c). By this letter, the Agency is reminding you of your general obligations under 40 CFR 159.195(a), and is informing you of certain specific types of information that must be reported under 40 CFR 159.195(c).

If DAS, any subsidiary of the company, or any consultant, attorney, or agent who acquired such information while acting as a consultant, attorney, or agent for DAS, has any information relating to Enlist Duo, 2,4-D-choline salt, or glyphosate that falls into the categories identified below, such information must be made available to the Agency in Washington, D.C. The Agency encourages DAS to provide available information as soon as possible and will accept information on a rolling basis; however, all existing information must be made available no later than 30 days from the date of this letter. To the extent the specific information listed in this letter overlaps with information specified in 40 CFR sections 159.165 through 159.188, the deadline for submitting the information is either 30 days from the date of this letter or the applicable deadline in 40 CFR 159.155, whichever is sooner. Please note that EPA is not asking attorneys to provide any opinions or conclusions rendered as the professional legal judgment of an attorney, as defined in the Model Code, as part of this letter. However, any factual information in the possession of attorneys that attorneys acquired while working for DAS that falls into the categories identified below, including any applicable expert opinions of non-attorneys, must be submitted pursuant to this letter.

At this time, any of the information listed below, in the possession of DAS or any of its consultants, attorneys, or agents, must be reported to EPA under section 6(a)(2) of FIFRA. Any information or studies that fall into the categories below, but that have previously been submitted to EPA's Office of Pesticide Programs, are excluded and need not be provided to the Agency again in response to this letter.

1) Any information, including but not limited to memoranda, reports, data, and studies, supporting the claims to "synergism" made in the Patent Application by DAS, the studies discussed in the Patent Application as supporting the claims to "synergism," and any other studies conducted or possessed by DAS that test the combined effects of Enlist Duo product co-formulants, including the entire product formulation, that indicate potential "synergism," as defined in the Patent Application. This information includes, at a minimum:

    a) All supporting laboratory and field study reports involving the efficacy of Enlist duo product co-formulants, including the entire product formulation as well as any laboratory or field studies involving phytotoxicity to target or non-target species of Enlist duo product co-formulants, including the entire product formulation, that were associated with the Patent Application evidence described on pages 7 through 10 of the Patent Application in support of the claimed "synergism," as defined in the Patent Application;

b) All information showing any phytotoxicity to target or non-target plants of the Enlist Duo product co-formulants alone or in combination, including all laboratory and field study efficacy and phytotoxicity reports of plant testing of the Enlist Duo product co-formulants alone and in combination that are not included in pages 7 through 10 of the Patent Application, and that indicate potential "synergism," as defined in the Patent Application;

c) All laboratory and field study efficacy and phytotoxicity reports of Enlist Duo product testing on plants that indicate potential "synergism," as defined in the Patent Application.

2) All studies and data, completed or in progress, pertaining to Enlist Duo's toxicity to plants, either target or non-target, through direct or indirect application, including but not limited to all efficacy studies, phytotoxicity studies, raw data, anecdotal reports, study summaries or discontinued studies indicating toxicity to plants, and that indicate potential "synergism," as defined in the Patent Application.

3) Any information not previously identified in this letter if, in light of the Agency's concern regarding the potential "synergy" of the Enlist Duo product co-formulants claimed in the Patent Application, you have reason to believe that EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of Enlist Duo or about the appropriate terms and conditions of registration of Enlist Duo (*i.e.*, information falling within the scope of 40 CFR 159.195(a)).

Moreover, as the requirements to report information to the Agency pursuant to section 6(a)(2) of FIFRA continue as long as the product is registered, any information that falls into the categories identified above, that DAS, any subsidiary, or any consultants, attorneys, or agents thereof, receives subsequent to the receipt of this letter must be made available to the Agency in Washington, D.C.

Any information you or any agent, attorney, or consultant working for you may have that falls into any of the categories outlined above should be sent to Dan Kenny, U.S. Environmental Protection Agency, Office of Pesticide Programs, 1200 Pennsylvania Ave., NW (Mail Code 7505P), Washington, DC 20460. Courier deliveries may be made to Dan Kenny, Office of Pesticide Programs, One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA 22202. If you have any questions about this letter, or whether particular pieces of information fall within the scope of this letter, please feel free to call Mr. Kenny at (703) 305-7546.

Sincerely,

Susan Lewis

Susan Lewis, Division Director
Registration Division
Office of Pesticide Programs
United States Environmental Protection Agency

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Natural Resources Defense Council, Inc., Petitioner, v. United States Environmental Protection Agency, Respondent, Dow Agrosciences, LLC, Respondent-Intervenor.	)	No. 14-73353 (Consolidated with 15-71207, 15-71213, and 14-73359)

DECLARATION OF DONALD BRADY, PH.D.

I, Donald Brady, Ph.D., declare as follows:

1. The following statements are true and correct to the best of my knowledge and belief and are based on either my personal knowledge, my review of information contained in the records provided to the U.S. Environmental Protection Agency ("EPA" or the "Agency"), or evaluations of such records supplied by current EPA employees.

2. I am the Director of the Environmental Fate and Effects Division ("EFED") in EPA's Office of Pesticide Programs ("OPP"). I have

worked for EPA for 41 years. I have served in various positions within EPA, including Acting Director of the Municipal Support Division, Chief of the Municipal Branch in the Permits Division in the Office of Wastewater Management, and Chief of the Watershed Branch in the Assessment and Watershed Protection Division in the Office of Wetlands, Oceans and Watersheds, all in the EPA Office of Water. I have been the Director of EFED since 2008.

3. EFED is the division assigned responsibility for assessing the ecological risk and environmental fate of both new and existing conventional pesticides under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). Part of this responsibility includes evaluating effects to species listed as threatened or endangered ("listed species") under the Endangered Species Act ("ESA") and preparing the biological evaluations that EPA provides to the National Marine Fisheries Service ("NMFS") and the United States Fish and Wildlife Service ("FWS") (collectively "Services") when it consults with the Services on pesticide actions that "may affect" listed species or their designated critical habitat. EPA's consultation obligations under the ESA involve extremely complex scientific assessments because rather than addressing effects of a discrete project at a specific location, EPA's pesticide

registration actions effectively address the entire United States and therefore involve the potential for effects to hundreds of listed species in numerous and varying aquatic and terrestrial habitats. It is important to note that EFED is not the division that makes the final registration determination that there are no unreasonable adverse effects on human health and the environment. In general, that determination is made by the Registration Division, taking into consideration the risk assessment performed by EFED.

4. On or about August 17 or 18, 2015, I was told by Dr. Edward Odenkirchen, Senior Advisor in EFED, that while searching the free patents online database (www.freepatentsonline.com/20150173371.pdf), he discovered a patent application submitted by Dow AgroSciences LLC ("Dow") that claimed their product Enlist Duo had "synergistic weed control" properties.

5. Prior to finding this patent application that claimed synergistic weed control, my staff conducted its risk assessments assuming that the two components of Enlist Duo did not have synergistic effects when applied according the approved label. In other words, the EFED risk assessments considered the toxicity of each active ingredient separately.

6. In its patent application, Dow used the following definition of synergy:

"an interaction of two or more factors such that the effect when combined is greater than the predicted effect based on the response of each factor applied separately." *See* Non-provisional patent application at [0020] citing to Shaner, D.L., Ed. *Herbicide Handbook*, 10th ed. Lawrence: Weed Science Society of America. 2014. Dow also stated that "the herbicidal active ingredients are more effective in combination than when applied individually." *See* Non-provisional patent application at [0020].

7. EFED agrees with the definition of "synergy" used by Dow in its patent application.

8. EFED did not have the information contained in the patent application when assessing whether there were any risks of concern during the registration process for Enlist Duo, including at the time it made its no effects determinations under the ESA.

9. If synergy is present in the Enlist Duo product, then the earlier assessments supporting the registration may not be accurate.

10. When making its original determinations as to whether Enlist Duo applications had risks of concern, EFED determined that a 30-foot downwind in-field buffer was necessary to make no effects determinations under the ESA as well as to making a finding as to

whether there were risks of concern for non-target organisms for purposes of a FIFRA registration decision.

11. After learning of the patent application information, receiving extensive information from Dow, and having discussions with the company concerning this information, Dr. Odenkirchen conducted a preliminary assessment of the new information. The results of that preliminary assessment led EFED to the initial determination that the 30-foot downwind in-field buffer may not be adequate to protect non-target organisms, including those listed as threatened or endangered.

12. EFED requires additional time to review this information more fully, and it expects to provide OPP management with its findings in a timely manner. At this time, EFED is not confident that the 30-foot downwind in-field buffer is adequate to protect non-target organisms, including those listed as threatened or endangered. If the 30-foot downwind in-field buffer is determined not to be adequate, then that will raise risks of concern for non-target organisms, including those listed as threatened or endangered.

Under 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on the 24th day of November, 2015.

11/24/15

Donald Brady, Ph.D., Director
Environmental Fate and Effects Division
Office of Pesticide Programs
United States Environmental Protection Agency