Office of the Clerk
United States Court of Appeals for the Ninth Circuit
Post Office Box 193939
San Francisco, California 94119-3939
415-355-8000

Molly C. Dwyer
Clerk of Court

March 21, 2017

No.: 17-70817
EPA No.: EPA-HQ-OPP-2016-0594
Short Title: NRDC v. Scott Pruitt, et al

Dear Petitioner/Counsel

Your Petition for Review has been received in the Clerk's office of the United States Court of Appeals for the Ninth Circuit. The U.S. Court of Appeals docket number shown above has been assigned to this case. You must indicate this Court of Appeals docket number whenever you communicate with this court regarding this case.

The due dates for filing the parties' briefs and otherwise perfecting the petition have been set by the enclosed "Time Schedule Order," pursuant to applicable FRAP rules. These dates can be extended only by court order. Failure of the petitioner to comply with the time schedule order will result in automatic dismissal of the petition. 9th Cir. R. 42-1.

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

FILED

MAR 21 2017

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

NATURAL RESOURCES DEFENSE COUNCIL,

Petitioner,

v.

SCOTT PRUITT, in his official capacity as Administrator of the United States Environmental Protection Agency; U.S. ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

No. 17-70817

EPA No. EPA-HQ-OPP-2016-0594
Environmental Protection Agency

TIME SCHEDULE ORDER

The parties shall meet the following time schedule.

Tue., March 28, 2017	Mediation Questionnaire due. If your registration for Appellate ECF is confirmed after this date, the Mediation Questionnaire is due within one day of receiving the email from PACER confirming your registration.
Fri., June 9, 2017	Petitioner's opening brief and excerpts of record shall be served and filed pursuant to FRAP 32 and 9th Cir. R. 32-1.
Mon., July 10, 2017	Respondents' answering brief and excerpts of record shall be served and filed pursuant to FRAP 32 and 9th Cir. R. 32-1.

The optional petitioner's reply brief shall be filed and served within fourteen days of service of the respondents' brief, pursuant to FRAP 32 and 9th Cir. R. 32-1.

Failure of the petitioner to comply with the Time Schedule Order will result in automatic dismissal of the appeal. See 9th Cir. R. 42-1.

FOR THE COURT:

MOLLY C. DWYER
CLERK OF COURT

By: Holly Crosby
Deputy Clerk
Ninth Circuit Rule 27-7

UNITED STATES COURT OF APPEALS for the NINTH CIRCUIT

Office of the Clerk

After Opening a Case – Counseled Non-Immigration Agency Cases

(revised April 2016)

Court Address – San Francisco Headquarters

Mailing Address for U.S. Postal Service	*Mailing Address for Overnight Delivery (FedEx, UPS, etc.)*	*Street Address*
Office of the Clerk James R. Browning Courthouse U.S. Court of Appeals P.O. Box 193939 San Francisco, CA 94119-3939	Office of the Clerk James R. Browning Courthouse U.S. Court of Appeals 95 Seventh Street San Francisco, CA 94103-1526	95 Seventh Street San Francisco, CA 94103

Court Addresses – Divisional Courthouses

Pasadena	*Portland*	*Seattle*
Richard H. Chambers Courthouse 125 South Grand Avenue Pasadena, CA 91105	The Pioneer Courthouse 700 SW 6th Ave, Ste 110 Portland, OR 97204	William K. Nakamura Courthouse 1010 Fifth Avenue Seattle, WA 98104

Court Website – www.ca9.uscourts.gov

The Court's website contains the Court's Rules and General Orders, information about electronic filing of documents, answers to frequently asked questions, directions to the courthouses, forms necessary to gain admission to the bar of the Court, opinions and memoranda, live streaming of oral arguments, links to practice manuals, and an invitation to join our Pro Bono Program.

Court Phone List

Main Phone Number	**(415) 355-8000**
Attorney Admissions	(415) 355-7800
Calendar Unit	(415) 355-8190
Docketing	(415) 355-7840
Death Penalty	(415) 355-8197
Electronic Filing – CM/ECF	Submit form at http://www.ca9.uscourts.gov/cmecf/feedback
Library	(415) 355-8650
Mediation Unit	(415) 355-7900
Motions Attorney Unit	(415) 355-8020
Procedural Motions Unit	(415) 355-7860
Records Unit	(415) 355-7820
Divisional Court Offices:	
Pasadena	(626) 229-7250
Portland	(503) 833-5300
Seattle	(206) 224-2200

Electronic Filing - CM/ECF

The Ninth Circuit's CM/ECF (Case Management/Electronic Case Files) system is mandatory for all attorneys filing in this Court, unless they are granted an exemption. All non-exempted attorneys who appear in an ongoing case are required to register for and to use CM/ECF. Registration and information about CM/ECF is available on the Court's website at www.ca9.uscourts.gov under *Electronic Filing–CM/ECF*. Read the Circuit Rules, especially Ninth Circuit Rule 25-5, for guidance on filing documents electronically via CM/ECF, and see the CM/ECF User Guide for a complete list of the available types of filing events.

Rules of Practice

The Federal Rules of Appellate Procedure (Fed. R. App. P.), the Ninth Circuit Rules (9th Cir. R.) and the General Orders govern practice before this Court. The rules are available on the Court's website at www.ca9.uscourts.gov under *Rules*.

Practice Resources

The Appellate Lawyer Representatives' Guide to Practice in the United States Court of Appeals for the Ninth Circuit is available on the Court's website www.ca9.uscourts.gov at *Guides and Legal Outlines* > *Appellate Practice Guide*. The Court provides other resources in *Guides and Legal Outlines*.

Admission to the Bar of the Ninth Circuit

All attorneys practicing before the Court must be admitted to the Bar of the Ninth Circuit. Fed. R. App. P. 46(a); 9th Cir. R. 46-1.1 & 46-1.2.

For instructions on how to apply for bar admission, go to www.ca9.uscourts.gov and click on the *Attorneys* tab > *Attorney Admissions* > *Instructions*.

Notice of Change of Address

Counsel who are registered for CM/ECF must update their personal information, including street addresses and email addresses, online at: https://pacer.psc.uscourts.gov/pscof/login.jsf 9th Cir. R. 46-3.

Counsel who have been granted an exemption from using CM/ECF must file a written change of address with the Court. 9th Cir. R. 46-3.

Payment of Fees

The $500.00 filing fee or a motion to proceed in forma pauperis shall accompany the petition. 9th Cir. R. 3-1.

A motion to proceed in forma pauperis must be supported by the affidavit of indigency found at Form 4 of the Federal Rules of Appellate Procedure, available at the Court's website, www.ca9.uscourts.gov, under *Forms*.

Failure to satisfy the fee requirement or to apply to proceed without payment of fees will result in the petition's dismissal. 9th Cir. R. 42-1.

Motions Practice

Following are some of the basic points of motion practice, governed by Fed. R. App. P. 27 and 9th Cir. R. 27-1 through 27-14.

- Neither a notice of motion nor a proposed order is required. Fed. R. App. P. 27(a)(2)(C)(ii), (iii).
- Motions may be supported by an affidavit or declaration. 28 U.S.C. § 1746.
- Each motion should provide the position of the opposing party. Circuit Advisory Committee Note to Rule 27-1(5); 9th Cir. R. 31-2.2(b)(6).
- A response to a motion is due 10 days from the service of the motion. Fed. R. App. P. 27(a)(3)(A); Fed. R. App. P. 26(c). The reply is due 7 days from service of the response. Fed. R. App. P. 27(a)(4); Fed. R. App. P. 26(c).
- A response requesting affirmative relief must include that request in the caption. Fed. R. App. P. 27(a)(3)(B).
- A motion filed after a case has been scheduled for oral argument, has been argued, is under submission or has been decided by a panel, must include on the initial page and/or cover the date of argument, submission or decision and, if known, the names of the judges on the panel. 9th Cir. R. 25-4.

Emergency or Urgent Motions

All emergency and urgent motions must conform with the provisions of 9th Cir. R. 27-3. Note that a motion requesting procedural relief (e.g., an extension of time to file a brief) is *not* the type of matter contemplated by 9th Cir. R. 27-3. Circuit Advisory Committee Note to 27-3(3).

Prior to filing an emergency motion, the moving party *must* contact an attorney in the Motions Unit in San Francisco at (415) 355-8020.

When it is absolutely necessary to notify the Court of an emergency outside of standard office hours, the moving party shall call (415) 355-8000. Keep in mind that this line is for true emergencies that cannot wait until the next business day (e.g., an imminent execution or removal from the United States).

Briefing Schedule

The Court sets the briefing schedule at the time the petition is docketed.

Certain motions (e.g., a motion for dismissal) automatically stay the briefing schedule. 9th Cir. R. 27-11.

The opening and answering brief due dates are not subject to the additional time described in Fed. R. App. P. 26(c). 9th Cir. R. 31-2.1. The early filing of petitioner's opening brief does not advance the due date for respondent's answering brief. *Id*.

Extensions of Time to file a Brief

Streamlined Request
Subject to the conditions described at 9th Cir. R. 31-2.2(a), you may request one streamlined extension of up to 30 days from the brief's existing due date. Submit your request via CM/ECF using the "File Streamlined Request to Extend Time to File Brief" event on or before your brief's existing due date. No form or written motion is required.

Written Extension
Requests for subsequent extensions or extensions of more than 30 days will be granted only upon a written motion supported by a showing of diligence and substantial need. This motion shall be filed at least 7 days before the due date for the brief. The motion shall be accompanied by an affidavit or declaration that includes all of the information listed at 9th Cir. R. 31-2.2(b).

The Court will ordinarily adjust the schedule in response to an initial motion. Circuit Advisory Committee Note to Rule 31-2.2. The Court expects that the brief will be filed within the requested period of time. *Id*.

Contents of Briefs and Record

The required components of a brief are set out at Fed. R. App. P. 28 and 32, and 9th Cir. R. 28-2, 32-1 and 32-2.

The content and filing of the record are governed by Fed. R. App. P. 16(a) and 17. If respondent does not file the record or certified list by the specified date, petitioner may move to amend the briefing schedule.

After the electronically submitted brief has been reviewed, the Clerk will request 7 paper copies of the brief that are identical to the electronic version. 9th Cir. R. 31-1. Do not submit paper copies until directed to do so.

Excerpts of Record

The Court requires Excerpts of Record rather than an Appendix. 9th Cir. R. 30-1.1. Please review 9th Cir. R. 17-1.3 through 17-1.6 to see a list of the specific contents and format. For Excerpts that exceed 75 pages, the first volume must comply with 9th Cir. R. 17-1.6 and 30-1.6(a). Excerpts exceeding 300 pages must be filed in multiple volumes. 9th Cir. R. 30-1.6(a).

Respondent may file supplemental Excerpts, and petitioner may file further Excerpts. 9th Cir. R. 17-1.7; 17-1.8; 30-1.7 and 30-1.8. If you are a respondent responding to a pro se brief that did not come with Excerpts, then your Excerpts need only include the contents set out at 9th Cir. R. 30-1.7.

Excerpts must be submitted in PDF format in CM/ECF on the same day the filer submits the brief. The filer shall serve a paper copy of the Excerpts on any party not registered for CM/ECF.

If the Excerpts contain sealed materials, you must submit the sealed documents electronically in a separate volume in a separate transaction from the unsealed volumes, along with a motion to file under seal. 9th Cir. R. 27-13(e). Sealed filings must be served on all parties by mail, or if mutually agreed by email, rather than through CM/ECF noticing.

After electronic submission, the Court will direct the filer to file 4 separately-bound paper copies of the excerpts of record with white covers.

Mediation Program

Mediation Questionnaires are required in all counseled agency cases except those cases seeking review of a Board of Immigration Appeals decision. 9th Cir. R.

15-2.

The Mediation Questionnaire is available on the Court's website at www.ca9.uscourts.gov under *Forms*. The Mediation Questionnaire should be filed within 7 days of the docketing of the petition. The Mediation Questionnaire is used only to assess settlement potential.

If you are interested in requesting a conference with a mediator, you may call the Mediation Unit at (415) 355-7900, email ca09_mediation@ca9.uscourts.gov or make a written request to the Chief Circuit Mediator. You may request conferences confidentially. More information about the Court's mediation program is available at http://www.ca9.uscourts.gov/mediation.

Oral Hearings

Approximately 14 weeks before a case is set for oral hearing, the parties are notified of the hearing dates and locations and are afforded 3 days from the date of those notices to inform the Court of any conflicts. Notices of the actual calendars are then distributed approximately 10 weeks before the hearing date.

The Court will change the date or location of an oral hearing only for good cause, and requests to continue a hearing filed within 14 days of the hearing will be granted only upon a showing of exceptional circumstances. 9th Cir. R. 34-2.

Oral hearing will be conducted in all cases unless all members of the panel agree that the decisional process would not be significantly aided by oral argument. Fed. R. App. P. 34(a)(2).

Oral arguments are live streamed to You Tube and can be accessed on the Court's website.

Ninth Circuit Appellate Lawyer Representatives
APPELLATE MENTORING PROGRAM

1. Purpose

The Appellate Mentoring Program is intended to provide mentoring on a voluntary basis to attorneys who are new to federal appellate practice or would benefit from guidance at the appellate level. In addition to general assistance regarding federal appellate practice, the project will provide special focus on two substantive areas of practice - immigration law and habeas corpus petitions. Mentors will be volunteers who have experience in immigration, habeas corpus, and/or appellate practice in general. The project is limited to counseled cases.

2. Coordination, recruitment of volunteer attorneys, disseminating information about the program, and requests for mentoring

Current or former Appellate Lawyer Representatives (ALRs) will serve as coordinators for the Appellate Mentoring Program. The coordinators will recruit volunteer attorneys with appellate expertise, particularly in the project's areas of focus, and will maintain a list of those volunteers. The coordinators will ask the volunteer attorneys to describe their particular strengths in terms of mentoring experience, substantive expertise, and appellate experience, and will maintain a record of this information as well.

The Court will include information about the Appellate Mentoring Program in the case opening materials sent to counsel and will post information about it on the Court's website. Where appropriate in specific cases, the Court may also suggest that counsel seek mentoring on a voluntary basis.

Counsel who desire mentoring should contact the court at mentoring@ca9.uscourts.gov, and staff will notify the program coordinators. The coordinators will match the counsel seeking mentoring with a mentor, taking into account the mentor's particular strengths.

3. The mentoring process

The extent of the mentor's guidance may vary depending on the nature of the case, the mentee's needs, and the mentor's availability. In general, the mentee should initiate contact with the mentor, and the mentee and mentor should determine together how best to proceed. For example, the areas of guidance may range from

basic questions about the mechanics of perfecting an appeal to more sophisticated matters such as effective research, how to access available resources, identification of issues, strategy, appellate motion practice, and feedback on writing.

4. Responsibility/liability statement

The mentee is solely responsible for handling the appeal and any other aspects of the client's case, including all decisions on whether to present an issue, how to present it in briefing and at oral argument, and how to counsel the client. By participating in the program, the mentee agrees that the mentor shall not be liable for any suggestions made. In all events, the mentee is deemed to waive and is estopped from asserting any claim for legal malpractice against the mentor.

The mentor's role is to provide guidance and feedback to the mentee. The mentor will not enter an appearance in the case and is not responsible for handling the case, including determining which issues to raise and how to present them and ensuring that the client is notified of proceedings in the case and receives appropriate counsel. The mentor accepts no professional liability for any advice given.

5. Confidentiality statement

The mentee alone will have contact with the client, and the mentee must maintain client confidences, as appropriate, with respect to non-public information.

United States Court of Appeals
for the Ninth Circuit

P.O. Box 31478
Billings, Montana 59107-1478

CHAMBERS OF
SIDNEY R. THOMAS
CHIEF JUDGE

December 1, 2014

TEL: (406) 373-3200
FAX: (406) 373-3250

Dear Counsel:

I want to take this opportunity to introduce you to the Court's mediation program. The court offers you and your clients professional mediation services, at no cost, to help resolve disputes quickly and efficiently and to explore the development of more satisfactory results than can be achieved from continued litigation. Each year the mediators facilitate the resolution of hundreds of cases, from the most basic contract and tort actions to the most complex cases involving multiple parties, numerous pieces of litigation and important issues of public policy.

The eight circuit mediators, all of whom work exclusively for the court, are highly experienced attorneys from a variety of practices; all have extensive training and experience in negotiation, appellate mediation, and Ninth Circuit practice and procedure. Although the mediators are court employees, the Court has adopted strict confidentiality rules and practices to ensure that what goes on in mediation stays in mediation. *See* Circuit Rule 33-1.

The first step in the mediation process is case selection. To assist the mediators in the case selection process, appellants/petitioners must file a completed Mediation Questionnaire within 7 days of the docketing of the case. *See* Circuit Rules 3-4, and 15-2. Appellees may also fill out and file a questionnaire. The questionnaire with filing instructions accompanies this letter and is also available at www.ca9.uscourts.gov/mediation/forms.php. All counsel are also invited to submit, by e-mail to ca09_mediation@ca9.uscourts.gov, additional, confidential information that might assist the mediators in the case selection process.

In most cases, the mediator will schedule a settlement assessment conference, with counsel only, to determine whether the case is suitable for mediation. Please be assured that participation in the mediation program will not slow down disposition of your appeal. Mediation discussions are not limited to the issues on appeal. The discussions can involve other cases and may include individuals who are not parties to the litigation, if doing so enables the parties to reach a global settlement.

Further information about the mediation program may be found on the court's website: www.ca9.uscourts.gov/mediation/. Please address questions directly to the Mediation Unit at 415-355-7900 or ca09mediation@ca9.uscourts.gov.

Our mediators do a terrific job. I hope you'll give them the opportunity to work on your case.

Sincerely,

Sidney R. Thomas

Sidney R. Thomas
Chief Circuit Judge

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Circuit Mediation Office
Phone (415) 355-7900 Fax (415) 355-8566
http://www.ca9.uscourts.gov/mediation

MEDIATION QUESTIONNAIRE

This form is available in a fillable version at *http://cdn.ca9.uscourts.gov/datastore/uploads/forms/Mediation_Questionnaire.pdf*.

The purpose of this questionnaire is to help the court's mediators provide the best possible mediation service in this case; it serves no other function. Responses to this questionnaire are ***not*** confidential. Appellants/Petitioners must electronically file this document within 7 days of the docketing of the case. 9th Cir. R. 3-4 and 15-2. Appellees/Respondents may file the questionnaire, but are not required to do so.

9th Circuit Case Number(s):

District Court/Agency Case Number(s):

District Court/Agency Location:

Case Name: v.

If District Court, docket entry number(s) of order(s) appealed from:

Name of party/parties submitting this form:

Briefly describe the dispute that gave rise to this lawsuit.

Briefly describe the result below and the main issues on appeal.

(Continue to next page)

Describe any proceedings remaining below or any related proceedings in other tribunals.

Provide any other thoughts you would like to bring to the attention of the mediator.

*Any party may provide additional information **in confidence** directly to the Circuit Mediation Office at ca09_mediation@ca9.uscourts.gov. Provide the case name and Ninth Circuit case number in your message. Additional information might include level of interest in including this case in the mediation program, the case's settlement history, issues beyond the litigation that the parties might address in a settlement context, or future events that might affect the parties' willingness or ability to mediate the case.*

CERTIFICATION OF COUNSEL

I certify that:

☐ a current service list with telephone and fax numbers and email addresses is attached (see 9th Circuit Rule 3-2).

☐ I understand that failure to provide the Court with a completed form and service list may result in sanctions, including dismissal of the appeal.

Signature

("s/" plus attorney name may be used in lieu of a manual signature on electronically-filed documents.)

Counsel for

***How to File*:** Complete the form and then convert the filled-in form to a static PDF (File > Print > PDF Printer or any PDF Creator). To file, log into Appellate ECF and select File Mediation Questionnaire. (*Use of the Appellate ECF system is mandatory for all attorneys filing in this Court, unless they are granted an exemption from using the system.)*

Case No. _____

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC.,

Petitioner,

v.

E. SCOTT PRUITT, in his official capacity as Administrator of the United States Environmental Protection Agency; and the UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

PETITION FOR REVIEW
of a final order of the U.S. Environmental Protection Agency

Margaret T. Hsieh
Natural Resources Defense Council
40 W. 20th Street
New York, NY 10011
Telephone: (212) 727-4652
Facsimile: (415) 795-4799
mhsieh@nrdc.org

Aaron Colangelo
Natural Resources Defense Council
1152 15th Street, NW, Suite 300
Washington, D.C. 20005
Telephone: (202) 289-2376
Facsimile: (415) 795-4799
acolangelo@nrdc.org

Counsel for Petitioner

Dated: March 21, 2017

PETITION FOR REVIEW

Pursuant to Rule 15 of the Federal Rules of Appellate Procedure and section 16(b) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136n(b), the Natural Resources Defense Council hereby petitions this Court to review and set aside the final order of the U.S. Environmental Protection Agency (EPA) granting conditional registration of Enlist Duo Herbicide for use in thirty-four states (EPA Registration Number 62719-649). The challenged final order was announced in two regulatory decision documents signed on January 12, 2017, and entered on EPA docket EPA-HQ-OPP-2016-0594. The order became final on January 26, 2017, at 1:00 p.m. eastern time, pursuant to 40 C.F.R. § 23.6. A copy of the final regulatory decision documents are attached as Exhibits A and B to this petition.

Dated: March 21, 2017

Respectfully submitted,

s/ Margaret T. Hsieh
Margaret T. Hsieh
Natural Resources Defense Council
40 W. 20th Street
New York, NY 10011
Telephone: (212) 727-4652
Facsimile: (415) 795-4799
mhsieh@nrdc.org

Aaron Colangelo
Natural Resources Defense Council
1152 15th Street, NW, Suite 300
Washington, D.C. 20005
Telephone: (202) 289-2376
Facsimile: (415) 795-4799
acolangelo@nrdc.org

Counsel for Petitioner

Exhibit A

U.S. Environmental Protection Agency,
Notice of Conditional Pesticide Registration for Enlist Duo
(January 12, 2017)

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration

EPA Reg. Number: 62719-649

Date of Issuance: 1/12/2017

Date of Expiration: See Below: Registration Term 5

Term of Issuance: Conditional

Name of Pesticide Product: Enlist Duo

Name and Address of Registrant (include ZIP Code):

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

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(B). You must comply with the following conditions:

1. This Notice of Pesticide Registration supersedes the Notice of Pesticide Registration dated October 15, 2014.

Signature of Approving Official:

Daniel Kenny, Chief
Herbicide Branch, Registration Division (7505P)

Date: 1/12/17

EPA Form 8570-6

2. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

3. You are required to comply with the data requirements described in the DCI identified below:

    a. 2,4-D GDCI-030063-1362

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

4. Submit one copy of the final printed label for the record before you release the product for shipment.

5. This registration will automatically expire on January 12, 2022.

6. You must maintain a website at http://EnlistTankMix.com. That website will include a list of products that have been tested pursuant to Appendix A and found, based upon such testing, not to adversely affect the spray drift properties of Enlist Duo. The website will identify a testing protocol, consistent with Appendix A, that is appropriate for determining whether the tested product will adversely affect the drift properties of Enlist Duo. The website will state that any person seeking to have a product added to the list must perform a study either pursuant to the testing protocol identified on the website or another protocol that has been approved for the purpose by EPA, and must submit the test data and results, along with a certification that the study was performed either pursuant to the testing protocol identified on the website or pursuant to another protocol approved by EPA and that the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of Enlist Duo, to EPA. EPA will notify you when the Agency determines that a product has been certified to be appropriately added to the list, and you will add appropriately certified products to the list no more than 90 days after you receive such notice from EPA. Testing of Tank-Mix Products must be conducted in compliance with procedures as stated forth in Appendix A.

7. All test data relating to the impact of tank-mixing any product with Enlist Duo on drift properties of Enlist Duo generated by you or somebody working for you must be submitted to EPA, along with a certification indicating whether the study was performed either pursuant to the testing protocol identified on the website or pursuant to another protocol approved by EPA and whether the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of Enlist Duo, at the following address: Chief of Environmental Risk Branch 1, Environmental Fate and Effects Division, Office of Pesticide Programs. If the certification states that the study was performed either pursuant to the testing protocol identified on the website or pursuant to another protocol approved by EPA, and

the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of Enlist Duo, you may add the product to the list.

8. The prohibition of using products in a tank-mix with Enlist Duo unless the product used is contained on the list at EnlistTankmix.com, and the identification of the website address, shall be included in educational and information materials developed for Enlist Duo, including the materials identified in Appendix D, Section B(1).

9. You must develop and follow an Herbicide Resistance Management Plan (HRM) as laid out in Appendix D regarding grower agreements, field detection and remediation, education, evaluation, reporting, and best management practices (BMPs).

10. On an annual basis, you must report your survey results on growers' adherence to the terms of the grower agreements regarding whether purchasers of Enlist seed are using forms of 2,4-D that do not have the low-drift/volatility characteristics of Enlist Duo. These reports must be submitted to the Agency no later than January 15th of each year. See Appendix D Section D.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy any of these requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 9/12/2011
- Alternate CSF 1 dated 9/12/2011

If you have any questions, please contact Emily Schmid by phone at 703-347-0189, or via email at schmid.emily@epa.gov.

Enclosure

APPENDIX A
Testing of Tank Mix Products

1. Products proposed for tank-mixing with Enlist Duo may be added to the list of products that will not adversely affect the spray drift properties of Enlist Duo contained on the web site if a study is performed under the testing conditions set forth below; the test information is reported as set forth below; and the results are interpreted as set forth below and the interpretation supports adding the tested product to the list of products that will not adversely affect the spray drift properties of Enlist Duo:

Testing Conditions

Spray chamber test using conditions described in ASTM E-2798-11; or Wind Tunnel test using conditions described in EPA Final Generic Verification Protocol for Testing Pesticide Application Spray Drift Reduction Technologies for Row and Field Crops (September 2013)

Testing Media: Enlist Duo and Enlist Duo + Proposed Tank Mix Product

Test Nozzle: AIXR 11004 at 40 psi

Number of Replicates: 3 for each tested medium

Reporting

Validation information as summarized in Appendix B

Full droplet spectrum to be reported for each replicate of each tested medium

Perform AGDISP (8.26) modeling run for each replicate droplet spectrum for each tested medium (AGDISP input parameters described in Appendix C)

Establish 30 foot spray drift deposition estimate from AGDISP run on each replicate for each tested medium

Establish mean and standard deviation of 30 foot deposition for the 3 replicates of each tested medium

One-tail (upper bound) t-test (p=0.1) to determine if proposed tank-mix product is above Enlist Duo 30 foot spray drift deposition

Interpretation of Results

If mean 30 foot deposition for proposed tank-mix product is not statistically greater than mean 30 foot deposition for Enlist Duo, proposed tank-mix product can be added to the list of products that will not adversely affect the spray drift properties of Enlist Duo contained on the web site. If mean 30 foot

deposition for proposed tank-mix product is statistically greater than mean 30 foot deposition for Enlist Duo, proposed tank-mix product cannot be added to the list of products that will not adversely affect the spray drift properties of Enlist Duo contained on the web site

2. Results from other testing protocols will be acceptable for adding products to the list of products that will not adversely affect the spray drift properties of Enlist Duo provided that EPA has determined in writing that such other protocol is appropriate for such purpose.

APPENDIX B

Validation Criteria

a. Detailed information of instrument setting and measurements
- The distance from the nozzle tips to the laser settings
- Measurements of airspeed and flow rate of liquid

b. Detailed information of test substances
- Volume composition and density of Enlist formulation (2,4-D choline and glyphosate) and tank mixes

c. Summary of the entire spray output distribution for each nozzle/tank mixes with statistical analysis of replicates.

d. Graphical outputs of Sympatec Helos laser diffraction particle size analyzer FOR individual spectrum Report of Dv0.1 (SD), Dv0.5 (SD), and DV0.9 (SD) as well as mean % fines of (≤ 141µm SD) fractions

APPENDIX C

AGDISP Input Parameters

Parameter	Value	comments
Application method section		
Method	Ground	
Nozzle type	Flat fan (Default)	The direct use of the DSD overrides the use of "Nozzle type.
Boom pressure	40 psi	If nozzles/tank mixes were tested at 40 psi. It has to be consistent with tank mix as well as Enlist for both TeeJet and AIXR nozzles.
Release height	3 ft	Default
Spray lines	20	Default
Meteorology section		
Wind type	Single height	Default
Wind speed	15 mph	Under bound from label
Wind direction	-90 deg	Worst-case and default
Temperature	65 F	Default
Relative humidity	50%	Default
Surface section		
Angles	0	Default
Canopy	None	Default
Surface roughness	0.12 ft	Mean of "crops" cover type
Application technique section		
Nozzles	54, even spacing	Standard boom setup
DSD	From wind tunnel results, imported in library	
Atmospheric stability	Strong	Default

Swath section		
Swath width	90 ft	Standard boom
Swath displacement	0 ft	Worst-case
Spray material section		
Spray volume rate	15 gal/acre	From Enlist Duo label
Volatile/nonvolatile fraction	Enlist Duo at 2.8% v/v	To calculate volatile/nonvolatile fraction in the tank mix for the model input, provide detailed information of the tested formulations and tank mixes. See sample calculation below used in WT study submitted by DOW (MRID 49384801)[1]

[1]The tested mixture was 2.8% (v/v) Enlist Duo in water. Enlist Duo has a density of 1.171 kg/L and contains 24.42 % (w/w) of 2,4-D choline salt (16.65% (w/w) 2,4-D acid equivalent) and 22.17% (w/w) glyphosate dimethylammonium salt.
For example, a 100-liter batch would contain the following:
Enlist Duo 2.8% * 100 L = 2.8L; 2.8L * 1.171 kg/L = 3.279 kg
Water: 100 -2.8 L = 97.2 L = 97.2 kg
Total weight: 3.279+97.2 = 100.497 kg
Active ingredient fraction: 3.279 kg * 16.65 % (a.e.) = 0.546 kg; 0.546 kg/100.497 kg = **0.0054** (dimensionless)
Non-volatile fraction: 3.279 kg* (24.42 % + 22.17%) = 1.528 kg; 1.528 kg/100.497 kg = **0.0152** (dimensionless)

APPENDIX D
Herbicide Resistance Management Plan

Dow AgroSciences (DAS) must:

A. Grower Agreements, Field Detection and Remediation Components:

1. Ensure that any person who purchases any Enlist seed sign a binding contract, enforceable by DAS, herein referred to as a "grower agreement." In such grower agreement, DAS will reinforce with users of Enlist Duo the critical importance of following resistance management practices. This includes stressing the need for pre- and post-application field scouting and that lack of herbicide efficacy should be reported promptly to DAS or its representative.

2. Provide a copy of the grower agreement to EPA;

3. Retain copies of all executed grower agreements for a period of 3 years from the date of execution, and make such copies available to EPA upon request;

4. If any grower informs you of a lack of herbicide efficacy, then you or your representative must make an effort to evaluate the field for "likely resistance" to Enlist Duo by applying the criteria set forth in Norsworthy, *et al*., "Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations," Weed Science 2012 Special Issue:31–62 (*hereinafter* "Norsworthy criteria");

5. Keep records of all field evaluations for "likely resistance" for a period of 3 years, and make such copies available to EPA upon request; and

6. If one or more of the Norsworthy criteria are met, then:

    a. Provide the grower with specific information and recommendations to control and contain likely resistant weeds, including retreatment and/or other non-chemical controls, as appropriate. If requested by the grower, DAS will become actively involved in implementation of weed control measures;

    b. Request, at the time of the initial determination that one or more of the Norsworthy criteria are met and prior to any application of alternative control practices, that the grower provide you with access to the relevant field(s) to collect specimens of the likely resistant weeds (potted specimens or seeds) for further evaluation in the greenhouse or laboratory, and so collect such specimens if possible (or, alternatively, request that the grower provide such specimens to you, at your expense);

    c. Commence greenhouse or laboratory studies to confirm resistance as soon as practicable following sample collection;

d. To the extent possible, contact or visit the grower in an appropriate timeframe after implementation of the additional weed control measures in order to evaluate success of such measures; and

e. If the additional weed control measures were not successful in controlling the likely resistant weeds, then:

i. Work with the grower to determine the reason(s) why the additional control measures were not successful;

ii. Report annually the inability to control the likely resistant weeds to relevant stakeholders; and

iii. Offer to further assist the grower in controlling and containing the likely resistant weeds, including retreatment and/or other non-chemical controls, as appropriate.

B. Educational / Informational Component:

1. Develop and implement an education program for growers that includes the following elements:

a. The education program shall identify appropriate best management practices (BMPs), set forth under "Best Management Practices (BMPs) Component," below, to avoid and control weed resistance, and shall convey to growers the importance of complying with BMPs;

b. The education program shall include at least one written communication regarding herbicide resistance management each year to purchasers of Enlist seed (separate and apart from the grower agreement document); and

c. You must make the education program available to DAS sales representatives for distribution to growers.

2. Provide to EPA the original education program within three months of the issuance of this registration.

C. Evaluation Component:

1. Annually conduct a survey of users of Enlist seed. This survey must be based on a statistically representative sample of users of Enlist seed. The sample size and geographical resolution should be adequate to allow analysis of responses within regions, between regions, and across the United States. This survey shall evaluate, at a minimum, the following:

a. Growers' adherence to the terms of the grower agreements, and

b. Whether growers have encountered any perceived issue with non-performance or lack of efficacy of Enlist Duo and, if so, how growers have responded.

2. Utilize the results from the survey described in paragraph 1 of this section to annually review, and modify as appropriate for the upcoming growing season, the following:

a. Efforts aimed at achieving compliance with the grower agreement;

b. Responses to incidents of likely resistance and confirmed resistance; and

c. The education program. At the initiative of either EPA or DAS, EPA and DAS shall consult about possible modifications of the education program.

D. Reporting Component:

1. Submit annual reports to EPA by January 15th of each year, beginning on January 15, 2016. Such reports shall include:

a. Annual sales of Enlist seed and Enlist Duo herbicide by state;

b. The current grower agreement;

c. The first annual report shall include the current education program and associated materials, and subsequent annual reports shall include updates of any aspect of the education program and associated materials that have materially changed since submission of the previous annual report;

d. Summary of your efforts aimed at achieving compliance with the grower agreements;

e. Summary of your determinations as to whether any reported lack of herbicide efficacy was "likely resistance," your follow-up actions taken, and, if available, the ultimate outcome (e.g., evaluation of success of additional weed control measures) regarding each case of "likely resistance." In the annual report, DAS will list the cases of likely resistance by county and state.

f. The results of the annual survey described in paragraph 1 under "Evaluation Component," above, including whether growers are implementing herbicide resistance BMPs, and a summary of your annual review and possible modification – based on that survey – of the education program, grower agreement compliance efforts, and response to reports of likely resistance, described in paragraph 2 under "Evaluation Component," above; and

g. Summary of the status of any laboratory and greenhouse testing performed by, or at the direction of, Dow AgroSciences following up on incidents of likely resistance, performed

in the previous year. Data pertaining to such testing need not be included in the annual reports, but such data must be made available to EPA upon request.

2. Following your submission of the annual report, you shall meet with the EPA at EPA's request in order to evaluate and consider the information contained in the report.

E. ***Best Management Practices (BMPs) Component:***

1. Best management practices (BMPs) must be identified in your education program. You must advise growers to follow them in your grower agreements. The following are examples of BMPs:

a. Regarding crop selection and cultural practices:

i. Understand the biology of the weeds present.

ii. Use a diversified approach toward weed management focused on preventing weed seed production and reducing the number of weed seeds in the soil seed-bank.

iii. Emphasize cultural practices that suppress weeds by using crop competitiveness.

iv. Plant into weed free fields, keep fields as weed free as possible, and note areas where weeds were a problem in prior seasons.

v. Incorporate additional weed control practices whenever possible, such as mechanical cultivation, biological management practices, crop rotation, and weed-free crop seeds, as part of an integrated weed control program.

vi. Do not allow weed escapes to produce seeds, roots or tubers.

vii. Manage weed seed at harvest and post-harvest to prevent a buildup of the weed seed-bank.

viii. Prevent field-to-field and within-field movement of weed seed or vegetative propagules.

ix. Thoroughly clean plant residues from equipment before leaving fields.

x. Prevent an influx of weeds into the field by managing field borders.

xi. Fields must be scouted before application to ensure that herbicides and application rates will be appropriate for the weed species and weed sizes present.

xii. Fields must be scouted after application to confirm herbicide effectiveness and to detect weed escapes.

xiii. If resistance is suspected, treat weed escapes with an alternate mode of action or use non-chemical methods to remove escapes.

b. Regarding herbicide selection:

i. Use a broad spectrum soil applied herbicide with a mechanism of action that differs from this product as a foundation in a weed control program.

ii. A broad spectrum weed control program should consider all of the weeds present in the field. Weeds should be identified through scouting and field history.

iii. Difficult to control weeds may require sequential applications of herbicides with alternative mechanisms of action.

iv. Fields with difficult to control weeds should be rotated to crops that allow the use of herbicides with alternative mechanisms of action.

v. Apply full rates of this herbicide for the most difficult to control weed in the field. Applications should be made when weeds are at the correct size to minimize weed escapes.

vi. Do not use more than two applications of this herbicide or any herbicide with the same mechanism of action within a single growing season unless mixed with another mechanism of action herbicide with overlapping spectrum for the difficult to control weeds.

vii. Report any incidence of lack of efficacy of this product against a particular weed species to Dow AgroSciences or a Dow AgroSciences representative.

This list may be updated or revised as new information becomes available.

Exhibit B

U.S. Environmental Protection Agency,
Final Registration Decision of Enlist Duo™ Herbicide
(January 12, 2017)

Final Registration Decision of Enlist Duo™ Herbicide

Approved by: _____

Jack E. Housenger, Director
Office of Pesticide Programs

Date: 1/12/17

Final Registration of Enlist Duo™ Herbicide

Background

This document represents the United States Environmental Protection Agency's (the EPA or the agency) decisions related to the Enlist Duo™ pesticide product. Enlist Duo™ is an end-use herbicide product developed by Dow Agrosciences LLC (DAS) that contains the active ingredients 2,4-dichlorophenoxyacetic acid (2,4-D) choline salt and glyphosate dimethylammonium salt (glyphosate). The 2,4-D active ingredient has a long history of being used through a variety of salt and ester formulations and registered to control broadleaf weeds on a wide range of food and feed uses, residential turf, and aquatic sites. The glyphosate active ingredient has been used as a pesticide since the 1970s. It is a non-selective herbicide registered for use on a wide variety of food and non-food field crops as well as non-crop areas. In addition, glyphosate has been registered for use on many crops that have been genetically engineered (GE) to be tolerant to glyphosate, including corn, soybeans, and cotton, since the 1990s. These glyphosate registrations for use on GE crops were originally registered as Round-Up Ready® products.

The EPA previously registered Enlist Duo™ for use on GE corn and soybeans, engineered to be tolerant to 2,4-D and glyphosate, in the 6 states of Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin on October 15, 2014. The EPA also amended that registration on March 31, 2015 to allow use of Enlist Duo™ on GE corn and soybean in the 9 additional states of Arkansas, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, North Dakota, and Oklahoma.

This final decision reaffirms the agency's earlier decision to register Enlist Duo™, on GE corn and soybean that are currently registered. Additionally, this decision includes a new registration decision to approve Enlist Duo™ for use on GE corn and soybean for an additional 19 states - Alabama, Arizona, Colorado, Delaware, Florida, Georgia, Kentucky, Maryland, Michigan, North Carolina, New Jersey, New Mexico, New York, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, and West Virginia. Additionally, this decision includes the approval of Enlist Duo™ for a new use on GE cotton in all the states already registered for GE corn and soybean as well at the aforementioned 19 additional states.

In summary, this document contains three new decisions for Enlist Duo™. First, EPA is issuing a new decision on the currently registered Enlist Duo™ for use on GE soybean and corn in 15 states, following the remand decision discussed below. Second, the EPA is granting the approval of Enlist Duo™ for use on GE soybean and corn in an additional 19 states. Third, EPA is granting a new use for Enlist Duo™ on GE cotton in 34 states (corresponding with the 15 states previously registered, plus the 19 additional states approved for use of Enlist Duo™ on GE corn and soybean).

The EPA proposed a new decision for the currently registered Enlist Duo™ for GE corn and soybean because after having issued the registration and amendment to add additional states for use of Enlist Duo™ on GE corn and soybean in 15 states, and while defending the registration decision in the 9th Circuit U.S. Court of Appeals, the EPA discovered that the registrant, DAS, had filed a patent application with the U.S. Patent and Trademark Office (USPTO) that claimed

"synergism" between the two active ingredients in Enlist Duo™ and cited studies in support of that claim.[1] The EPA granted the registration and amendment to add additional states based on the data and information provided by the registrant (which did not include the data cited to the USPTO), and found no evidence of synergism. Because the EPA became aware of previously-existing information about possible synergistic effects after it had made its registration decision, the agency could no longer represent to the Court that its conclusions were correct regarding whether issuance of the registration met the standard in FIFRA and the finding that the registration would have no effect upon threatened or endangered plant species. The EPA therefore moved the Court for remand and vacatur on November 24, 2015. On January 25, 2016, the Court granted the motion for remand and denied the motion for vacatur, so that the registration has remained in effect while the agency determined whether changes to the registration were necessary.

As is the case for the Enlist Duo™ registration for use on GE corn and soybean, this new use for use on GE cotton is new only for the 2,4-D component of this product, not for glyphosate. As stated above, Enlist Duo™ uses on GE corn, soybeans, and cotton are already registered on other glyphosate products and are currently in use on these crops. Since no new use patterns and no new exposures for glyphosate are being considered with this registration action, no new assessment is needed for glyphosate. However, GE corn, soybeans and cotton are new uses for the choline salt of 2,4-D. Therefore, this document discusses the results of the EPA's findings specifically to the assessment of the choline salt of 2,4-D on GE corn, soybeans, and cotton.

In general, when the EPA receives an application for a registration action to add a "new use" as defined pursuant to 40 CFR 152.3,[2] the agency assesses the risks and benefits associated with the new use before making a decision on the application. In situations like Enlist Duo™ where a company submits an application for a new use on a product that contains two or more active ingredients (combination product), and the use being requested for this combination product is currently registered for one or more of the active ingredients, the EPA only assesses the risks and benefits of the active ingredient that does not currently have products registered for that use.

For the other active ingredient(s), in this case glyphosate, the EPA treats the application as if it were a "me-too,"[3] and does not conduct new assessments for the already registered uses.

---

[1] DAS's Patent Application claimed and defined "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)." Dow AgroSciences LLC's (DAS) United States Patent Application, filed Dec. 11, 2014, Pub. No. US 2015/0173371 A1, Pub. Date June 25, 2015, at 2, paragraph [0020].

[2] A "new use" is defined as any proposed use pattern if: (1) it requires a new tolerance action under the Federal Food, Drug, and Cosmetic Act; (2) it is a changed use pattern -- e.g., first outdoor use or first aquatic use; or (3) it may significantly increase exposure or change the route of exposure to humans or the environment. 40 C.F.R. § 152.3.

[3] The EPA has the authority to issue conditional registrations for pesticide products that are identical or substantially similar in their uses and formulation to one or more products or for a combination of previously approved products

Instead, the EPA determined that the glyphosate in Enlist Duo™ would not cause unreasonable adverse effects on the environment because the use conditions authorized under the Enlist Duo™ registration are identical or substantially similar to use conditions already authorized for glyphosate in other existing glyphosate registrations, and the EPA does not expect the registration of Enlist Duo™ to significantly change the locations, methods, or volume of glyphosate used on corn, soybeans, or cotton. Thus, any decision on the Enlist Duo™ registration would likely have no effect on whether glyphosate continues to be used on corn, soybeans, and cotton – the decision would only impact which glyphosate product would be used. Reevaluation of registered active ingredients (and all registered uses) generally will occur in registration review pursuant to FIFRA section 3(g). This practice of not conducting a new assessment each time the EPA registers a pesticide product that is already registered for the proposed use is reasonable and consistent with the intent of FIFRA and its implementing regulations.

As stated above, this new use action is specific to the 2,4-D component of Enlist Duo™. Here, the EPA is not taking any action as it relates to the glyphosate component of Enlist Duo™. Although the EPA considers the glyphosate portion of the product as if it were a me-too, the EPA is not registering the product as a me-too since the application in front of EPA is for a new use for 2,4-D choline salt. That new use is being conditionally registered under FIFRA section 3(c)(7(B) because of outstanding data that will be part of the registration review process. This section 3(c)(7)(B) registration adds the cotton use as well as expands the use of the currently registered uses of soybean and cotton to an additional 19 states.

Regarding synergistic effects, prior to registering Enlist Duo™ for use on GE corn and soybean in the original 6 states, the EPA evaluated the available data on the two chemicals individually as well as any available formulation-specific information and found no indication of synergism for mammals, freshwater fish and freshwater invertebrates and believed it reasonable to use that determination as to plants as well. In addition, the formulation-specific data did not show greater toxicity to mammals compared to either compound alone.

As described above, however, in light of newly discovered information concerning patent claims made by DAS, on October 13, 2015, the EPA directed the registrant to provide to the agency certain information regarding potential "synergy," which ultimately resulted in the registrant's submission of Enlist Duo™ formulation-specific plant vegetative vigor and seedling emergence toxicity test data conducted using OCSPP 850 guideline protocols. These data were used to address any uncertainty in the ecological risk assessment, endangered species effects determinations, and critical habitat modification determinations arising due to the "synergistic effects" claims made in patent applications for the two constituent herbicides (2,4-D and glyphosate), and to determine whether the original buffers were still appropriate.

After reviewing the data submitted by DAS, the EPA determined that the information supports the original decision. Details of the EPA's review of the data are discussed later in this document and can be found in the document entitled, *2,4-D Choline: Review of Seedling*

---

that are already registered and marketed in the United States and would not significantly increase the risk of unreasonable adverse effects on the environment. These types of registrations are often referred to as a "me-too" or "follow-on."

Emergence and Vegetative Vigor Terrestrial Plant Studies for the Formulated Product Enlist Duo, found in docket EPA-HQ-OPP-2016-0594.

Now that the EPA has resolved the "synergy" issue, the agency has made the decision to maintain the previously approved uses of Enlist Duo™ on GE corn and soybeans in 15 states with no changes to the original registration, as amended. Additionally, the EPA approved an additional 19 states to the Enlist Duo™ label, and adding the new use for Enlist Duo™ on GE cotton in all 34 states. The cotton use is for pre-plant, pre-emergence, or post-emergence application to GE cotton. The EPA is granting a maximum single application rate of 1.0 lb acid equivalent (ae)/acre and for post-emergence applications, a maximum of two applications are permitted with a minimum of 12 days between applications.

The EPA accepted comments on the proposed decision for 30 days and received 20,029 comments. Comments received were both in favor of and opposed to the decisions. The EPA reviewed and evaluated all comments received before issuing this final regulatory decision. These comments are addressed in the document, *Response to Public Comments Received Regarding the Evaluation of Enlist Duo™ on Enlist Corn, Cotton, and Soybeans*, which can be found on regulations.gov in docket EPA-HQ-OPP-2016-0594.

For convenience, documents generated post-remand are in new docket number EPA-HQ-OPP-2016-0594 at regulations.gov, but documents in docket number EPA-HQ-OPP-2014-0195 established pre-remand for the 2014 registration and 2015 amendment remain part of the record of this new decision, and both dockets should be referenced for supporting material.

I. Chemical Information

Chemical Name: Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, 2-(2,4-dichlorophenoxy)acetic acid hydroxide (1:1:1)

EPA PC Code: 051505

Chemical Abstracts Service (CAS) Number: 1048373-72-3

Mode of Action: 2,4-D is an herbicide in the phenoxyacetic acid family that is used for selective control of broadleaf weeds. 2,4-D, a synthetic auxin herbicide, causes disruption of plant hormone responses.

Registrant: Dow AgroSciences LLC

Product: Enlist Duo™ (EPA Registration Number: 62719-649), an end-use product containing 24.4% 2,4-D choline salt and 22.1% Glyphosate, to be used on Enlist™ AAD-1 Corn (Trait Code: DAS-40278-9), Enlist™ AAD-12 Soybean (Trait Code: DAS-68416-4) and Enlist™ AAD-12 Cotton (Trait Code: DAS-81910-7).

II. Human Health Risk

A summary of the human health effects and risk of 2,4-D choline salt as assessed in the EPA documents entitled, *2,4-D. Human Health Risk Assessment for a Proposed Use of 2,4-D Choline on Herbicide-Tolerant Corn and Soybean*, found in docket EPA-HQ-OPP-2014-0195, and *2,4-D. Human Health Risk Assessment for a Proposed Use of 2,4-D Choline on Herbicide-Tolerant Cotton,* found in docket EPA-HQ-OPP-2016-0594, is provided below.

A. Summary of Toxicological Effects

The toxicology database on 2,4-D is complete and sufficient for assessing the toxicity and characterizing the hazard of all formulations of 2,4-D, including the choline salt. Data on other forms of 2,4-D were also used to assess the choline formulation.

2,4-D has been classified as having low acute toxicity via the oral, dermal, and inhalation routes of exposure (Toxicity Category III). It is not a dermal irritant (Toxicity Category IV) or dermal sensitizer, but it is a severe eye irritant (Toxicity Category I).

The toxicity profile of the active ingredient 2,4-D shows that the principal toxic effects are changes in the kidney, thyroid, liver, adrenal, eye, and ovaries/testes in the rat following exposure to 2,4-D *via* the oral route at dose levels above the threshold of saturation of renal clearance. No systemic toxicity was observed in rabbits following repeated exposure *via* the dermal route at dose levels up to the limit dose. Neurotoxicity was observed in the acute neurotoxicity study in rats at the high dose. In an extended one-generation reproductive toxicity study in rats, reproductive toxicity, developmental neurotoxicity, and immunotoxicity were not observed. The thyroid effects observed at dose levels up to/approaching renal saturation were considered treatment-related (i.e., resulted from dosing with 2,4-D), although not adverse (i.e., the effects are not harmful to the organism). Maternal and developmental toxicity were observed at high dose levels exceeding the threshold of saturation of renal clearance. There are no residual uncertainties for pre- and/or postnatal toxicity.

2,4-D is classified as "not classifiable as to human carcinogenicity," based upon bioassays in rats and mice that showed no statistically significant tumor response in either species. The agency determined, based on several reviews of epidemiological studies, in addition to the animal studies, that the existing data did not support a conclusion that links human cancer to 2,4-D exposure.

B. Toxicological End Points and Doses Used in the Human Health Risk Assessment

Once a pesticide's toxicological profile is determined, the EPA identifies toxicological Points of Departure (POD) and Levels of Concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL; No Observed Adverse Effect Level) and the lowest dose at which adverse effects of concern are identified (the LOAEL; Lowest Observed Adverse Effect Level). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a

Population-adjusted Dose (PAD) or a Reference Dose (RfD) - and a safe Margin of Exposure (MOE). For non-threshold risks, the EPA assumes that any amount of exposure will lead to some degree of risk. Thus, the EPA estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles the EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

1. Acute Dietary

a. General Population (Including Infants and Children)

An acute dietary endpoint for the general population, including infants and children, was selected from the acute neurotoxicity study in rats with a NOAEL of 67 mg/kg. At the study LOAEL of 225 mg/kg, an increased incidence of incoordination and slight gait abnormalities (forepaw flexing or knuckling) and decreased motor activity were observed. A 100X uncertainty factor was applied to account for inter- and intra-species variability. As discussed in section C below, the Food Quality and Protection Act (FQPA) safety factor was reduced to 1X, resulting in an acute Population Adjusted Dose (aPAD) of 0.67 mg/kg/day.

b. Females of Child-Bearing Age (13-49 years old)

An acute dietary endpoint for females 13+ was selected from the developmental toxicity study in rats with a NOAEL of 25 mg/kg/day. At the study LOAEL of 75 mg/kg/day, fetal skeletal malformations (14th rudimentary ribs) were observed. A 100X uncertainty factor was applied to account for inter- and intra-species variability and the FQPA safety factor was reduced to 1X, resulting in an acute Population Adjusted Dose aPAD of 0.25 mg/kg/day.

2. Chronic Dietary

The chronic dietary endpoint was selected from the extended one-generation reproduction toxicity study in rats with a NOAEL of 21 mg/kg/day. At the study LOAEL of 55.6 mg/kg/day for males and 46.7 mg/kg/day for females, kidney toxicity, manifested as increased kidney weights and increased incidence of degeneration of the proximal convoluted tubules, was observed and decreased body weight in pups was observed throughout lactation. A 100X uncertainty factor was applied to account for inter- and intra-species variability and the FQPA safety factor was reduced to 1X, resulting in a chronic Population Adjusted Dose (cPAD) of 0.21 mg/kg/day.

3. Incidental Oral, Short and Intermediate Term

Short-term and intermediate-term incidental oral endpoints for risk assessment were selected from the extended one-generation reproduction toxicity study in rats with a NOAEL of 21 mg/kg/day. This is a robust study that assessed several durations of exposure and life stages and included a thorough assessment of the F1 offspring for potential effects on the nervous system, immune system, reproductive and endocrine systems, thyroid function, and other systemic toxicity parameters. At the study LOAEL of 55.6 mg/kg/day for males and 46.7 mg/kg/day for

females, kidney toxicity, manifested as increased kidney weights and increased incidence of degeneration of the proximal convoluted tubules, was observed and decreased body weight in pups was observed throughout lactation. A 100X uncertainty factor was applied to account for inter- and intra-species variability and the FQPA safety factor was reduced to 1X, resulting in a target MOE of 100 for non-dietary risk assessment.

4. Inhalation, Short and Intermediate Term

Short-term and intermediate-term inhalation endpoints for risk assessment were selected from the route-specific 28-day inhalation toxicity study in rats with a LOAEL of 0.05 mg/L/day. A NOAEL for portal-of-entry effects was not determined. At the study LOAEL of 0.05 mg/L/day, squamous metaplasia and epithelial hyperplasia with increased mixed inflammatory cells within the larynx, which was not totally resolved following a 4-week recovery period, were observed. Human Equivalent Concentrations (HEC)/Human Equivalent Doses (HED) for residential and occupational scenarios were calculated. A 3X uncertainty factor was applied to account for inter-species variability (to account for the pharmacodynamic differences), a 10X uncertainty factor was applied to account for intra-species variability, and a 10X uncertainty factor was applied to account for the lack of a NOAEL. Although there was no assessment of the thyroid in the inhalation study, the rat extended one-generation reproduction toxicity (oral) study performed an assessment of the thyroid for several age groups at dose levels up to/approaching renal saturation. The changes in thyroid hormones observed, along with thyroid histopathological findings, were considered treatment related, although not adverse. The lack of an assessment of the thyroid in the inhalation study is considered inconsequential because the portal of entry endpoint is protective of potential thyroid effects expected to occur at higher concentrations; *i.e.*, at doses that exceed the level of renal clearance. Portal-of-entry effects were observed at all dose levels, and an additional 10X uncertainty factor is applied to the LOAEL to obtain an extrapolated NOAEL used for the inhalation risk assessments. The use pattern indicates that dose levels required to exceed the renal clearance mechanism would not be attained following human inhalation exposure.

5. Dermal (All Durations)

No quantification of dermal risk is required. Although the dermal toxicity study did not evaluate developmental endpoints, the following were noted:

a. There was no dermal or systemic toxicity observed following repeated dermal applications to rabbits at the Limit Dose (1000 mg/kg/day).

b. There was no quantitative susceptibility observed in the developmental or reproductive toxicity studies.

c. The use of a 10% human dermal absorption factor (DAF) with the oral developmental LOAEL of 90 mg/kg/day established in the rabbit developmental toxicity study yields a dermal equivalent dose (DED) of 900 mg/kg/day, which is numerically similar to the high-end dermal NOAEL (1000 mg/kg/day) in the dermal rabbit study.

d. The use of the 10% human DAF with the oral developmental LOAEL of 75 mg/kg/day established in the rat developmental study yields a DED of 750 mg/kg/day.

e. The developmental findings in the rat and rabbit occurred at oral dose levels exceeding renal clearance, and clear NOAELs were obtained (dermal equivalent doses of 250 and 300 mg/kg/day).

f. Although there was no assessment of the thyroid in the dermal study, the rat extended one-generation reproduction toxicity (oral) study performed an assessment of the thyroid for several age groups at dose levels up to/approaching renal saturation. The changes in thyroid hormones (↓ T_3 and T_4 with ↑TSH levels) observed, along with thyroid histopathological findings, were considered treatment-related, and not adverse (NOAEL for thyroid effects is ≈40 mg/kg/day; DED of 400 mg/kg/day).

g. The use pattern indicates that dose levels required to exceed the renal clearance mechanism would not be attained following human dermal exposure.

6. Cancer

The Cancer Peer Review Committee (CPRC; TXR No. 0050017, dated January 29, 1997) classified 2,4-D as "not classifiable as to human carcinogenicity," based upon bioassays in rats and mice that showed no statistically significant tumor response in either species. At that time, the EPA determined, based on several reviews of epidemiological studies, in addition to the animal studies, that the existing data did not support a conclusion that links human cancer to 2,4-D exposure.

C. FQPA Safety Factor

The EPA determined that the 10X FQPA Safety Factor (for the protection of infants and children mentioned above) could be reduced to 1X for the following reasons:

The toxicity database is complete and adequate to assess safety for infants and children. There is evidence of increased susceptibility in the rat developmental toxicity study and in the rat two-generation reproduction study; however, these studies have clearly defined NOAELs/LOAELs, and the PODs used in the risk assessment are below where these findings occur and are protective. There are acute and subchronic neurotoxicity studies, a developmental neurotoxicity study, a detailed evaluation of thyroid function across life stages, and a developmental immunotoxicity study on 2,4-D. Therefore, the agency has a complete database addressing potential hazard to infants and children. The exposure assessment will not underestimate children's exposure to 2,4-D. Further details may be found in the following sections:

1. Completeness of the Toxicology Database

The toxicology database for 2,4-D is complete. Acceptable rat and rabbit developmental toxicity studies, a rat two-generation reproduction study, an extended one-generation rat reproduction toxicity study (F1 offspring evaluated for potential effects on the nervous system,

immune system, reproductive and endocrine systems, thyroid function, and other systemic toxicity parameters), and acute, subchronic, and developmental neurotoxicity studies in rats are available.

2. Evidence of Neurotoxicity

Evidence of neurotoxicity was observed in the acute neurotoxicity study in rats, as evidenced by an increase in the incidence of incoordination and slight gait abnormalities (forepaw flexing or knuckling) during the Functional Observation Battery (FOB) assessment at the high dose in both sexes. In the subchronic neurotoxicity study, relative forelimb grip strength was significantly increased in rats of both sexes at the high-dose level, although there was no treatment-related change in absolute grip strength. Clinical signs of neurotoxicity (decreased motor activity, ataxia, loss of righting reflex, extremities cold to the touch) were observed in maternal rabbits in the developmental toxicity study. Developmental neurotoxicity was not observed in the developmental neurotoxicity study in rats. Neuropathological effects were not observed in any study.

3. Evidence of Sensitivity/Susceptibility in the Developing or Young Animal

There is evidence of increased susceptibility following *in utero* exposure to 2,4-D in the rat developmental toxicity study and following *in utero* and/or pre-/post-natal exposure in the rat two-generation reproduction study. There is no evidence of increased susceptibility following *in utero* exposure to 2,4-D in the rabbit developmental toxicity study or following *in utero* and/or pre-/post-natal exposure in the rat extended one-generation reproduction toxicity study.

2,4-D has been evaluated for potential developmental effects in the rat and rabbit. Maternal toxicity included decreased body weight gains in the rat study at the same dose level where developmental effects (occurrence of skeletal malformations) were observed. Maternal toxicity in the rabbit included decreased body weight gain, clinical signs of toxicity (decreased motor activity, ataxia, loss of righting reflex, extremities cold to the touch), and abortions, the latter being indicative of potential developmental toxicity. Decreased maternal body weight gains were observed in the rat two-generation reproduction study at a dose that exceeded renal saturation and resulted in reduced viability of the F1 pups. There are clearly established NOAELs and LOAELs for the population of concern, there are no data gaps in the toxicology database, and the PODs are protective of susceptibility.

4. Residual Uncertainty in the Exposure Database

There are no residual uncertainties in the exposure database. The dietary exposure estimates are unrefined and reflect primarily tolerance-level residue in food, 100% crop treated, and upper-bound drinking water estimates based on modeling. Additionally, non-occupational exposure estimates were determined using the Residential Standard Operating Procedures which utilize a combination of central tendency and high end inputs designed to result in protective exposure estimates which will not underestimate residential exposures.

D. Cumulative Effects

2,4-D is an herbicide in the phenoxyacetic acid family of pesticides. This class also includes MCPA, 2,4-DB, and 2,4-DP. A cumulative risk assessment has not been performed as part of this human health risk assessment because the EPA has not made a determination as to which of these compounds, if any, to which humans may be exposed, have a common mechanism of toxicity. Unlike other pesticides for which the EPA has followed a cumulative risk approach based on a common mechanism of toxicity, the EPA has not made a common mechanism of toxicity finding as to 2,4-D and any other substances. For the purposes of this action, therefore, the EPA has not assumed that 2,4-D has a common mechanism of toxicity with other substances.

For information regarding the EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on the EPA's website at http://www.epa.gov/pesticides/cumulative/.

E. Dietary (Food + Drinking Water) Risk

2,4-D is a phenoxyacetic acid herbicide used to control a variety of broadleaf weeds. It is a longstanding active ingredient (ai) registered for a variety of food/feed uses. Permanent tolerances for 2,4-D are established under 40 CFR 180.142 for a wide variety of crops and livestock commodities. The EPA confirms that residues associated with this registration decision are safe within the context of the safety standards of section 408 of FFDCA.

Acute and chronic aggregate (food + dietary drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA).

1. Acute Dietary Risk

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with the EPA policy, per capita exposure and risk are reported for analyses.

The resulting acute food plus drinking water risk estimates are not of concern to the EPA (≤100% aPAD) at the 95th percentile of the exposure distribution for the general population and all population subgroups. The resulting acute risk estimate for children 1 to 2 years old, the subgroup with the greatest exposure, was 23% of the aPAD at the 95th percentile of the

exposure. The acute dietary assessment is unrefined; to further refine the 2,4-D dietary exposure and risk estimates, percent crop treated (%CT), anticipated residues, or monitoring data, if available, could be used.

2. Chronic Dietary Risk

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

The resulting chronic food plus drinking water risk estimates are not of concern to the EPA for the general population and all population subgroups. The most highly exposed population was children 1 to 2 years old utilizing 20% of the cPAD. The chronic dietary assessment is unrefined; to further refine the 2,4-D dietary exposure and risk estimates, percent crop treated, anticipated residues, or available monitoring data could be used.

F. Residential (Non-Occupational) Exposure/Risk Characterization

There are registered uses of 2,4-D on turf including lawns, golf courses and parks as well as aquatic uses; therefore, residential handler exposure and post-application exposure to treated turf and aquatic sites is possible. There is no hazard *via* the dermal route for 2,4-D, therefore the handler assessment included quantification of risks for only the inhalation route of exposure and the post-application assessment included only the inhalation and incidental oral route of exposure. The residential handler and post-application risk estimates are not of concern for 2,4-D for all scenarios and all routes of exposure.

For non-dietary exposures, the EPA uses the term Margin of Exposure (MOE) to refer to the risk associated with the exposure estimate. The MOE is defined as the ratio of the selected toxicological POD, usually the NOAEL, to the estimated human exposure. A target MOE of 300 means that the estimated level of human exposure is 300 times lower than the highest dose that produced no adverse effects in the relevant toxicology study. Risk estimates that are not of concern are indicated by an actual MOE of 300 or greater for residential handler exposure and 100 or greater for post-application exposure.

1. Residential Handler Exposure

Residential handlers may receive short-term dermal and inhalation exposure to 2,4-D when mixing, loading, and applying the pesticide to ornamental turf as well as aquatic uses. Only inhalation risk estimates were quantitatively assessed because there is no hazard via the dermal route for 2,4-D. The handler inhalation exposure scenarios considered were mixing, loading and applying:

- Liquid/Wettable Powder (WP)/Dry Flowable (DF) to Lawns/Turf with Hose-End Sprayer
- Liquid/WP in Water Soluble Packets (WSP) to Lawns/Turf/Aquatic Sites with manually-pressurized handwand
- Ready-to-Use/WP in WSP to Lawns/Turf with Hose-End Sprayer
- Liquid to Lawns/Turf/Aquatic Sites with Backpack
- Liquid/WP/DF to Lawns/Turf with Manually-pressurized handwand or backpack
- Granules to Lawns/Turf with Push-type spreader or Belly Grinder

The MOEs for the six exposure scenarios range from 5,500 to 130,000. Since there is potential risk concern only when MOEs are less than 300, residential handler exposures are not a concern.

2. Post-Application Exposure

There is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with 2,4-D. The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenarios:

- Incidental ingestion (i.e., hand-to-mouth, object-to-mouth, soil ingestion exposure) from contact with treated turf (children 1 to < 2 years old only)
- Episodic granular ingestion on treated turf (children 1 to < 2 years old only)
- Incidental ingestion of water during recreational swimming (both adults and children 3 to < 6 years old).

Assessment of post-application exposure to turf treated with liquid formulations is protective of exposure to solid formulations. The lifestages selected for assessment are health protective for the exposures and risk estimates for any other potentially exposed lifestages.

a. Residential Post-Application Exposure for Turf Use

Incidental oral risk estimates were quantitatively assessed for residential post-application exposure for turf use. The incidental oral scenarios (i.e., hand-to-mouth and object-to-mouth) have been considered inter-related as it is likely that they occur interspersed amongst each other over time. Episodic granular ingestion on treated turf was not combined as this exposure would not occur as a result of routine behavior and is considered an episodic event related to poisoning.

The residential post-application risk estimates for turf use have MOEs that range from 640 to 410,000 for all incidental oral scenarios so are not of concern for 2,4-D.

b. Residential Post-Application Exposure for Aquatic Use

2,4-D is used for aquatic weed control of surface and submerged weeds. Many treatments are applied to aquatic areas where recreational swimming is not likely to occur but some subsurface treatments are made at recreational lakes. Since this can result in individuals being exposed to 2,4-D residues in water by entering these areas if they have been previously

treated, there is a 24-hour swimming restriction. The extent of exposure during recreational swimming is assumed to be short-term in duration. Risk estimates were calculated for post-application incidental oral ingestion while swimming in treated lakes or ponds. Inhalation exposure is expected to be negligible for swimmers; therefore, a post-application inhalation assessment was not conducted. Furthermore, the inhalation assessment for residential handlers is expected to be protective of potential post-application exposure and risk.

The residential post-application risk estimates for aquatic use have MOEs that range from 8,000 to 84,000 for incidental oral ingestion so are not of concern for 2,4-D.

3. Residential Bystander Post-Application Inhalation Exposure (Volatilization)

The potential exposure to bystanders from the vapor phase 2,4-D residues emitted from treated fields was evaluated for the use of 2,4-D choline salt on genetically engineered corn, cotton, and soybean. The two main factors that bystander exposure depends on are the rate at which these chemicals come off of a treated field which is described as the off-gassing, emission or flux, and how those vapors are dispersed in the air over and around the treated field. Volatilization can occur during the application process or thereafter. It can result from aerosols evaporating during application, while deposited sprays are still drying or after as dried deposited residues volatilize. The volatilization assessment used an analysis after sprays dried.

Flux data was submitted measuring flux rates of 2,4-D ethylhexyl ester (EHE), 2,4-D dimethylamine salt (DMA salt) and 2,4-D choline salt. 2,4-D choline salt was found to have a reduced potential for volatility. For this assessment, the data from the 2,4-D choline salt applications only were used as this action specifically seeks registration for 2,4-D choline salt product use in conjunction with GE corn, cotton, and soybean with resistance traits.

Volatilization modeling for a single day was completed using Probabilistic Exposure and Risk model for fumigants (PERFUM). There are a variety of factors that potentially affect the emission rates of 2,4-D choline salt and subsequent offsite transport and to the extent possible, these factors were considered. They include field condition (e.g., bare soil, growing, or mature crop canopy), field parameters (e.g., soil type, moisture, etc.), formulation type, meteorological conditions, and application scenario (e.g., rate, method). Flux estimates from all monitored trials, a number of field sizes, and various meteorological data were used with PERFUM to estimate risk based on the 2,4-D choline salt field volatility study data.

The field volatility study suggests that volatilization of 2,4-D choline salt from treated crops does occur and could result in bystander exposure to vapor phase 2,4-D choline salt. However, results of PERFUM modeling indicate that airborne concentrations, even at the edge of the treated fields, are not above our levels of concern.

4. Spray Drift

Without considering mitigation measures, it is reasonable to assume spray drift may be a potential source of exposure to residents nearby to spraying operations. Off-target movement of pesticides can occur via many types of pathways and it is governed by a variety of factors.

Sprays that are released and do not deposit in the application area end up off-target and can lead to exposures to those it may directly contact. They can also deposit on surfaces where contact with residues can eventually lead to indirect exposures (e.g., children playing on lawns where residues have deposited next to treated fields). The potential risk estimates from these residues can be calculated using drift modeling coupled with methods employed for residential risk assessments for turf products.

The approach to be used for quantitatively incorporating spray drift into risk assessments is based on a premise of compliant applications which, by definition, should not result in direct exposures to individuals because of existing label language and other regulatory requirements intended to prevent them. Direct exposures would include inhalation of the spray plume or being sprayed directly. Rather, the exposures addressed here are thought to occur indirectly through contact with impacted areas, such as residential lawns, when compliant applications are conducted. Given this premise, exposures for children (1 to 2 years old) and adults who have contact with turf where residues are assumed to have deposited via spray drift thus resulting in an indirect exposure are the focus of this analysis analogous to how exposures to turf products are considered in risk assessment.

Several 2,4-D products have existing labels for use on turf, thus it was considered whether the risk assessment for that use may be considered protective of any type of exposure that would be associated with spray drift. If the maximum application rate on crops adjusted by the amount of drift expected is less than or equal to existing turf application rates, the existing turf assessment is considered protective of spray drift exposure. The maximum single application rate of 2,4-D choline salt on GE corn, cotton, and soybean is 1 lb ae/acre. This is less than the previously registered application rate on turf of 1.5 lb ae/acre, which has been previously assessed and which was updated based on the revised Standard Operating Procedures (SOPs) for Residential Exposure Assessment. Thus, even if 100% of the application rate of the choline salt formulation on GE corn, cotton, and soybean is deposited on an adjacent lawn, calculated risk estimates from drift would not be of concern. This again is because all existing registered uses on lawns have been previously assessed and no risks of concern were identified.

5. Aggregate Risk Assessment

In accordance with the FQPA amendments to the Federal Food, Drug, and Cosmetic Act, the EPA must aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the EPA considers both the route and duration of exposure.

a. Acute Aggregate Risk

The acute aggregate risk assessment includes only food and water exposure. The acute food plus drinking water risk estimates are not of concern to the EPA ($\leq$100% aPAD) at the 95th percentile of the exposure distribution for the general population and all population subgroups.

b. Short-Term Aggregate Risk

The short-term aggregate risk assessment includes food, water, and residential exposure. The resulting short-term aggregate risks are not of concern to the EPA (MOEs > LOC of 100) for adults and children.

c. Intermediate-Term Aggregate Risk

Intermediate-term residential exposures are not likely because of the intermittent application of 2,4-D by homeowners; therefore, the intermediate-term aggregate risk assessment is not required.

d. Long-Term Aggregate Risk

The chronic (long-term) aggregate risk assessment includes only food and water exposure. The chronic food plus drinking water risk estimates are not of concern to the EPA for the general population and all population subgroups.

6. Occupational Risk Assessment

a. Short- and Intermediate-Term Handler Risk

Based on the anticipated use patterns and current labeling, types of equipment and techniques that can potentially be used (mixing/loading liquids for groundboom application, applying sprays with groundboom equipment), occupational handler exposure is expected from the uses.

Occupational handler risk estimates are not of concern (i.e., MOEs > LOC of 300) for all scenarios for use of 2,4-D choline salt on GE corn, cotton, and soybean. At baseline personal protective equipment (PPE) (i.e., no respirator), the occupational handler inhalation MOE is 12,000 for mixer/loaders and 3,700 for applicators using groundboom equipment.

b. Short- and Intermediate-Term Post-Application Risk

The EPA uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as reentry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests or harvesting. Post-application exposure levels vary over time and depend on such things as the type of activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities, can greatly reduce the potential for post-application exposure.

i. Dermal Post-Application Risk

There is no potential hazard *via* the dermal route for 2,4-D choline salt; therefore, a quantitative occupational post-application dermal risk assessment was not completed.

ii. Inhalation Post-Application Risk

Based on the EPA's current practices, a quantitative occupational post-application inhalation exposure assessment was not performed for 2,4-D choline salt at this time primarily because of the low acute inhalation toxicity (Toxicity Category III) and vapor pressure (1.4×10^{-7} mm Hg at 25°C for 2,4-D acid).

Although a quantitative occupational post-application inhalation exposure assessment was not performed, an inhalation exposure assessment was performed for occupational/commercial handlers and showed no risks of concern. Handler exposure resulting from application of pesticides outdoors is anticipated to result in higher exposure than post-application exposure. Therefore, it is expected that these handler inhalation exposure estimates would be protective of most occupational post-application inhalation exposure scenarios. Furthermore, a quantitative volatilization inhalation exposure assessment was assessed for bystanders and indicates no risk of concern for bystanders.

III. Environmental Risk

A summary of the environmental fate and ecological effects and risks of 2,4-D choline salt as assessed in the agency document titled, *2,4-D Choline Salt: EFED Ecological Risk Assessment and Listed Species effects determinations for GF2726 formulation of 2,4-D choline on GE corn, GE cotton, and GE soybean in AL, AR, AZ, CO, DE, FL, GA, IA, IL, IN, KS, KY, LA, MD, MI, MN, MO, MS, NC, ND, NE, NJ, NM, NY, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV,* found in docket EPA-HQ-OPP-2016-0594, is provided below.

A. Environmental Fate

The 2,4-D choline salt, a derivative of 2,4-D acid, has been shown to dissociate rapidly (within 6 seconds) in water. Since all salt including 2,4-D choline and ester forms of 2,4-D are derivatives of 2,4-D acid, the environmental fate strategy for 2,4-D is based on bridging the data on the degradation of 2,4-D esters and 2,4-D salts to 2,4-D acid.

1. Degradation

The degradation of 2,4-D occurs via oxidative microbially-mediated mineralization in terrestrial environments, and photodegradation in water. Degradation under aerobic soil conditions is rapid to moderately rapid with half-lives ranging from 1.4 to 12.4 days. In terrestrial field dissipation studies, 2,4-D acid half-lives range from 1.1 days to 42.5 days. There are three major degradates (2,4-DCP, 1,2,4-bezenetriol, and chlorohydroquinone (CHQ)) and three minor degradates (include 4-chlorophenol, 4-CPA and 2,4-DCA) of 2,4-D. Formation of these degradates varies by environmental component (e.g., soil vs. water), and availability of oxygen. Under natural conditions certain degradates may be less likely to occur.

2. Mobility

Under most environmental conditions 2,4-D is an anionic acid, hence it is expected to be mobile to moderately mobile. Risk of bioaccumulation is low for 2,4-D given the low value of the log octanol/water partition coefficient (log Kow = 0.18 at neutral pH). The vapor pressure (1.4 × 10-7 mm Hg) and Henry's Law Constant (8.56 x 10-6 atm-m3/mol) indicate that 2,4-D acid has a low volatility. Preliminary results from a field volatility study performed with 2,4-D choline salt, 2,4-D ethylhexyl ester (EHE), and 2,4-D dimethylamine salt (DMA salt) indicate that the estimated volatility flux rate of 2,4-D choline salt is lower than the EHE and DMA salt formulations.

B. Ecological Risk

Ecological risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of integrating the results of exposure and ecotoxicity data is called the risk quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic (RQ = Exposure / Toxicity). RQs are then compared to the EPA's levels of concern (LOCs). The LOCs are criteria used by the agency to indicate potential risk to non-target organisms. The criteria indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms.

The risk quotient method was used to determine if 2,4-D choline salt has the potential to cause adverse effects to non-target organisms based on the new use patterns for 2,4-D choline salt. Birds are considered a surrogate for terrestrial-phase amphibians and reptiles, in the absence of taxa-specific data. Submitted ecotoxicity data for 2,4-D choline salt (algae, freshwater fish, and honeybee) support bridging 2,4-D choline salt to 2,4-D acid ecotoxicity data. Only the most sensitive 2,4-D toxicity value from the broader 2,4-D dataset were used in risk quotient calculations, as needed. The major degradates of 2,4-D were considered, and all except 2,4-DCP were eliminated as likely degradates of concern. 2,4-DCP is a major degradate in certain aquatic environments; therefore, 2,4-D and 2,4-DCP were considered stressors of concern in aquatic environments, and 2,4-D alone was considered in terrestrial environments.

The following explains the EPA's assessment process starting with a screening-level risk assessment followed by a species-specific Effects Determination. The agency begins with a screening-level assessment that includes a basic ecological risk assessment based on its 2004 Overview of the Ecological Risk Assessment Process document.[4] That assessment uses broad default assumptions to establish estimated environmental concentrations of particular pesticides. If the screening-level assessment results in a determination that no LOCs are exceeded, then the EPA concludes its analysis. On the other hand, where the screening-level assessment does not rule out potential effects (exceedances of any LOC) based on the broad default assumptions, the EPA then uses increasingly specific methods and exposure models to refine its estimated environmental exposures. At each screening step, the EPA compares the more refined exposures to the toxicity of the pesticide active ingredient to determine whether the pesticide exceeds LOCs

[4] http://www.epa.gov/oppfead1/endanger/litstatus/riskasses.htm

established for listed aquatic and terrestrial species. The EPA determines that there is no effect on listed species if, at any step in the screening-level assessment, no LOCs are exceeded. If, after performing all of the steps in the screening-level assessment, a pesticide still exceeds the agency's levels of concern for listed species, the EPA then conducts a species-specific refined assessment to make effects determinations for individual listed species. The refined assessment, unlike the screening-level assessment, takes account of species' habitats and behaviors to determine whether any listed species may be affected by use of the pesticide.

The screening-level ecological risk assessment generates a series of taxonomic (e.g., mammals, birds, fish, etc.) RQs that are the ratio of estimated exposures to acute and chronic effects endpoints. These RQs are then compared to the EPA established LOCs to determine if risks to any taxonomic group are of concern. The LOCs address risks for both acute and chronic effects. Acute effects LOCs range from 0.05 for aquatic animals that are federally-listed threatened or endangered species (listed species) to 0.5 for aquatic non-listed animal species and 0.1 to 0.5 for terrestrial animals for listed and non-listed species. The LOC for chronic effects for all animal taxa (listed and non-listed) is 1. Plant risks are handled in a similar manner, but with different toxicity thresholds (NOAEC/EC_{05} and EC_{25}, respectively) used in RQ calculation for listed and non-listed species and an LOC of 1 used to interpret the RQ. When a given taxonomic RQ exceeds either the acute or chronic LOC, a concern for direct toxic effects is identified for that particular taxon. If RQs fall below the LOC, a no effect determination is identified for the corresponding taxon.

The results of the screening-level risk assessment for the Enlist Duo™ decisions indicates that the RQs did not exceed the agency's LOC for freshwater fish, estuarine/marine fish, freshwater invertebrates, estuarine/marine invertebrates, terrestrial insects, or aquatic plants for either acute or chronic exposures. RQs for chronic exposures to birds, reptiles, and land-phase amphibians also did not exceed the agency's LOC for chronic exposures only.

Additionally, the screening-level analysis indicates that the RQs for acute exposures to birds, reptiles, and land-phase amphibians exceed the agency's LOC for acute exposures. And, the RQs in the screening-level assessment for mammals exceed the agency's LOC for both acute and chronic exposures. The RQs for plants exceed the agency's LOC for both terrestrial monocots and terrestrial dicots. However, spray drift analysis indicates that spray drift mitigations on the current label for Enlist Duo™ reduce exposures off-site to levels well below risk concern levels for both birds and mammals, thereby limiting any potential risks of concern to the treatment site itself. The following sections discuss the results of the screening-level analyses for these taxonomic groups where the RQs exceed the agency's LOC, characterization of those risks, as well as how the agreed-to mitigation measures will reduce these potential risks of concern to 2,4-D choline salt.

1. Risk to Birds:

The screening-level analysis indicates that potential risks from the 2,4-D choline salt uses result in RQs that exceed the agency's LOC for birds within the treatment site only on an acute basis.

The acute oral toxicity study was conducted with the northern bobwhite quail and resulted in a classification of "moderately toxic" to birds on an acute oral basis. Toxic symptoms prior to

death were lethargy, reduced reaction to external stimuli, depression, lower limb weakness, wing droop, prostrate posture, loss of righting reflex, and a ruffled appearance. Sub-lethal effects included a drop in body weight at two of the treatment levels (218.7 and 135 mg ae/kg-bw). There was also a decrease in food consumption at the 218.7 mg ae/kg-bw treatment level during the first 3 days after dosing, but this was compensated for by a 2-3 times higher food consumption rate from days 4 through 14.

Three acute dietary studies were available, classifying 2,4-D choline salt as "practically non-toxic" on an acute dietary basis to birds. No mortalities occurred in the studies. The northern bobwhite quail study exhibited a slight decrease in body weight gain at the 3035 and 1706 mg ae/kg-diet treatment levels. The mallard duck study exhibited a decrease in body weight gain and feed consumption, but only at the highest treatment level (3035 mg ae/kg-diet). The third study involved testing of 2,4-D acid with the passeriformes canary. This dietary study was performed in lieu of an acute oral study because reliable oral dosing with passeriformes was problematic due to regurgitation of the test substance and so testing shifted to a subacute dietary test. No mortalities were observed at doses as high as 4790 mg/kg-diet and the NOAEL for the study was 983 mg/kg-diet for effects including reduced food consumption, transient motor incoordination, and lethargy.

In order to make the most conservative risk estimation, acute toxicity risk quotients were based on the oral toxicity study for the northern bobwhite quail. RQs ranged from 0.01 to 2.67, which were then compared to the agency's LOC for non-listed species (0.5). The agency's screening-level assessment employed residue estimates based on reasonable upper bound assumptions and the maximum labeled rate of the pesticide to determine the RQ values. At this high end exposure, residues for a variety of food items combined with a variety of body sizes triggered the screening concern threshold when compared to the most sensitive oral dose toxicity estimate. While risks of concern were identified, further consideration of all lines of evidence suggests that risks under more usually encountered circumstances may be lower. For example, high end residues compared to toxicity study endpoints using chemical actually incorporated in the animal's diet do not trigger non-endangered species concerns. This suggests that 2,4-D choline consumed in the diet may possibly be less available than assumed using dose-based exposures. Further, more realistically expected residues levels, such as mean or median estimates of exposure would be lower by a factor of two or more, suggesting that residues are often not likely to trigger concerns for many food items. In addition, screening-level estimates of exposure and risk are maximal at the actual point of application, right on the field. Available information in the agency risk assessments indicates that the transport of pesticide off field by spray drift decreases with distance, suggesting that exposures to 2,4-D choline salt and attendant risks can be substantially lower for organisms with territories established at distance from the field. With this last line of evidence in mind, a mitigation measure has been incorporated into the pesticide label to require a 30-foot in-field buffer from areas likely to be habitat for birds in order to further reduce off-site exposure for birds. Spray drift analyses indicate that spray drift mitigations on the current label for Enlist Duo™ would reduce exposures off site to levels well below the agency's LOC; therefore, there are no risks of concern for birds beyond the treatment site.

2. Risk to Mammals:

The screening-level analysis indicates that potential risks from the 2,4-D choline salt uses result in RQs that exceed the agency's LOC for mammals within the treatment site in chronic scenarios only.

The EPA assesses chronic risk to mammals using both dose-based and dietary-based endpoints. Risk quotients for mammals within the treatment site exceeded the agency's LOCs for mammals for chronic dose-based exposure. The chronic dose-based RQs ranged from 0.02 to 2.91; the LOC (1.0) that was exceeded was for all size classes of mammals consuming short grass, and other vegetative matter in small to medium mammals. Arthropod food consumption only triggered concerns for chronic effects in small mammals. Chronic dietary-based risk quotients ranged from 0.02 to 0.34, thereby not exceeding the LOC of 1.0. Since the dose-based approach results in more conservative RQs, they were used for risk assessment.

As in the case for birds, RQs for mammals span a range of outcomes. The principal focus is on the LOCs for reproduction effects, where RQ values range from <1 to 50, some of which exceed the agency's screening-level LOC (1) for non-listed species. Again, the agency's screening-level risk assessment employed residue estimates based on reasonable upper bound assumptions and the maximum labeled rate of the pesticide to determine the RQ values. Consideration of more realistic residue estimates and other lines of evidence such as food preferences and foraging ranges relative to distance from the site of application can lead to markedly reduced concerns for adverse effects in larger mammals with more varied diets, with larger home ranges with increased potential to be feeding well away from treatment areas.

Consideration of these lines of evidence also produces reduced risk estimates for small herbivorous mammals but do not reduce risk estimates for these organisms to the point that LOCs are not exceeded. As in the case for birds, the required 30-foot buffer from areas potentially comprising habitat for such mammals is intended to reduce the areas where such risks may occur and contain these risks to the treated field. As discussed above, spray drift analyses indicate that spray drift mitigations on the current label for Enlist Duo™ would reduce exposures off site to levels well below risk concern levels; therefore, there are no risks of concern for mammals that are not within the treatment site.

3. Risk to Plants:

As is expected with herbicides, terrestrial plants are sensitive to 2,4-D residues. Risk quotients ranged from 0.14 to 1.55 for monocots and 0.59 to 5.80 for dicots. Risk quotients exceeded the LOC of 1.0 for listed and non-listed plants only under the semi aquatic exposure scenario. Risk was attributed to both spray drift (calculated under conditions of standard model spray drift assumptions and without buffers in place) and runoff from treated fields. A refined spray drift analysis indicates that spray drift mitigations (buffers, application nozzle restrictions, etc.) on the current label for Enlist Duo™ reduce exposures off-site to levels well below risk concern levels for listed and non-listed species, thereby containing risks to the treatment site. As 2,4-D is primarily a foliarly-absorbed herbicide with limited root uptake, the EPA expects that much of the off-site plant community will not experience foliar contact with the herbicide in runoff sheet flow. A 24-hour rainfast period is also included on the label to reduce mass runoff;

therefore, the EPA concludes that all available lines of evidence support the conclusion that runoff exposure should not occur for off-field listed and non-listed plants. Analysis of volatilization information for 2,4-D choline indicates that volatilization from the treatment site to off-site areas is not of concern.

Although the RQ analysis indicated there may be risks to terrestrial plants from runoff and spray drift, data submitted on the Enlist Duo™ formulation demonstrates that the formulation has some properties that will reduce spray drift to non-target areas. The registrant submitted additional studies for spray drift analysis, using the specific low drift nozzles and the specific Enlist Duo™ formulation. The analysis indicates that this 2,4-D choline salt formulation applied through specific low drift nozzles is protective of non-listed dicots from exposures of 2,4-D choline when an adequate buffer is incorporated between the application equipment and the downwind edge of the treated field. Therefore, to mitigate against potential risks to plants from spray drift, the product labeling requires the use of a 30-foot buffer zone and specific nozzle specifications, thus reducing the potential spray drift exposure of non-target plants to 2,4-D choline salt residues. Public comments on the earlier risk assessments and effects determinations pointed out that the agency did not explicitly include a consideration of the risk findings for non-target plants as a result of off-field runoff. The agency considered the spray drift exposure to be the principal risk issue associated with the labeled use of 2,4-D choline, owing to a variety of lines of evidence, including past experience with other 2,4-D formulations and associated spray drift incident reporting. However, in light of the public comments, the EPA reconsidered the runoff risks and the effects of the mitigation to limit off-site runoff in listed species effects determinations, as follows.

Spray drift and runoff were considered as exposure pathways for 2,4-D choline salt to terrestrial plants and aquatic organisms. For aquatic organisms, the consideration of both spray drift and runoff loadings to surface waters did not trigger concerns. Risk concerns from spray drift to terrestrial plants were mitigated with an in-field 30-foot buffer that takes into account wind direction during application, and this mitigation yielded no spray drift concerns off field, when incorporated into spray drift modeling.

The in-field spray drift buffer is intended to mitigate for spray drift, but it is not intended to mitigate concerns from runoff. There is no labeling requirement for a vegetative "buffer strip" between the edge of the field and sensitive habitat. The agency does not currently have a tool to evaluate the effectiveness of vegetative buffers in reducing pesticide exposure via runoff. The agency has implemented vegetative buffer or filter strips in a few instances to lessen herbicide loading in runoff waters, however after consideration of information concerning 2,4-D, the EPA found there are no risk concerns for aquatic organisms from runoff. To assess runoff exposure to terrestrial plants, the agency looked at several lines of evidence to determine potential effects, as described below.

2,4-D is absorbed by both shoots and roots and is active at the growing points of the shoot and root. Translocation to the site of action is primarily via the symplastic pathway (with photosynthates in the phloem) and accumulates principally at the growing point of the shoot and root. 2,4-D is not translocated as well in the apoplast (carried with the water and nutrients in the xylem), which would occur with root uptake. Therefore, growth inhibition tends to be

more pronounced with foliar uptake than with root uptake (Shaner 2002). Consequently, 2,4-D in runoff waters would not be readily available for mature plant uptake. The agency is including a statement on the label based on the rainfast period for 2,4-D that prohibits the application of Enlist Duo™ if rain or irrigation is expected within 24 hours. A rainfast period is the time required for the herbicide to be absorbed into the plant after application and before a rain/irrigation event so as to provide reasonable weed control. The provision of a labeled rainfast period would increase the time available for on-field herbicide adsorption, thereby reducing the amount available for runoff. This, in combination with 2,4-D's limited uptake by roots of terrestrial plants, is anticipated to further reduce the amount of 2,4-D choline salt that could adversely affect plants via runoff.

Further, the EPA has evaluated the assumptions regarding runoff of 2,4-D from treated fields to adjacent terrestrial habitat. The model TerrPlant assumes, for a chemical with the solubility of 2,4-D in the most mobile acid form, that runoff would amount to 5% of the field applied mass of the herbicide. This modeling approach does not account for pesticide degradation and for pesticide partitioning. These processes that account for loss are important in the mechanistic pesticide runoff models used by the EPA (Pesticide Root Zone Model (PRZM)) and in the field. The agency has compared the TerrPlant assumption of 5% runoff to the runoff predictions for PRZM runs used to characterize pesticide runoff for aquatic exposure. This comparison revealed that runoff predicted by TerrPlant for 2,4-D is grossly overestimated. The total annual runoff is less than a fifth of the amount predicted by TerrPlant for a single runoff event.

4. Synergy

The agency views synergism to be a rare event and follows the National Research Council's recommendation for government agencies to proceed with estimating effects of pesticide mixtures with the assumption that the components have additive effects[5] in the absence of any data to support the hypotheses of a synergistic interaction between pesticide active ingredients. However, as described above, post-registration for Enlist Duo™ on GE corn and soybean for use in certain states, the EPA discovered that data were being cited in connection with patent claims submitted to the U.S. Patent and Trademark Office (USPTO) for claims of synergism for specific combinations of 2,4-D with other herbicides (which data had not been cited to the EPA).

Many USPTO filings suggest that combined mixtures have enhanced activity or synergistic effects. The endpoints in these patent application studies tend to be based on visual observations of weed control and injury, and so were not directly applicable to the EPA's quantitative risk assessment process for plants, in which measures of sublethal effects (plant height and weight) serve as sensitive effects thresholds for risk estimation purposes. The EPA believes this quantitative approach is much more scientifically rigorous and is a very reliable method of assessing risk for the purpose of potential toxicity to plants.

[5] The phrase 'additive effects' is used when the effect of the combination of chemicals can be estimated directly from the sum of the scaled exposure levels (dose addition) or of the responses (response addition) of the individual components.

As described above, however, in light of newly discovered information concerning patent claims made by DAS, on October 13, 2015 the EPA directed the registrant to provide to the agency information regarding potential "synergy," which ultimately resulted in the registrant's submission of Enlist Duo™ formulation-specific plant vegetative vigor and seedling emergence toxicity test data conducted using OCSPP 850 guideline protocols. For the combination of choline 2,4-D and glyphosate that is used in the Enlist Duo™ formulation, the standard vegetative vigor and seedling emergence studies were submitted for a suite of commonly tested plant species for which existing single-herbicide testing indicated plant sensitivity to 2,4-D or glyphosate. Surpassing the normal requirement of ten plant species, this testing spanned fifteen commonly tested monocot and dicot crop species: buckwheat, cabbage, corn, cucumber, mustard, oat, oilseed rape, onion, radish, sorghum, soybean, sugarbeet, sunflower, tomato, and wheat. In addition, the agency required and received vegetative vigor and seedling emergence studies with three weed species identified in the data set submitted to the USPTO as having the potential for exhibiting enhanced sensitivity to the 2,4-D choline/glyphosate combination in excess of simple addition of individual active ingredient effects. These species included lambs quarters (*Chenopodium album*), horseweed (*Conyza canadensis*), and quackgrass (*Agropyron repens*). These data were used to better understand the toxicity effects of the combination of 2,4-D and glyphosate on plants. These data demonstrate that the combination of 2,4-D choline and glyphosate in Enlist Duo™ does not show any increased toxicity to plants and is therefore not of concern. Details of the EPA's review of this data can be found in the document entitled, *2,4-D Choline: Review of Seedling Emergence and Vegetative Vigor Terrestrial Plant Studies for the Formulated Product Enlist Duo*, found in docket EPA-HQ-OPP-2016-0594.

5. Endangered Species Assessment for 2,4-D Choline Salt

In the screening-level risk assessment performed for new uses of 2,4-D choline salt on GE corn, cotton, and soybean, the EPA determined that direct effect concerns were unlikely for aquatic plants (vascular and non-vascular), freshwater fish (acute and chronic), estuarine/marine fish (acute and chronic), freshwater invertebrates (acute and chronic), estuarine/marine invertebrates (acute and chronic), and terrestrial insects. While direct effect concerns were found to be unlikely for birds, reptiles and terrestrial phase amphibians for chronic risk, they could not be excluded for acute risk. In addition, potential direct effect risk concerns could not be excluded for mammals (acute and chronic) and terrestrial plants. Additionally, in the screening-level assessment indirect effect risk concerns were found to be possible for any species that has dependencies on species that are directly affected. These effects were further considered when assessing listed species.

Registration of Enlist Duo™ is currently being considered for use in specific states. Based on the EPA's LOCATES database and data submitted by DAS, 531 listed species were identified as inside the "action area" (area of concern where use of pesticide may result in exposure to endangered species) associated with the new GE corn, cotton, and soybean uses within these states. Additional states may be considered once an assessment is completed and demonstrates that a No Effects determination is appropriate for any such state.

The following criteria are used to make a species-specific effects determination:

- For listed individual species inside the action area but not part of an affected taxa nor relying on the affected taxa for services involving food, shelter, biological mediated resources necessary for survival and reproduction, use of a pesticide would be determined to have NO EFFECT.
- For listed individual species outside the action area, use of a pesticide would be determined to have NO EFFECT.
- Listed individual species inside the action area may either fall into the NO EFFECT or MAY EFFECT categories depending upon their specific biological needs and circumstances of exposure.
- Those that fall under the MAY EFFECT category are found to be either LIKELY or NOT LIKELY TO ADVERSELY AFFECT the listed species.
- A NOT LIKELY TO ADVERSELY AFFECT determination is made using criteria that categorizes the effect as insignificant, highly uncertain, or wholly beneficial.

In light of the spray drift mitigation language on the label, the EPA expects that spray drift will remain confined to the 2,4-D choline treated field, and therefore the action area is limited to this field. Consequently, 508 of the 531 species originally identified as potentially at-risk can be given a No Effect determination because they are not expected to occur on corn, cotton, or soybean fields.

The 23 remaining listed species that were not ruled out because their range contains areas that include treated fields were considered in more depth to refine the assessment. Species-specific biological information and 2,4-D choline salt use patterns were considered. After utilizing processes such as refined modeling incorporating species-specific information and migration habits, the EPA made No Effect determinations for 19 of these species for all three crop uses.

For the remaining 4 species, a May Effect/Not Likely To Adversely Affect (NLAA) determination was made for the Eskimo curlew, the Sonoran pronghorn antelope in cotton in certain Arizona counties, and Audubon's Crested Caracara in cotton in one Florida county. A May Effect/ Likely To Adversely Affect (LAA) determination was made for the Spring Creek bladderpod in one Tennessee county, and Audubon's Crested Caracara in corn in certain Florida counties.

The EPA initiated informal consultation with the U.S. Fish and Wildlife Service (FWS) for the Eskimo curlew. The FWS concurred with the NLAA Effects Determination and no further action need be taken relative to this species.

A No Effect determination will be achieved for the NLAA and LAA species listed above with the following actions:

- Audubon's Caracara – Include a label statement which precludes use of the product on corn in Brevard, Broward, Charlotte, Collier, DeSoto, Glades, Hardee, Hendry, Highlands, Hillsborough, Indian River, Lee, Manatee, Martin, Miami-Dade, Okeechobee, Orange, Osceola, Palm Beach, Polk, Sarasota, and St. Lucie Counties in Florida, and off-label use of the product in cotton in Palm Beach County, FL.

- Spring Creek bladderpod - Include a label statement which precludes use of the product in Wilson County, Tennessee.

- Sonoran pronghorn antelope - Include a label statement which precludes use on cotton in Yuma, Pinal, Maricopa, Pima, La Paz and Santa Cruz Counties in Arizona.

The label the EPA has approved for the decisions discussed in this document includes off-labeling of the counties mentioned above, therefore the agency made a No Effect determination for these species.

For more details on these findings, refer to the EPA document titled, *2,4-D Choline Salt: EFED Ecological Risk Assessment and Listed Species effects determinations for GF2726 formulation of 2,4-D choline on GE corn, GE cotton, and GE soybean in AL, AR, AZ, CO, DE, FL, GA, IA, IL, IN, KS, KY, LA, MD, MI, MN, MO, MS, NC, ND, NE, NJ, NM, NY, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV*, available in docket EPA-HQ-OPP-2016-0594.

As noted earlier in this decision, glyphosate is already registered for these uses and did not undergo review as part of the assessment for this pesticide product. However, glyphosate currently is in the registration review process and an endangered species analysis for this active ingredient will be part of that process.

IV. Resistance Management

The emergence of herbicide resistant weeds is an increasing problem that has become a significant economic issue to growers. This has led to a concern that the use of 2,4-D on GE crops may result in the development of more resistant weeds. In an effort to address this issue, as part of the registration for use of Enlist Duo™ on GE corn and soybean in the original 6 states, the EPA required DAS to develop an Herbicide Resistance Management (HRM) plan to promote herbicide resistance management efforts. The plan mandates that DAS must investigate any reports of lack of herbicide efficacy and submit annual reports to the EPA. The initial mechanism users can use for communicating directly with DAS is a toll-free number to get advice on how to resolve any uncontrolled weeds.

Academia, growers, USDA, and other leaders involved with pest management all acknowledge the importance of scouting in herbicide resistance management. Fields should be scouted before application of Enlist Duo™ to identify the weed species present as well as their stage of growth. Fields should also be scouted after each Enlist Duo™ application to identify poor performance or likely resistance. In the event that a user encounters a non-performance issue, the toll-free number is available to report the issue, which will initiate an intervention against that weed population.

When a lack of herbicide efficacy is identified and reported to the registrant, DAS or its representative will investigate and conduct a site visit if needed, to evaluate the lack of herbicide efficacy using decision criteria identified by leading weed science experts (Norsworthy, et al. 2012), in order to determine if "likely herbicide resistance" (possible resistance) is present. This is distinct from the term "lack of herbicide efficacy," as explained below. For purposes of this

decision, a report of lack of herbicide efficacy to DAS will be the trigger to start this investigation.

"Lack of herbicide efficacy" refers to inadequate weed control with various possible causes, including but not limited to: application rate, stage of growth, environmental conditions, herbicide resistance, plugged nozzle, boom shut off, tank dilution, post-application weed flush, unexpected rainfall event, weed misidentification, etc. The EPA recognizes that it can be challenging to distinguish emerging weed resistance from other causes at an early stage. Therefore, the EPA has selected criteria that should be used to evaluate instances of "lack of herbicide efficacy" to determine if they do in fact constitute "likely herbicide resistance." These "likely herbicide resistance criteria are: (1) failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds; (2) a spreading patch of uncontrolled plants of a particular weed species; and (3) surviving plants mixed with controlled individuals of the same species (Norsworthy, et al., 2012). The identification of one or more of these criteria in the field indicates that "likely herbicide resistance" is present.

When DAS or its representative applies the Norsworthy, et al., criteria cited above and likely herbicide resistance is identified, then to the extent possible, DAS must proactively engage with the grower to control and contain likely resistant weeds in the infested area. This may be accomplished by re-treating with an herbicide or using mechanical control methods. After implementing these measures, DAS must follow-up with the growers, to the extent possible, to determine if the likely resistant weed(s) has/have been controlled. DAS must also annually report to the EPA findings of likely herbicide resistance. In addition, prior to implementing control measures, DAS will make best efforts to obtain samples of the likely herbicide resistant weeds and/or seeds, and as soon as practicable, laboratory or greenhouse testing must be initiated in order to confirm whether resistance is the reason for the lack of herbicide efficacy.

Per the original Enlist Duo™ registration requirement to submit annual summary reports to the EPA on or before January 15th of each year, DAS submitted an annual report on January 15, 2016. Under the proposal, DAS would continue to submit annual summary reports to the EPA. These reports must include a summary of the number of instances of likely and confirmed resistance to Enlist Duo™ by weed species, crop, county and state. They will also summarize the status of laboratory or greenhouse testing for resistance. The annual reports will also address the disposition of incidents of likely or confirmed resistance reported in previous years.

As a component of this registration, DAS also would report annually any inability to control likely resistant weeds to relevant stakeholders. To accomplish this, the EPA understands that DAS will establish websites to facilitate delivery of resistance information.

Several management practices that are designed to help users avoid initial occurrences of weed resistance appear on the product labeling under the Herbicide Resistance Management heading of the label. These practices are discussed in Section VII.B.3 of this document.

Refer to Section VII.C below for the EPA's delineation of necessary terms of registration to address the issue of weed resistance.

V. Benefits

The need for additional tools to manage resistant weeds has become important as resistance to glyphosate and other herbicides has become a significant economic and pest management issue to growers. The new uses of 2,4-D choline salt will expand options for weed control in corn, cotton, and soybean and enable control of additional broadleaf weeds, including some resistant biotypes. Current registered uses of non-choline 2,4-D in corn allow for over-the-top broadcast applications only up to 8 inches tall which would be increased to up to 48 inches tall with GE 2,4-D tolerant corn. Similarly, the currently registered use of non-choline 2,4-D in soybeans allows pre-plant applications only, however new uses of 2,4-D choline salt will expand uses to include over-the-top broadcast applications to GE soybeans. Currently registered uses of non-choline 2,4-D in cotton allow for a preplant application or a fall postharvest broadcast or spot treatment. The new use of 2,4-D choline salt in GE cotton will allow Enlist Duo™ to be applied post-emergence during the growing season. The addition of this new tool to the production of corn, cotton, and soybeans is expected to have a significant impact to weed management.

Since Enlist Duo™ is a premix formulation combining 2,4-D choline salt and glyphosate, its introduction for use on Enlist™ corn, cotton, and soybeans can provide additional benefits. The use of a premix of 2,4-D choline salt and glyphosate utilizes multiple mechanisms of action and it, if utilized as part of a weed resistance management plan, could delay the development of herbicide resistant weeds. The pairing of two well-established herbicides into a systems approach with a GE crop will allow growers and applicators the opportunity to control many weeds in a way which fulfills the important principle of using multiple mechanisms of action, which the weed science community has been touting for many years.

The use of 2,4-D choline salt and glyphosate on the Enlist™ corn, cotton, and soybean seed technology will provide efficacious control of broadleaf weeds later in the growing season, resulting in reduced spread and persistence of many broadleaf weeds, thus maintaining yields. If widely adopted by growers, the herbicide combination in this weed control systems approach could potentially prolong the effectiveness of the glyphosate technology if the two herbicides are controlling weeds that are not resistant to either herbicide. In addition, this system could maintain the positive effect of reducing the need for tillage, thus preventing unnecessary erosion, in areas where 2,4-D choline salt will control glyphosate resistant broadleaf weeds.

The use of the 2,4-D choline salt offers environmental benefits over the use of traditional forms of 2,4-D as well. Specifically, the EPA has determined that the choline salt is less volatile than other forms of 2,4-D. Data also indicates that 2,4-D choline salt has less potential for off-site movement through spray drift than other forms of this herbicide. This will reduce the potential for damage to non-target plants, including vulnerable crops, where 2,4-D choline salt is to be used.

VI. Registration Decision

In accordance with FIFRA, the EPA only registers a pesticide when it determines that it will not cause unreasonable adverse effects on man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide. Under FIFRA,

the EPA is charged with balancing the uncertainties and risks posed by a pesticide against its benefits. The EPA must determine if the benefits in light of its use outweigh the risks in order for the agency to register a pesticide.

In the case for the new use of 2,4-D choline salt on GE corn, soybeans, and cotton, and in consideration of all best available data and assessment methods, the EPA finds that the registration of these uses meets the requirements of FIFRA. The database submitted to support the assessment of human health risk is sufficient for a full hazard evaluation and is adequate to evaluate risks to infants and children. The agency has not identified any risks of concern in regards to human health, including all population subgroups, or for occupational handlers.

In terms of ecological risk, some LOCs were exceeded for certain birds, reptiles, amphibians, and mammals that may be in the fields that would be treated. No LOCs were exceeded for animals outside the treatment area. For birds, reptiles, amphibians, and mammals that may be in the treated fields, the agency notes that these are very conservative risk estimates using screening-level (worst case) assumptions. For example, it is assumed that animals within the treatment site would forage for food exclusively in the treated area consuming only the treated crop, neither of which is likely to be true. Additionally, the protections afforded by the labeling, such as the requirement of in-field buffers, would reduce the likelihood of spray drift and volatilization that could affect organisms located beyond the treated field. Because of these additional restrictions that limit adverse effects to within the treatment site itself, the EPA expects these uses to have less environmental impact than other currently registered products contain either of these active ingredients that do not require the same buffers. It is also noted that, if further refinements that included more realistic exposure scenarios were conducted, these risks would likely fall below the agency's levels of concern.

On the benefits side of the analysis, use of Enlist Duo™ on GE corn, soybeans, and cotton is expected to become an important part of a resistance management strategy for these crops. Corn, soybeans, and cotton are extremely important agricultural commodities in the United States and the world. According to the USDA's National Agricultural Statistics Service, corn is grown on approximately 94 million acres, soybeans are grown on approximately 85 million acres, and cotton is grown on approximately 9 million acres. USDA's Economic Research Service describes corn as one of the world's major feed grains, and the primary feed grain in the US, describes soybeans as the world's largest source of animal protein feed and the second largest source of vegetable oil, and describes cotton as one of the most important textile fibers in the world, accounting for around 35 percent of total world fiber use. USDA's Economic Research Service also states that the United States is the world's leading corn and soybeans producer and exporter, and together with China and India, provides two-thirds of the world's cotton.

USDA estimates the gross value of corn and soybeans production at approximately 49 and 48 billion dollars, respectively, in the United States. Corn and soybeans are grown throughout the United States with the majority concentrated in the upper Midwest. The gross cotton production is estimated by USDA at over 6 billion dollars in the United States, and is grown in 17 states stretching across the southern half of the United States. However, resistance to glyphosate, the current market leader herbicide used in corn, soybeans, and cotton, is having severe economic consequences in the production of these crops. The Weed Science Society of America and other weed control experts warn that the problem of glyphosate resistance is increasing, and that

significant economic consequences will continue to increase without effective alternatives for weed control.

Consequentially, use of Enlist Duo™ on GE corn, soybeans, and cotton will be beneficial as it provides an effective tool to treat especially noxious weeds such as marestail, giant ragweed, common waterhemp, and Palmer amaranth, including glyphosate-resistant biotypes that threaten corn, soybeans, and cotton production today. By adding an effective tool to combat glyphosate-resistant weeds, 2,4-D will help reduce this difficult weed pressure and aid significantly in production, reducing economic losses to corn, soybeans, and cotton growers. In addition, effective treatment of glyphosate-resistant weeds can help control the spread of resistance. And, as stated previously, using 2,4-D for these uses according to the labeling restrictions including in-field buffers, best practice requirements for drift management and application techniques, and active resistance management stewardship of weed populations will provide further protections and sustainability.

After weighing all the risks of concern against the benefits, the EPA finds that with the required mitigation measures on the approved labeling, the risks that may remain are minimal, if they exist at all, while the benefits are potentially great. Therefore, the benefits outweigh the risks and registering these uses will not generally cause unreasonable adverse effects on human health or the environment during the 5-year time limited registration (a 5-year registration is granted so that any unexpected weed resistance issues that may result from the uses can be addressed before granting an extension or the EPA can allow the registration to terminate if necessary). It is noted that a 5-year time limited registration was granted in October, 2014 for use of Enlist Duo™ on GE corn and soybeans. However, according to information submitted by DAS, no appreciable use of Enlist Duo™ on those crops occurred in the 2015 and 2016 use seasons; therefore, the EPA believes that no appreciable exposures have occurred that would contribute to the development of resistance at this point. Since it was determined that data resulting from 5 years of appreciable use would be needed to reliably indicate if resistance is developing, the EPA has determined that it would be appropriate to revise the original expiration date to 5 years from the date of the EPA's final decisions on these registrations. The EPA believes that the available data and scientific assessments as well as the overall considerations for benefits for weed management in these important crops support a FIFRA Section 3(c)(7)(B) registration finding for these new uses.

A. Data Requirements

Although there are currently no outstanding data required to support the registration of this action, the EPA has identified data that will be required in connection with registration review activities for 2,4-D. Those requirements will be applicable to 2,4-D uses and products in general and will be handled in accordance with the registration review process. Because data have been identified in the registration review process, the EPA is registering these new uses under FIFRA section 3(c)(7)(B).

B. Labeling Requirements

In order to properly protect farm workers, bystanders, and the environment, the new (and on currently registered Enlist Duo™ for GE corn and soybean) labeling language includes

restrictions intended to keep the pesticide on the treatment area, thereby reducing the potential for exposure of non-target plants and animals. For example, spray drift management labeling advises users of applicator responsibilities and requires specific techniques to reduce the possibility of spray drift. In addition, required surface and ground water advisories on the labeling may further reduce residues in drinking water and exposure of non-target organisms.

1. Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift or runoff may adversely affect aquatic invertebrates and non-target plants. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment washwaters or rinsate.

This chemical has properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination. Application around a cistern or well may result in contamination of drinking water or groundwater.

2. Worker Protection

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear (goggles, faceshield, or safety glasses)

3. Resistance Management

To aid in the prevention of developing weeds resistant to this product, the following steps should be followed:

- Scout fields before application to ensure herbicides and rates will be appropriate for the weed species and weed sizes present.
- Apply full rates of Enlist Duo™ for the most difficult to control weed in the field at the specified time (correct weed size) to minimize weed escapes.
- Scout fields after application to detect weed escapes or shifts in weed species.

- Report any incidence of non-performance of this product against a particular weed species to your Dow AgroSciences retailer, representative or call 1-855-ENLIST-1(1-855-365-4781)
- If resistance is suspected, treat weed escapes with an herbicide having a mode of action other than Group 4 or 9 and/or use non-chemical methods to remove escapes, as practical, with the goal of preventing further seed production.

Additionally, users should follow as many of the following herbicide resistance management practices practical:

- Use a broad spectrum soil-applied herbicide with other modes of action as a foundation in a weed control program.
- Utilize sequential applications of herbicides with alternative modes of action.
- Rotate the use of this product with non-Group 4 and non-Group 9 herbicides.
- Incorporate non-chemical weed control practices, such as mechanical cultivation, crop rotation, cover crops and weed-free crop seeds, as part of an integrated weed control program.
- Thoroughly clean plant residues from equipment before leaving fields suspected to contain resistant weeds.
- Avoid using more than two applications of Enlist Duo™ and any other Group 4 or Group 9 herbicide within a single growing season unless in conjunction with another mode of action herbicide with overlapping spectrum.
- Manage weeds in and around fields, during and after harvest to reduce weed seed production.

Contact the local agricultural extension service, Dow AgroSciences representative, ag retailer or crop consultant for further guidance on weed control practices as needed.

4. Spray Drift Management

a. Tank Mix Instructions:

TANK-MIXING INSTRUCTIONS:

Enlist Duo™ may only be tank-mixed with products that have been tested and found not to adversely affect the spray drift properties of Enlist Duo™. A list of those products may be found at EnlistTankmix.com

DO NOT TANK-MIX ANY PRODUCT WITH Enlist Duo™ unless:

1. You check the list of tested products found not to adversely affect the spray drift properties of Enlist Duo™ at EnlistTankmix.com no more than 7 days before applying Enlist Duo™; and
2. The product you tank-mix with Enlist Duo™ is identified on that list of tested products.

b. Droplet Size:

Use of Enlist Duo™ required the use of specific nozzle and spray pressure combinations. A chart is included in the product label that lists the specific nozzle and pressure combinations that are allowed.

c. Groundboom Application:

Use the minimum boom height based upon the nozzle manufacturer's directions. Spray drift potential increases as boom height increases. Spray drift can be minimized if nozzle height is not greater than the maximum height specified by the nozzle manufacturer for the nozzle selected.

d. Wind Speed:

Do not apply at wind speeds greater than 15 mph.

e. Temperature and Humidity:

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

f. Temperature Inversions:

Applications should not occur during a local, low level temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of the smoke from a ground source generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing

g. Application Restrictions:

Do not aerially apply this product.

Do not irrigate treated fields for at least 24 hours after application of Enlist Duo™.

Do not make application of Enlist Duo™ if rain is expected in the next 24 hours.

5. Protection of Sensitive Areas:

To ensure the protection of threatened or endangered species, residues of this product from spray drift must be below levels of concern for threatened and endangered species for any area adjacent to the application site that is not excluded as possible habitat for these organisms. Therefore, the following mitigation will be required on the label:

a. Buffer

You must maintain a 30-foot downwind in field buffer (in the direction in which the wind is blowing) from any area except:

- Roads, paved or gravel surfaces.
- Planted agricultural fields. (Except those crops listed in "Susceptible Plants" section)
- Agricultural fields that that have been prepared for planting.
- 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.

b. Wind Direction

To maintain the required downwind buffer zone:

- Measure wind direction prior to the start of any swath that is within 30 feet of a sensitive area.
- No application swath can be initiated in, or into an area that is within 30 feet of a sensitive area if the wind direction is towards the sensitive area.

6. Susceptible Plants:

Do not apply under circumstances where spray drift may occur to food, forage, or other plantings that might be damaged or crops thereof rendered unfit for sale, use or consumption. Do not allow contact of herbicide with foliage, green stems, exposed non-woody roots of crops, desirable plants; including trees and cotton without the Enlist trait, because severe injury or destruction may result. Small amounts of spray drift that may not be visible may injure susceptible broadleaf plants. Before making an application, please refer to your state's sensitive crop registry (if available) to identify any commercial specialty or certified organic crops that may be located nearby.

At the time of application, the wind cannot be blowing toward adjacent commercially grown tomatoes and other fruiting vegetables (EPA crop group 8), cucurbits (EPA crop group 9), grapes, and cotton without the Enlist trait.

C. Registration Terms

The EPA has determined that certain registration terms are needed to ensure that likely weed resistance as discussed in section IV can be adequately addressed. The EPA believes that it is important to address likely weed resistance and not wait until confirmation of resistance has been found. The EPA is basing the registration terms on a list of criteria, presented in the peer-reviewed publication, Norsworthy, et al., "Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations," *Weed Science* 2012 Special Issue: 31–62 (Norsworthy criteria).

1. Stewardship Program

The EPA has determined that the registration must contain a term that requires DAS to have a stewardship program for Enlist Duo™. DAS' program is focused on educating and training retailers, farmers and applicators on the appropriate use of the Enlist™ technology. The EPA has determined that the stewardship program must include the following measures (also to be included as terms on the registration) that would minimize the potential for off-target movement and avoid the development of weed resistance.

a. Investigation

The EPA has determined that the registration must contain a term that requires DAS or its representative to investigate reports of non-performance as reported by users following "scouting" (as part of best management practices). When investigating these reports, DAS or its representative may support the response by conducting site visits.

b. Reporting of the Incidence of Likely Herbicide Resistance

The EPA has determined that the registration must contain a term that requires DAS to use the Norsworthy criteria for determining likely herbicide resistance and inform the EPA if likely resistance has been identified. This information must be submitted to the agency on an annual basis.

c. Remediation

The EPA has determined that the registration must contain a term that requires DAS to take appropriate and direct action, to the extent practicable, to assist the grower to effectively manage likely resistant weeds in the infested area as well as requiring DAS to collect material for further testing.

d. Annual Reporting of Herbicide Resistance to the EPA

The EPA has determined that the registration must contain a term that requires DAS to submit annual summary reports to the EPA that include a summary of the number of instances of likely and confirmed weed resistance by weed species, crop, county and state. The annual reports must include summaries of the status of laboratory or greenhouse testing for resistance. The annual reports would also address the disposition of incidents of likely or confirmed resistance reported in previous years. These reports would be in addition to adverse effects reporting required under FIFRA 6(a)(2).

e. Reporting of Likely Resistance to other Interested Parties

The EPA has determined that the registration must contain a term that requires DAS to inform growers and other stakeholders of likely and confirmed resistance to Enlist Duo™. The information will include details of weed species and crop. The EPA understands that DAS meet this term by providing this information through websites.

f. Reporting on the development of diagnostic tests

The EPA has determined that the registration must contain a term that requires that DAS would inform the EPA of DAS's progress toward practical diagnostic testing for evaluating resistant weed species.

g. Monitoring the use of Enlist Duo™ on Enlist™ Seed

The EPA believes it is important to require DAS to monitor whether Enlist Duo™ is being used on the Enlist™ seed purchased from DAS. The EPA has determined that the registration must contain a term that requires DAS to survey whether Enlist Duo™ is being used on Enlist™ seed purchased from DAS and not the non-choline 2,4-D products that are not registered for these application windows. DAS must provide the EPA with the results of the survey as part of the required annual reporting.

h. Training and Education

The EPA has determined that the registration must contain a term that requires DAS to provide training on the use of Enlist Duo™ when it provides training on the Enlist™ Seed technology. The training would focus on proper use of the technology to avoid off-target movement as well as avoid weed resistance.

2. The EPA's Continued Control over the Registration

Because the issue of weed resistance is an extremely important issue to keep under control and can be very fast moving, this registration will expire unless this term is removed or modified by the EPA. As described above, the date of expiration will be 5 years from the date of the Registration Notice. This will ensure that the EPA retains the ability to easily modify the registration or allow the registration to terminate if necessary.

3. Geographic Limitation on Use of Enlist Duo™

The EPA has determined that Enlist Duo™ shall be allowed to be sold and used only for those states and counties for which an endangered species assessment has been completed and resulted in a No Effect determination. Additional states may be added to the labeling if assessments for those states are completed and demonstrate that a No Effect determination is appropriate.

CORPORATE DISCLOSURE STATEMENT

Natural Resources Defense Council, Inc. (NRDC) is a non-profit corporation with no parent corporation and no outstanding stock shares or other securities in the hands of the public. NRDC does not have any parent, subsidiary, or affiliate that has issued stock shares or other securities to the public. No publicly held corporation owns any stock in NRDC.

Dated: March 21, 2017

Respectfully submitted,

s/ Margaret T. Hsieh
Margaret T. Hsieh
Natural Resources Defense Council
40 W. 20th Street
New York, NY 10011
Telephone: (212) 727-4652
Facsimile: (415) 795-4799
mhsieh@nrdc.org

Aaron Colangelo
Natural Resources Defense Council
1152 15th Street, NW, Suite 300
Washington, D.C. 20005
Telephone: (202) 289-2376
Facsimile: (415) 795-4799
acolangelo@nrdc.org

Counsel for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing Petition for Review, the exhibits thereto, and Corporate Disclosure Statement to be served by certified mail on respondents at the following addresses:

E. Scott Pruitt, Administrator
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, NW
Mail Code: 1101A
Washington, DC 20460

Correspondence Control Unit
Office of General Counsel (2311)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

I also certify that I caused the listed documents to be served by certified mail on counsel for respondents at the address below:

Jefferson Sessions III
United States Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Dated: March 21, 2017

s/ Margaret T. Hsieh
Margaret T. Hsieh