

Comments of the Natural Resources Defense Council on Dow AgroSciences' Application to Register Enlist Duo Herbicide Containing the Choline Salt of 2,4-D and Glyphosate

EPA-HQ-OPP-2014-0195

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The Natural Resources Defense Council (NRDC) is a national, non-profit environmental organization of lawyers, scientists, and other professionals. NRDC presents these comments on behalf of our 1.3 million members and online activists. NRDC does not have any financial interest in the topic of these comments.

Dow AgroSciences (DAS) has submitted an application for registration of Enlist Duo, an herbicide containing the active ingredients glyphosate dimethylammonium salt (glyphosate) and 2,4-dichlorophenoxyacetic acid (2,4-D) choline salt, for use on corn and soybean crops (Enlist crops) that have been genetically engineered (GE) to be tolerant to glyphosate and 2,4-D. On April 30, 2014, EPA issued a proposal to grant DAS's application for registration. *See* EPA, Proposed Registration of Enlist Duo™ Herbicide (Apr. 30, 2014). NRDC submits these comments in response to EPA's proposal to register Enlist Duo for use on Enlist AAD-1 Corn (Trait Code: DAS-40278-9) and Enlist AAD-12 Soybean (Trait Code: DAS-68416-4).

I. INTRODUCTION

NRDC has serious concerns about the expanded use of glyphosate and 2,4-D that would follow EPA's registration of Enlist Duo for use on GE corn and soybeans.

A. GLYPHOSATE

Glyphosate is an herbicide that has been registered for many agricultural and non-agricultural uses.¹ EPA has approved glyphosate's use on over 100 terrestrial food crops,

¹ U.S. EPA, Glyphosate Final Work Plan (FWP): Registration Review Case No. 0178, at 2 (2009) [hereinafter 2009 Glyphosate Final Work Plan].

including fruit, vegetable, and field crops.² The agency has also registered glyphosate for use in non-crop settings, often to achieve total vegetation control.³ Non-crop areas to which glyphosate is applied include residential, industrial, forestry, greenhouse, ornamental, aquatic, and other sites.⁴ When applied at lower rates, glyphosate also functions as a plant growth regulator.⁵

EPA first registered glyphosate for use in pesticides in 1974. As a non-selective herbicide, glyphosate does not discriminate between target and non-target plant species. Because of its damage to crops, glyphosate's use was initially limited. Since glyphosate was reregistered in 1993, however, the development of genetically-modified, glyphosate-resistant crops has facilitated a dramatic rise in the herbicide's application. As of 2009, approximately 182 million pounds of glyphosate were applied to over 261 million acres annually—compared to about 18.7 million pounds used on 13 to 20 million acres annually between 1989 and 1991. Having experienced an approximately ten-fold increase in use since its reregistration, glyphosate is now the most widely used herbicide in the United States.⁶

² *Id.*

³ U.S. EPA, Reregistration Eligibility Decision Facts: Glyphosate 1 (1993) [hereinafter 1993 Glyphosate R.E.D. Facts].

⁴ 2009 Glyphosate Final Work Plan, *supra* note 1, at 2; 1993 Glyphosate R.E.D. Facts, *supra* note 3, at 1.

⁵ 1993 Glyphosate R.E.D. Facts, *supra* note 3, at 1.

⁶ M.J. Livingston, *Economics of Pest Control*, in 2 Encyclopedia of Energy, Natural Resource, and Environmental Economics 66 (Jason Shogren ed., 2013); U.S. EPA, 2006-2007 Pesticide Market Estimates: Usage (Page 2), http://www.epa.gov/opp00001/pestsales/07pestsales/usage2007_2.htm (last visited June 30, 2014); *see also* U.S. Geological Survey, Glyphosate Found in Wastewater Discharged to Streams, http://toxics.usgs.gov/highlights/glyphosate_wastewater.html (last visited June 30, 2014) (noting that glyphosate is also the most widely used herbicide in the world).

The unprecedented increase in glyphosate use has adversely affected the North American monarch butterfly, *Danaus plexippus*, an iconic species that migrates through the United States as part of its annual life cycle. Over the last decade, there has been a sharp decline in the monarch population that traverses the American Midwest and overwinters in Mexico. By eliminating milkweed—the exclusive food source for monarch larvae—the pervasive use of glyphosate has contributed to the monarch’s decline. The decimation of milkweed communities, particularly from agricultural areas, has been associated with an 81% decrease in the production of monarchs in the Midwest and a 65% decrease in the size of the entire monarch population that overwinters in Mexico between 1999 to 2010. This winter’s annual monarch census in Mexico reported the lowest population levels ever measured, down from last year’s record low.

EPA is currently reevaluating glyphosate to determine if it still meets the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for registration. The final registration review process is scheduled to end in 2015.

B. 2,4-D

2,4-D is a widely used herbicide with nearly 40 million pounds used on agricultural crops in 2011. Dermal contact, ingestion of contaminated food and water, and inhalation represent the major routes of human exposure. 2,4-D has been implicated in a number of adverse human health endpoints (*see* NRDC comments 2012, Appendix A) including Non-Hodgkin’s lymphoma, decreased fertility, and higher rates of birth defects. Unfortunately, EPA’s assessment of both the toxicity of 2,4-D and the relevant exposure pathways to Enlist Duo are critically flawed and fall short of what is necessary to protect human health. In addition, the Agency’s proposal to eliminate the ten-fold FQPA safety factor cannot be justified.

Furthermore, EPA proposes to register this chemical without an updated risk assessment for its other component, glyphosate. The Agency's current glyphosate assessment is 21 years old, and over 3000 studies have been published since that time, many of which provide a basis for a much more stringent RfD for this chemical. NRDC strongly objects to the evaluation of Enlist Duo without an updated assessment of its glyphosate component. EPA cannot properly find that Enlist Duo will not cause unreasonable adverse effects on human health or the environment, and, therefore, cannot make a final registration decision for Enlist Duo until it has completed its review of glyphosate and the public has had a chance to review it.

In evaluating DAS's application to register Enlist Duo for use on GE corn and soybean, EPA is required to consider whether registration would lead to unreasonable adverse impacts on human health and the environment. As discussed in these comments, the agency must consider the substantial adverse impacts to monarchs caused by increased use of glyphosate. Moreover, it is improper for EPA to register this pesticide before finalizing its glyphosate review process, which is still ongoing. Finally, the agency must also consider mounting evidence of human health risks caused by exposure to 2,4-D.

II. LEGAL STANDARD

FIFRA requires EPA to register any pesticide before it is sold or distributed in the United States. 7 U.S.C. § 136a(a). A FIFRA registration is a product-specific license setting forth the terms and conditions under which the product can be legally distributed, sold, and used. *See id.* §§ 136a(a), (c)-(e). EPA can register a pesticide only upon determining that "it will perform its intended function without unreasonable adverse effects on the environment," *id.* § 136a(c)(5)(C), and that "when used in accordance with widespread and commonly recognized practice it will

not generally cause unreasonable adverse effects on the environment,” *id.* § 136a(c)(5)(D).

FIFRA has defined “[u]nreasonable adverse effects on the environment” to include “any unreasonable risk to . . . the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide,” *id.* § 136(bb).

Registration under FIFRA is either conditional or unconditional. *Hardin v. Jackson*, 625 F.3d 739, 740 (D.C. Cir. 2010) (citing 7 U.S.C. §§ 136a(c)(5), 136a(c)(7)). An applicant seeking conditional registration “shall submit such data as would be required to obtain registration of a similar pesticide under [the provisions for unconditional registration].” *Id.* If the applicant is unable to submit datum because it has not yet been generated, however, EPA may register the pesticide “under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered.” *Id.* § 136(7)(A).

The regulations for conditional registration further provide that EPA “may approve an application for registration . . . of a pesticide product, each of whose active ingredients is contained in one or more other registered pesticide products,” only if the agency has determined that “(1) [i]t possesses all data necessary to make the determinations required by FIFRA sec. 3(c)(7)(A) . . . with respect to the pesticide product which is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application),” and “(2) [a]pproval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment.” 40 C.F.R. § 152.113(a) . Notwithstanding the satisfaction of these requirements, EPA “will not approve the conditional registration of any pesticide” unless the agency has determined that “the applicant’s product and its proposed use are identical or substantially similar to a currently registered pesticide and use,

or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.” *Id.* § 152.113(b).

III. ARGUMENT

A. EPA MUST CONSIDER GLYPHOSATE’S IMPACTS ON MONARCHS

Glyphosate has contributed to significant harm to the monarch butterfly by destroying milkweed, which provides essential monarch food and habitat. The increased use of glyphosate across the country, spurred by widespread adoption of glyphosate-resistant GE crops (including Roundup Ready crops), has drastically reduced the presence of agricultural milkweed over the last decade. The pervasive suppression of milkweed has, in turn, contributed to a sharp decline in the monarch population. In 1997, before the widespread adoption of glyphosate-resistant crops, approximately one billion monarchs journeyed across the country between summer havens in the United States and Canada and a single winter home in Mexico.⁷ As of this year, only about 35 million butterflies reached their winter refuge.⁸ Scientists have warned that the annual monarch migration may be in danger of effectively vanishing.⁹

In its proposed registration for Enlist Duo, EPA concluded that “no new assessment is needed for glyphosate” because “the use on GE crops . . . is not a new use for glyphosate containing products.” EPA, Proposed Registration 1. Glyphosate, however, has never been

⁷ Michael Wines, *Migration of Monarch Butterflies Shrinks Again Under Inhospitable Conditions*, N.Y. Times, Jan. 29, 2014; Sylvia Fallon, *Monarch Butterfly Population Hits a New Low*, *Switchboard: Natural Resources Defense Council Staff Blog* (Jan. 29, 2014), http://switchboard.nrdc.org/blogs/sfallon/monarch_butterfly_population_h.html.

⁸ *Id.*

⁹ *Id.*; see also Michael Wines, *Monarch Migration Plunges to Lowest Level in Decades*, N.Y. Times, Mar. 13, 2013; see also Tracy Wilkinson, *U.S., Mexico and Canada are Asked to Protect Monarch Butterflies*, L.A. Times, Feb. 14, 2014.

registered for use on glyphosate-resistant corn and soybean. Use on these GE crops *is* thus a new use of products containing glyphosate, even if glyphosate has previously been registered for use on non-GE variants of these crops. Furthermore, EPA never considered adverse impacts to monarchs when it first registered glyphosate for use on crops. Accordingly, the agency must consider those impacts now.

1. Glyphosate Use Has Increased Significantly Since Reregistration in 1993

EPA first registered glyphosate for use in pesticide products in 1974.¹⁰ As a non-selective herbicide,¹¹ glyphosate does not discriminate between target and non-target plants. Because of its harm to crops, glyphosate's early use was relatively limited.¹² In a typical year between 1989 and 1991, 18.7 million pounds of glyphosate were applied as an active ingredient to between 13 and 20 million acres.¹³ Out of this aggregate amount of glyphosate used across all types of acreage, 1.1 to 1.2 million pounds of the herbicide were applied to between 1.3 and 1.7 million acres of corn, and 2.2 to 2.4 million pounds of the herbicide were applied to between 2.6 and 4.8 million

¹⁰ Nat'l Pesticide Info. Ctr., Glyphosate Technical Fact Sheet 1, *available at* <http://npic.orst.edu/factsheets/glyphotech.pdf>.

¹¹ 2009 Glyphosate Final Work Plan, *supra* note 1, at 2.

¹² See J.M. Pleasants & K.S. Oberhauser, *Milkweed Loss in Agricultural Fields Because of Herbicide Use: Effects on the Monarch Butterfly Population*, *Insect Conservation and Diversity* 1, 2 (2012).

¹³ Special Review and Reregistration Div., Office of Pesticide Programs, U.S. EPA, Reregistration Eligibility Decision Document: Glyphosate 9 (1993) [hereinafter 1993 Glyphosate R.E.D.].

acres of soybeans.¹⁴ In deciding to reregister glyphosate in 1993, EPA assumed that the pesticide was used in accordance with these estimates.¹⁵

Following the reregistration of glyphosate in 1993, however, genetically-modified, glyphosate-resistant crops were introduced in American agriculture. Glyphosate-resistant soybeans first appeared in 1996,¹⁶ followed by glyphosate-resistant corn in 1998.¹⁷ By 1999, glyphosate-resistant soybeans comprised the majority of all soybean crops.¹⁸ The ascendancy of glyphosate-resistant crops is reflected in data from the corn-soy belt; by 2006, for example, 75% of farmers in Iowa reported planting continuous glyphosate-resistant crops.¹⁹ By 2011, 94% of all soybean crops, and 72% of all corn crops, were glyphosate-resistant.²⁰

The proliferation of glyphosate-resistant crops facilitated a dramatic expansion in glyphosate use.²¹ In a screening level usage analysis based only on reported numbers, EPA estimated that, in an average year between 2004 and 2011, 95% of all soybean crops and 60% of all corn crops were treated with glyphosate; this required 86.4 million pounds of glyphosate for

¹⁴ *Id.* at 7-8.

¹⁵ *See id.* at 8-9.

¹⁶ G.M. Dill, et al., *Glyphosate-resistant Crops: Adoption, Use and Future Considerations*, 64 *Pest Mgmt. Sci.* 326, 326 (2008).

¹⁷ Pleasants & Oberhauser, *supra* note 12, at 2.

¹⁸ R.G. Hartzler, *Reduction in Common Milkweed (Asclepias Syriaca) Occurrence in Iowa Cropland from 1999 to 2009*, 29 *Crop Protection* 1542, 1542 (2010).

¹⁹ *Id.*

²⁰ Pleasants & Oberhauser, *supra* note 12, at 2.

²¹ *See* Pleasants & Oberhauser, *supra* note 12, at 1-2; Ctr. for Food Safety, Comments to EPA on Opening of Glyphosate Docket for Registration Review 2-8 (Sept. 21, 2009) [hereinafter 2009 Ctr. for Food Safety Comments].

soybeans annually and 54.6 million pounds of glyphosate for corn annually.²² Between 2008 and 2009, approximately 182 million pounds of glyphosate²³ were applied to over 261 million acres²⁴—a more than ten-fold increase from the amounts and acreage underlying EPA’s decision to reregister glyphosate in 1993.

In 2009, EPA initiated a registration review for glyphosate.²⁵ Extensive public comment submitted to the agency identified “profound changes in the usage patterns” of glyphosate, driven in part by the “widespread adoption of transgenic, glyphosate-resistant” crops.²⁶ EPA affirmed its “aware[ness] of the tremendous growth in the use of glyphosate since it was reregistered, and its relationship with the development of herbicide tolerant crops.”²⁷ The agency moreover recognized that “[a]ccurate estimates of current use patterns will indeed be important

²² Memorandum (EPA Updated Screening Level Usage Analysis (SLUA) Report in Support of Registration Review of Glyphosate) from Sepehr Haddad, Env’tl. Prot. Specialist, Bio. and Econ. Analysis Div., EPA, to Carissa Cyran, Chem. Review Manager, Pesticide Re-Evaluation Div., EPA (Dec. 6, 2012).

²³ 2009 Ctr. for Food Safety Comments, *supra* note 21, at 4 (converting EPA’s estimate of 135 million pounds of glyphosate in acid equivalent form to 182 million pounds of glyphosate in isopropylamine salt form, the most common form of glyphosate as an active ingredient).

²⁴ Am. Farm Bur. Fed’n, Comments to EPA in Support of Reregistration of Glyphosate 1 (Sept. 17, 2009).

²⁵ Registration Review; Glyphosate Docket Opened for Review and Comment, 74 Fed. Reg. 36,217 (July 22, 2009).

²⁶ 2009 Ctr. for Food Safety Comments, *supra* note 21, at 1, 3.

²⁷ Memorandum (BEAD Responses to Selected Glyphosate Comments) from Derek Berwald, Economist, Bio. and Econ. Analysis Div., EPA, to Jude Andreasen, Chemical Review Manager, Pesticide Re-Evaluation Div., EPA 5 (Dec. 16, 2009).

for evaluating the . . . environmental effects of glyphosate.”²⁸ EPA’s registration review for glyphosate is scheduled for completion in 2015.²⁹

2. Increased Use of Glyphosate Has Contributed to Monarch Population Decline

The expanded use of glyphosate has contributed to a sharp decrease in monarch population levels through the herbicide’s large-scale suppression of milkweed. Milkweed is a perennial plant in the *Asclepiadaceae* family, and common milkweed is native to North-Central and Northeastern United States.³⁰ Members of this plant family constitute the sole food source for monarch larvae.³¹ Stable isotope analysis has revealed that 50% of the North American monarch population that overwinters in Mexico fed on milkweed in the Midwestern United States during their lifecycle.³²

Glyphosate is applied in part to control milkweed.³³ Because glyphosate is also detrimental to crops, however, its use was not widespread until the creation and approval of glyphosate-resistant crops.³⁴ The rapid replacement of traditional crop strains with glyphosate-

²⁸ *Id.*

²⁹ 2009 Glyphosate Final Work Plan, *supra* note 1, at 4.

³⁰ R.G. Hartzler & D.D. Buhler, Occurrence of Common Milkweed (*Asclepias syriaca*) in Cropland and Adjacent Areas, 19 Crop Protection 363, 363 (2000).

³¹ *Id.*

³² L.I. Wassenaar & K.A. Hobson, *Natal Origins of Migratory Monarch Butterflies at Wintering Colonies in Mexico: New Isotopic Evidence*, 95 Proc. Nat’l Acad. Sci. U.S. 15436, 15439 (1998).

³³ See Pleasants & Oberhauser, *supra* note 12, at 2; W.A. Pline et al., *Weed and Herbicide-resistant Soybean (Glycine max) Response to Glufosinate and Glyphosate Plus Ammonium Sulfate and Pelargonic Acid*, 14 Weed Tech. 667, 667 (2000).

³⁴ See *supra* Section III.A.

resistant strains substantially accelerated an increase in the use of glyphosate, contributing to a significant decline in milkweed communities.³⁵ Prior to the widespread adoption of glyphosate-resistant crops, for example, a 1999 survey of croplands in Iowa found that approximately 50% of all corn and soybean fields contained common milkweed.³⁶ By 2009, milkweed was found in only 8% of surveyed fields.³⁷ Additionally, the area occupied by common milkweed in these fields was reduced by 90%.³⁸ Since 1996, the adoption of herbicide-resistant corn and soybeans has contributed to approximately 150 million acres of habitat loss for monarchs; this loss is likely to increase as uncultivated lands are increasingly converted into cropland planted with glyphosate-resistant crops.³⁹

There has been a pronounced loss of both agricultural and non-agricultural habitat for monarchs since the adoption of glyphosate-resistant crops.⁴⁰ Agricultural milkweed has disappeared at a faster rate, however, and its loss is particularly detrimental to monarchs.⁴¹ Studies have shown that monarchs in the Midwest preferentially use milkweed in agricultural

³⁵ *See id.*

³⁶ Hartzler, *supra* note 18, at 1542.

³⁷ *Id.*

³⁸ *Id.*

³⁹ *See* Chip Taylor, *Monarch Population Status*, MonarchWatch.org (Jan. 29, 2014, 12:10 PM), <http://monarchwatch.org/blog/2014/01/monarch-population-status-20/>; *see also* Scott Faber et al., *Plowed Under: How Crop Subsidies Contribute to Massive Habitat Losses* 8 (2012), available at http://static.ewg.org/pdf/plowed_under.pdf (documenting numbers of acres of grasslands, wetlands, and shrub lands converted to corn and soybean farmland between 2008 and 2011).

⁴⁰ *See* Pleasants & Oberhauser, *supra* note 12, at 3-5.

⁴¹ *See id.* at 3-6

habitat versus non-agricultural habitat, with soy and corn fields producing over 70 times more monarchs than non-agricultural habitats in Iowa, Minnesota, and Wisconsin.⁴² This pattern of monarchs preferring agricultural over non-agricultural sites was recently confirmed by Pleasants and Oberhauser in 2012.⁴³

The disappearance of milkweed along monarch migratory paths has had a significant impact on monarch production.⁴⁴ Adult females must now travel further and expend more energy to find milkweed plants on which to lay their eggs.⁴⁵ With depleted body fat, the butterflies lay fewer eggs and face a heightened risk of dying before having the chance to reproduce.⁴⁶ Over the period marked by increased glyphosate-use and planting of glyphosate-resistant corn and soy, Pleasants and Oberhauser examined monarch production in the Midwest as measured by the number of eggs and larvae on milkweed.⁴⁷ They found a 58% decline in milkweed across the Midwest landscape and an 81% decrease in monarch production in the Midwest from 1999 to 2010.⁴⁸ During this time, there was also a 65% decrease in the size of the entire monarch population overwintering in Mexico.⁴⁹

⁴² See K.S. Oberhauser et al., *Temporal and Spatial Overlap Between Monarch Larvae and Corn Pollen*, 98 Proc. Nat'l Acad. Sci. U.S. 11913, 11917 (2001).

⁴³ Pleasants & Oberhauser, *supra* note 12, at 8.

⁴⁴ See *id.* at 1-10; see also Ctr. for Food Safety, *Correlation Between Glyphosate Use and Monarch Migration Routes and Breeding*, <http://www.centerforfoodsafety.org/issues/304/pollinators-and-pesticides/map-of-monarch-migration-breeding-and-glyphosate-use#> (last visited June 30, 2014).

⁴⁵ Wines, *supra* note 7.

⁴⁶ *Id.*

⁴⁷ See Pleasants & Oberhauser, *supra* note 12, at 1.

⁴⁸ See *id.*

According to a survey of this population, taken this past winter, the area inhabited by overwintering monarchs has shrunk to an all-time low: a mere 1.65 acres, the equivalent of about one-and-a-quarter football fields.⁵⁰ Not only was this a record low, but it was only 56% percent of last year's acreage, which was itself a record low.⁵¹ The area of winter habitat occupied by monarchs, which has been surveyed annually since 1993, provides a proxy for the number of butterflies that survive the arduous, 2,500-plus-mile journey between Canada and Mexico.⁵² This past winter's survey reflected a remaining population of only about 33.5 million butterflies—down from a long-term average annual count of approximately 350 million individuals over the last 15 years.⁵³

The migrating monarch population has so diminished that its prospects for recovering to levels observed even five years ago are fading.⁵⁴ With fewer individuals, the population may be increasingly vulnerable to stressors such as climate change, extreme weather events, and

⁴⁹ *Id.* at 8; see also L.P. Brower et al., *Decline of Monarch Butterflies Overwintering in Mexico: Is the Migratory Phenomenon at Risk?*, *Insect Conservation and Diversity*, at 1 (2011).

⁵⁰ Wines, *supra* note 7; see E. Rendón-Salinas & G. Tavera-Alosno, *Monitoreo de la Superficie Forestal Ocupada por las Colonias de Hibernación de la Mariposa Monarca en Diciembre de 2013*, at 1, http://awsassets.panda.org/downloads/monitoreo_mariposa_monarca_en_mexico_2013_2014.pdf (last visited June 30, 2014); World Wildlife Fed'n, *La Migración de la Mariposa Monarca en Riesgo de Desaparecer*, WWF Mexico (June 30, 2014), <http://www.wwf.org.mx/?214870/La-migracin-de-la-mariposa-Monarca-en-riesgo-de-desaparecer>.

⁵¹ Wines, *supra* note 7.

⁵² *Id.*

⁵³ Fallon, *supra* note 7.

⁵⁴ Wines, *supra* note 7.

deforestation.⁵⁵ The potential approval of new herbicide-resistant crops,⁵⁶ which may facilitate substantial increased use of other herbicides that further eliminate milkweed, poses an additional threat to monarchs. In the face of steep, continuing population decline, the phenomenon of monarch migration is at risk of disappearing.⁵⁷

3. EPA Must Consider Whether Use of Glyphosate on Enlist Corn and Soybeans Will Cause Any Unreasonable Adverse Effects on the Environment

“EPA may not register . . . a pesticide if it determines that the pesticide would cause ‘unreasonable adverse effects on the environment.’” *Natural Resources Def. Council v. EPA*, 658 F.3d 200, 202 (2d Cir. 2011) (quoting 7 U.S.C. § 136a(c)(5)(C)). In its proposed registration decision for Enlist Duo, EPA stated that “no new use pattern and no new exposures for glyphosate are being considered.” EPA, Proposed Registration of Enlist Duo Herbicide 1. On this basis, the agency concluded that “a new assessment for the application of glyphosate to Enlist crops [i.e., GE corn and soybeans] does not require a new human health or environmental risk assessment.” *Id.* at 24-25.

EPA’s rationale for declining to conduct new risk assessments for Enlist Duo cannot be justified for two reasons. First, use of glyphosate on Enlist corn and soy *is* a new use for products containing glyphosate. Second, even if use on Enlist corn and soybean were not a new use for glyphosate, EPA has never before considered adverse impacts to monarchs in making

⁵⁵ Pleasants & Oberhauser, *supra* note 12, at 9; Wines, *supra* note 7.

⁵⁶ See Animal Plant and Health Inspection Serv. (APHIS), USDA, *Petitions for Determination of Nonregulated Status*, http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml#not_reg (last visited June 30, 2014) (listing genetically modified crops, including those with tolerance to various herbicides, for which petitions for determination of nonregulated status have been filed).

⁵⁷ Wines, *supra* note 7.

registration decisions for pesticides containing glyphosate. Accordingly, the agency must consider those impacts now.

a. Use of glyphosate on Enlist corn and soybean constitutes a “new use.”

Contrary to EPA’s determination in its proposed registration for Enlist Duo, use of glyphosate on Enlist corn and soybean qualifies as a “new use” within the meaning of FIFRA regulations. Pursuant to those regulations, a “new use” includes, among other things, “[a]ny aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern” and “[a]ny additional use pattern that would result in a significant increase in the level of exposure . . . to the active ingredient of man or other organisms.” 40 C.F.R. § 152.3(2), (3). Use of a pesticide on a crop constitutes a “new use” if the active ingredients in the pesticide have not previously been registered for use on that crop. *See* EPA, Pesticide Registration Manual: Chapter 6 – Amending a Registered Pesticide Product, available at <http://www.epa.gov/pesticides/bluebook/chapter6.html#amending>.

Glyphosate was last reregistered in 1993—several years before the advent of glyphosate-resistant GE corn and soy. Because EPA has never registered glyphosate for use on glyphosate-resistant corn and soy, use on these crops constitutes a “new use” for the pesticide. The agency’s conclusion that “no new use pattern and no new exposures for glyphosate are being considered,” EPA, Proposed Registration of Enlist Duo™ Herbicide 1, is incorrect. Although glyphosate has been registered for use on *non-GE* corn, it has never been registered for use on *glyphosate-resistant* corn, which constitutes a distinct crop. *Cf., e.g.*, Proposed Section 3 Label for Enlist Duo 11, <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2014-0195-0008> (providing separate sprayer clean-out instructions with respect to “glyphosate-tolerant corn” and “all other crops”). EPA’s conclusion that no new use pattern is at issue is based on the faulty assumption

that the use of an herbicide on an herbicide-tolerant crop does not constitute a “new use” within the meaning of FIFRA if that herbicide has already been registered for use on a non-GE variant of that crop.

This assumption is contrary to the FIFRA regulations, which define a “new use” to include “[a]ny additional use pattern that would result in a significant increase in the level of exposure . . . to the active ingredient of man or other organisms.” 40 C.F.R. § 152.3(2), (3). The application of glyphosate to glyphosate-resistant corn and soy over the past fifteen years has contributed to a dramatic increase in glyphosate use over this same period, leading to increased exposure among humans and other organisms. EPA has affirmed its “aware[ness] of the tremendous growth in the use of glyphosate since it was reregistered, and its relationship with the development of herbicide tolerant crops.” Berwald, *supra*, at 5. The agency has moreover recognized that “[a]ccurate estimates of current use patterns will indeed be important for evaluating the . . . environmental effects of glyphosate.” *Id.*

USDA has likewise acknowledged that use of an herbicide will increase significantly if the herbicide is approved for use on crops resistant to that herbicide. The agency has predicted, for example, that “[d]eregulation of Enlist™ crops and approval of use of 2,4-D on those crops will cause growers to change management practices; namely 2,4-D use is expected to increase beyond the increase expected without these crops. Furthermore, 2,4-D use is expected to be used over a wider part of the growing season.” APHIS, Draft Environmental Impact Statement for Dow AgroSciences Petitions (09-233-01p, 09-349-01p, and 11-234-01p) for Determinations of Nonregulated Status for 2,4-D-Resistant Corn and Soybean Varieties (2013). To illustrate the magnitude of such an increase, APHIS estimated that 2,4-D use would rise by only 75% by 2020 if the agency did not deregulate Enlist corn and soybean; in comparison, it projected, “If EPA

registers Enlist Duo™ herbicide for Enlist™ corn and soybean and APHIS [deregulates those GE crops], APHIS expects that 2,4-D use will further increase by another two fold to six fold . . . relative to current use.” *Id.*

EPA’s approval of Enlist Duo for use on Enlist corn and soybean would, similarly, increase the quantities of glyphosate used to levels far beyond what they would otherwise reach. Accordingly, the agency must consider whether registration of Enlist Duo for use on GE corn and soybean would substantially increase the risk of any unreasonable adverse environmental impacts—including impacts on monarchs and their habitat from increased glyphosate use.

b. EPA must consider the incremental risk that the proposed registration poses to monarchs.

Even if use of Enlist-Duo on Enlist corn and soybean does not constitute a “new use,” 40 C.F.R. § 152.3, EPA is still required to consider the impacts of this use on monarch butterflies. Before registering a pesticide, the agency must determine that, when used “in accordance with widespread and commonly recognized practice,” 7 U.S.C. § 136a(c)(5)(D), the pesticide will not generally cause “*any* unreasonable risk to . . . the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide,” *id.* § 136(bb) (emphasis added).

Under the FIFRA regulations, EPA may not conditionally register a pesticide unless (among other requirements) the agency possesses, “at a minimum, data needed to characterize *any incremental risk* that would result from approval of the application.”⁵⁸ 40 C.F.R.

⁵⁸ Enlist Duo would not, in any event, be eligible for conditional registration. FIFRA authorizes EPA to conditionally approve a pesticide only if the agency determines that “the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof.” 7 U.S.C. § 136a(c)(7)(A). Enlist Duo is not substantially similar to “any currently registered pesticide,” insofar as no other “currently registered pesticide” contains *both* 2,4-D and glyphosate as active ingredients. EPA’s disaggregated treatment of 2,4-D and

§ 152.113(a) (emphasis added). Insofar as the data requirements for conditional registration are necessary, but not sufficient, for unconditional registration, lack of information on the “incremental risk that would result from approval of [an] application,” *id.*, likewise precludes EPA from unconditionally approving that application.

Since EPA last reregistered glyphosate in 1993, new information has emerged demonstrating significant adverse effects on monarchs from increased use of glyphosate. The agency has yet to consider these impacts in registering pesticide products containing glyphosate. Accordingly, EPA cannot rest on its previous registration analyses for glyphosate-containing products to conclude that registration of Enlist Duo will not generally cause an unreasonable risk to the environment. Instead, the agency must now consider the substantial and mounting evidence that increased use of glyphosate—which would follow from registration of Enlist Duo—will have significant adverse effects on monarchs and their habitat.

B. EPA CANNOT MAKE A FINAL REGISTRATION DECISION FOR ENLIST DUO UNTIL THE GLYPHOSATE REVIEW PROCESS IS COMPLETE

Glyphosate was the most commonly used herbicide in the United States in 2007⁵⁹ (latest data available), with nearly 225 million pounds used on agricultural crops in 2011⁶⁰. In the 21 years since the glyphosate RED was completed, considerable research has been undertaken that provides a greatly increased basis for concern about this chemical’s health impacts. Over 3,000 studies have been published in peer-reviewed journals, with increasing evidence suggesting

glyphosate impermissibly omits from consideration during FIFRA risk assessment any synergistic effects of the two ingredients.

⁵⁹ Grube A, Donaldson, Kiely T, Wu L. Pesticide industry sales and usage: 2006 and 2007 market estimates. Bio. and Econ. Div., Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, U.S. EPA. February 2011. Table 3.6. (http://www.epa.gov/opp00001/pestsales/07pestsales/market_estimates2007.pdf; last visited June 24, 2014)

⁶⁰ Stone WW. Estimated annual agricultural pesticide use for counties of the conterminous United States, 1992–2009: U.S. Geological Survey Data Series 752, 2013. Table 4.

increased kidney toxicity⁶¹, pre-term deliveries, miscarriages, attention deficit hyperactivity disorder, neural tube defects, and other birth defects as potential adverse health impacts of glyphosate usage⁶². Given that EPA is currently in the process of reviewing glyphosate's registration⁶³, and given the prolific increase in publications since 1993, NRDC anticipates that the preliminary risk assessment for glyphosate will have relevance for the Enlist Duo registration. EPA cannot make a final registration decision for Enlist Duo until it has completed its review of glyphosate and the public has had a chance to review it.

C. EPA MUST PROPERLY ANALYZE THE HEALTH EFFECTS OF 2,4-D

1. EPA must set reference doses (RfDs) or population adjusted doses (PADs) for 2,4-D that are adequately protective of sensitive developmental endpoints (e.g, brain development) and of human health

In order to be protective of infants, children, and pregnant women, EPA must use, at a minimum, a developmental Lowest Observed Adverse Effect Level (LOAEL) of 5 mg/kg/day with a 10X uncertainty factor as the point of departure for dietary exposure of sensitive populations. EPA itself has stated that “[i]f a LOAEL is used, another uncertainty factor, generally 10x, is also used”⁶⁴. EPA's current point of departure, 25 mg/kg/day, is not adequately protective against thyroid toxicity and population health.

⁶¹ Jayasumana C, Gunatilake S, Senanayake P. Glyphosate, Hard Water and Nephrotoxic Metals: Are They the Culprits Behind the Epidemic of Chronic Kidney Disease of Unknown Etiology in Sri Lanka? *Int J Environ Res Public Health*. 2014;11(2):2125-2147. doi:10.3390/ijerph110202125.

⁶² Antoniou M, Habib MEM, Howard CV, et al. Teratogenic Effects of Glyphosate-Based Herbicides: Divergence of Regulatory Decisions from Scientific Evidence. *J Environ Anal Toxicol*. 2012, S4:006. doi:10.4172/2161-0525.S4-006; and Garry VF, Schreinemachers D, Harkins ME, Griffith J. Pesticide applicators, biocides, and birth defects in rural Minnesota. *Environ Health Perspect*. 1996;104(4):394-399. doi:10.2307/3432683.

⁶³ EPA docket number: EPA-HQ-OPP-2009-0361

⁶⁴ http://www.epa.gov/risk_assessment/dose-response.htm; last visited June 23, 2014.

This additional 10x uncertainty factor applied to the LOAEL is *separate from, and in addition to*, the additional 10x children's uncertainty factor discussed below that is presumptively required to ensure that pesticide tolerances are protective of children under the Food Quality Protection Act (FQPA), 21 U.S.C. § 346a(b)(2)(C)(ii). An adequately protective Population Adjusted Dose of 0.0005 mg/kg/day [with a 10X LOAEL to NOAEL conversion, a 10X uncertainty factor for animal to human extrapolation (interspecies), 10X difference between people (intraspecies), and 10X juveniles being more sensitive than adults (FQPA)] is recommended.

a. EPA Incorrectly Evaluated and Dismissed Evidence of Thyroid Toxicity and Other Endocrine Effects.

NRDC is gravely concerned that EPA uses NOAELs that inadequately account for thyroid toxicity. In the assessment, EPA uses a developmental NOAEL of 25 mg/kg/day for acute dietary exposures in women of reproductive age and a NOAEL of 21 mg/kg/day for chronic dietary exposures for all populations. These levels do not adequately take into account thyroid toxicity made clear in the studies within the Agency's own record of adverse effects to the thyroid in adult and young animals. In particular, ample evidence for thyroid effects are clear from the Extended One Generation Reproductive Toxicity rat study⁶⁵, the 90-day oral toxicity study in dogs⁶⁶, a combined chronic toxicity/carcinogenicity study in rats⁶⁷, and the chronic

⁶⁵ U.S. EPA. 2,4-D: Review of Extended 1-Generation Reproduction Study and Dose-Range Finding and Pharmacokinetic Titration Studies. 2010. EPA data evaluation record MRID:47972101

⁶⁶ U.S. EPA. Data Evaluation Report on Subchronic Toxicity in Dogs with 2,4-Dichlorophenoxyacetic acid. 1990. Data evaluation record MRID: 41737301

⁶⁷ Jeffries, TK, Yano, BL, Ormand, JR and Battjes, JE. "2,4-Dichlorophenoxyacetic Acid: Chronic Toxicity/Oncogenicity Study In Fischer 344 Rats-Final" The Toxicology Research Laboratory, Dow Chemical Co., Midland, Michigan. Study ID: K-002372-064. 3/28/95. MRID No. 43612001

toxicity/carcinogenicity study with a chronic neurotoxicity screening battery substudy⁶⁸. The thyroid is particularly important for the proper neurodevelopment of developing fetuses, infants, and children, therefore we recommend a significantly lower RfD, aPAD, and cPAD for all sensitive populations.

Thyroid hormones are important for a myriad of bodily functions, including metabolism, proper maintenance of body temperature, differentiation of cell types within the body, and fetal and postnatal brain development. Chemicals that alter the tightly controlled thyroid system can cause devastating and irreversible changes during sensitive life stages, as EPA's own Science Advisory Board has noted.⁶⁹ The SAB's finding that "hypothyroxinemia (i.e., low levels of thyroid hormone) is a more appropriate indicator of the potential adverse health effects than the more pronounced decreases in thyroid hormone associated with hypothyroidism"⁷⁰, suggests that even small changes in thyroid hormone levels (e.g., those resulting in sub-clinical thyroid disease) in the mother should be considered adverse for the developing brain of her fetus. In its evaluation of the Extended One Generation Reproductive Toxicity (EOGRT) study, EPA notes in its data evaluation record⁷¹ that both offspring and dams exhibit low levels of the thyroid hormones T4 and T3 after exposure to 2,4-D, and increased levels of thyroid stimulating hormone (TSH) – all signs of thyroid toxicity.

⁶⁸ Mattsson J, Jeffries T, Yano B (1994b). 2,4-Dichlorophenoxyacetic acid: Chronic neurotoxicity study in Fischer 344 rats. Lab Project Number K-002372-064N, K-002372-064. Unpublished study prepared by The Dow Chemical Co. 1091 p. MRID: 43293901

⁶⁹ EPA Science Advisory Board, SAB Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate, 2013. See page 2 [http://yosemite.epa.gov/sab/sabproduct.nsf/0/86E44EE7F27EEC1A85257B7B0060F364/\\$File/EPA-SAB-13-004-unsigned2.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/0/86E44EE7F27EEC1A85257B7B0060F364/$File/EPA-SAB-13-004-unsigned2.pdf).

⁷⁰ *Id.*

⁷¹ U.S. EPA. 2,4-D: Review of Extended 1-Generation Reproduction Study and Dose-Range Finding and Pharmacokinetic Titration Studies. 2010. EPA data evaluation record MRID: 47972191.

There is ample evidence that 2,4-D is an endocrine disruptor. The adverse thyroid effects seen in the *in vivo* studies EPA cites, epidemiology studies showing increased hypothyroidism in farm workers exposed to 2,4-D⁷², decreased thyroid hormone (T4) production in zebrafish larva exposed to 2,4-D⁷³, along with the demonstrated ability of 2,4-D to bind to the thyroid receptor in *in vitro* experiments, indicate these effects. Tox21⁷⁴ data add to the weight of evidence, and add uncertainty to studies suggesting a lack of endocrine activity⁷⁵, by revealing that 2,4-D is active in the thyroid receptor antagonist assay (as well as in the estrogen, androgen, and arylhydrocarbon receptor assays)⁷⁶. EPA is thus not justified in dismissing evidence of thyroid toxicity in its hazard evaluation.

Furthermore, EPA has improperly considered the levels at which these thyroid effects can occur. Specifically, the EOGRT study shows thyroid effects at multiple doses:

Table 1. Thyroid Hormone- GD 17 Satellite Females				
Parameter	0 ppm	100 ppm	300 ppm	600 ppm
Females				
N=	11	10	10	12
T3 (ng/dL)	73.12±14.17	71.69±11.42	69.64±10.67 ↓5%	68.12±19.04 ↓7%
Range	52.83-95.78	53.99-93.33	47.94-89.35	35.95-104.12
T4 (µg/dL)	1.26±0.28	1.22±0.43	1.16±0.64 ↓8%	1.15±0.42 ↓9%
Range	0.82-1.66	0.77-1.42	0.46-2.17	0.61-1.87
TSH(ng/mL)	2.92±1.56	2.76±0.84	2.60±1.37	3.65±1.59 ↑25%

⁷² Goldner WS, Sandler DP, Yu F, et al. Hypothyroidism and Pesticide Use Among Male Private Pesticide Applicators in the Agricultural Health Study. *Journal of Occupational and Environmental Medicine*. 2013;55(10):1171-1178. doi:10.1097/JOM.0b013e31829b290b.

⁷³ Raldua D, Babin PJ. Simple, Rapid Zebrafish Larva Bioassay for Assessing the Potential of Chemical Pollutants and Drugs to Disrupt Thyroid Gland Function. *Environmental Science & Technology*. 2009;43(17):6844-6850. doi:10.1021/es9012454.

⁷⁴ A multi-agency collaborative (including EPA) aimed at investigating the use of cost effective, high-throughput, *in vitro* technologies to screen and predict the toxicity of large numbers of untested chemicals (<http://www.epa.gov/ncct/Tox21/>; last visited June 15, 2014)

⁷⁵ Coady KK, Lynn Kan H, Schisler MR, et al. Evaluation of potential endocrine activity of 2,4-dichlorophenoxyacetic acid using in vitro assays. *Toxicology in vitro : an international journal published in association with BIBRA*. 2014;28(5):1018-25. doi:10.1016/j.tiv.2014.04.006.

⁷⁶ Data accessed via <http://actor.epa.gov/dashboard/>

range	1.03-5.62	1.47-4.02	1.17-3.45 (6.01) ^A	1.25-6.23 ^B
#>4	2	1	1 ^A	5
Data from Table 59, page 305 of study report; ^A identified as outlier in report; ^B not identified as outlier in report. (Data Evaluation Record MRID: 43293901; Table 21, page 42-3)				
Table 2. Thyroid Hormone – F1 PND 4 (culled) pups				
Parameter	0 ppm	100 ppm	300 ppm	600/800 ppm
Males				
T3 (ng/dL)	34.51±5.83 (9)	35.90±5.99 (8)	35.46±7.07 (8)	32.19±8.17 ↓7%
T4 (µg/dL)	0.64±0.25	0.62±0.32 (8)	0.55±0.21 ↓14%	0.56±0.19 ↓12%
TSH(ng/mL)	1.12±0.31	0.98±0.26 (7)	1.06±0.27 (9)	1.09±0.20
Females				
T3 (ng/dL)	41.99±9.78	38.64±8.28 ↓8%	36.59±7.15 (6) ↓13%	40.29±8.06 (9)
T4 (µg/dL)	0.85±0.16	0.99±0.16	0.72±0.32 (9) ↓15%	0.73±0.23 ↓14%
TSH(ng/mL)	0.97±0.24	1.06±0.35 ↑9%	0.90±0.18 (9)	1.15±0.34 ↑19%
Data from Tables 73 and 74, pages 324 and 325 of report; n=10, unless () (Data reproduced from Data Evaluation Record MRID: 43293901 ; Table 31, page 48)				

Table 3. Thyroid Hormone – F1 PND 22 Weanlings				
Parameter	0 ppm	100 ppm	300 ppm	600/800 ppm
Males				
T3 (ng/dL)	107.22±16.59	100.82±12.88	86.56±9.16* ↓19%	93.46±15.06 ↓13%
T4 (µg/dL)	3.62±0.84	4.40±0.54	2.98±0.75	2.59±1.04* ↓28%
TSH(ng/mL)	1.32±0.24	1.25±0.59	1.48±0.73 ↑12%	1.27±0.37
Females				
T3 (ng/dL)	99.14±14.68	110.43±20.01	99.42±15.02	107.42±11.68
T4 (µg/dL)	3.57±0.75	3.99±1.19	3.55±0.77	2.85±0.66 ↓20%
TSH(ng/mL)	0.99±0.26	1.13±0.33	0.94±0.22	1.02±0.16
Data from Tables 75 and 76. Pages 326 and 327 of report; n=10; * α=0.05 Males not given adult dietary concentration until PND 35. (Data reproduced from Data Evaluation Record MRID: 43293901 ; Table 32, page 49)				

Table 4. Thyroid Hormone – F1 Set 1a Males (PND 62-64)				
parameter	0 ppm	100 ppm	300 ppm	600/800 ppm
Males				
T3 (ng/dL)	78.69±12.07	69.78±7.91	66.77±9.69	72.03±17.40
range	63.03-102.07	58.34-80.05	46.97-84.54	43.51-94.29
T4 (µg/dL)	4.75±0.92	4.46±1.23	5.31±1.09 ↑12%	4.11±0.85 ↓13%
Range	3.50-6.44	2.93-6.56	2.79-6.35	2.63-5.45
TSH(ng/mL)	2.95±0.74	3.21±1.29	3.72±0.97 ↑26%	3.62±1.20 ↑23%

Range	2.12-3.42 (4.73) ^A	1.91-5.66	2.77-5.26	2.11-5.77
Females				
T3 (ng/dL)	67.08±17.71	66.89±10.71	70.45±12.99	74.28±14.67
Range	51.49-81.31 (109.79) ^A	46.65-79.02	57.25-96.84	↑11% 58.13-100.28
T4 (µg/dL)	2.35±±1.05	2.27±0.85	2.80±1.43 ↑19%	2.79±1.08 ↑19%
Range	1.00-4.72	0.99-3.36	1.54-5.65	1.29-5.03
TSH(ng/mL)	1.89±0.53	2.05±0.61	2.10±0.42 ↑11%	2.34±0.67 ↑24%
Range	0.93-2.60	1.24-3.00	1.84-2.46 (1.03) ^A	1.66-2.41 (4.15) ^A
Data from Tables 77 and 78, pages 328 and 329 of report; n=10; ^A outlier (Data reproduced from Data Evaluation Record MRID: 43293901 ; Table 33, page 50)				

Despite ample evidence showing significant, and in some cases sustained, changes in thyroid hormone production at 2,4-D dose levels as low as 100 ppm, EPA incorrectly selected 600/800 ppm as a NOAEL and inappropriately ignored thyroid effects.

NRDC has two concerns about this determination. First, a NOAEL of 600/800 ppm cannot be justified because thyroid effects occurred at lower levels. Second, thyroid effects are reported at the lowest dose tested, 100 ppm (5 mg/kg/day). Thus, the 100 ppm dose can be used appropriately only to develop a LOAEL.

EPA selected the highest dose, 600/800 ppm, as its point of departure by dismissing observed thyroid effects at lower levels as adaptive rather than adverse. Such a determination is flawed because it relies too heavily on a traditional monotonic dose-response relationship paradigm (e.g., the dose makes the poison and dose-response curves must be monotonic) to define the association between 2,4-D exposure and thyroid outcomes⁷⁷. Current scientific understanding of hormone disrupting chemicals do not support this rationale and suggest, instead, that EPA should consider the possibility that 2,4-D dose-response curves are nonmonotonic. The National Academies of Sciences in its *Review of the Environmental*

⁷⁷ U.S. EPA. 2,4-D: Review of Extended 1-Generation Reproduction Study and Dose-Range Finding and Pharmacokinetic Titration Studies. 2010. EPA data evaluation record MRID: 47972191 at 6.

*Protection Agency's State-of-the-Science Evaluation of Nonmonotonic Dose-Response Relationships as they Apply to Endocrine Disruptors*⁷⁸ wrote that EPA should use caution with concepts like adaptation because “effects that are adaptive in some people are adverse in others”⁷⁹. The NAS additionally notes that, “consideration should be given to potential windows of susceptibility (for example, during fetal development), sensitive populations (for example, those with pre-existing health conditions), and other factors (such as multiple chemical exposures) in making these [adaptive versus non-adaptive] distinctions.”⁸⁰ EPA’s blatant disregard for the current scientific understanding of dose-response in endocrine disruption leads it to a wholly insufficient point of departure for 2,4-D.

On the basis of this evidence, EPA must use, at a minimum, the more protective 100 ppm (5 mg/kg/day) and 10X uncertainty factor for LOAEL to NOAEL extrapolation as the Point of Departure. To calculate the Population Adjusted Dose (PAD), the PoD should be adjusted further with the standard 10X for animal to human extrapolation (interspecies), 10X for differences between people (intraspecies), and 10X for juveniles being more sensitive than adults (FQPA)⁸¹.

b. EPA’s Exposure Estimates Are Insufficient To Protect Sensitive Populations.

In addition to underestimating the toxicity of 2,4-D, EPA has underestimated the higher frequencies of exposure that will occur with expanded use in this new formulation, as well as important potential exposure pathways. These flawed exposure estimates, combined with RfDs

⁷⁸*Review of the Environmental Protection Agency's State-of-the-Science Evaluation of Nonmonotonic Dose-Response Relationships as They Apply to Endocrine Disruptors*. The National Academies Press; 2014. Available at: http://www.nap.edu/openbook.php?record_id=18608.

⁷⁹ *Id.* at 7.

⁸⁰ *Id.*

⁸¹ U.S. EPA. 2,4-D. Human Health Risk Assessment for a Proposed Use of 2,4-D Choline on Herbicide-Tolerant Corn and Soybean. 2013. See Table 4.5.4.1, p. 18.

and PADs that are not sufficiently protective, leave pregnant women, fetuses, infants, and children particularly vulnerable to 2,4-D's toxic effects.

1. EPA's dietary risk assessments do not adequately capture all reasonable exposure risks.

In its calculation of acute and chronic dietary risk estimates, EPA did not clearly articulate the assumptions made in calculating exposures for various sub-populations. We are especially concerned that EPA labels both the acute and chronic dietary assessments "unrefined"⁸², which appear to be rough estimates that may be inaccurate given a lack of data on key variables such as anticipated residues. EPA's proposal is insufficiently transparent to determine the nature and extent of data gaps leading to its "unrefined" estimate, and it is thus impossible for NRDC, or other members of the public, to determine whether the resulting proposal adequately protects human health.

2. EPA does not properly consider drinking water exposure.

EPA states in the *Environmental Fate and Effects Division's Risk Assessment for the Reregistration Eligibility Document for 2,4-Dichlorophenoxyacetic Acid*⁸³, that EPA SCIGROW groundwater models do not accurately predict maximum concentrations of 2,4-D in groundwater. Also, by its own admission, EPA's use of the maximum monitored National Water Quality Assessment (NAWQA) concentration in the proposal is also likely to be an underestimate because the USGS and EPA monitoring data come from "non-targeted" sampling areas. EPA specifically states:

"EFED has determined that the available monitoring data is non-targeted to 2,4-D use because it was not collected with the intention of capturing maximum acute and chronic

⁸² *Id.* at 25 (acute) and 26 (chronic)

⁸³ U.S. EPA. *Environmental Fate and Effects Division's Risk Assessment for the Reregistration Eligibility Document for 2,4-Dichlorophenoxyacetic Acid*. See page 52 (<http://www.epa.gov/espp/litstatus/effects/24d/attachment-b.pdf>; last visited June 25, 2014)

2,4-D concentrations. Targeted monitoring data should be collected with a sampling frequency designed to capture peak runoff events coinciding with a specific pesticide use, with a duration designed to provide sufficient data to estimate long term exposures, and be specifically tailored to the individual geography and crop uses of the target pesticide. The monitoring data used in this assessment, while plentiful and of high quality, was not collected specifically with 2,4-D use in mind and is therefore considered to be non-targeted to 2,4-D use but was used in this assessment for comparison against model predictions.”⁸⁴

In fact, there is reason to believe that EPA’s selection of 15 ppb as a maximum value is flawed. Though the Agency dismissed its STORET monitoring data due to concerns about QA/QC that it did not describe, STORET monitoring has detected a peak groundwater concentration of 7500 µg ae/L⁸⁵, giving rise to additional uncertainty in the adequacy of EPA’s presumed groundwater concentrations. Moreover, as the EFED summary above indicates, water concentrations that would occur during peak runoff are likely to be far higher than detected using standard non-targeted monitoring, adding to the likely underestimate and additional uncertainty. The groundwater concentration of 15 ppb used by EPA for its dietary risk assessment is, therefore, likely to have missed higher concentrations that could be found in areas with high 2,4-D use.

These underestimates pose particular risk in the six states where EPA proposes to allow the use of this new herbicide because so much of them use groundwater for drinking water. In fact, 94% of all the public water systems in these six states (87% in Illinois, 97% in Indiana, 92% in Iowa, 94% in Ohio, 78% in South Dakota, and 99% in Wisconsin) rely on ground water as their primary source of water⁸⁶, and 11% of the groundwater withdrawals in the proposed states (9% in Illinois, 17% in Indiana, 5% in Iowa, 15% in Ohio, 3% in South Dakota, and 9% in

⁸⁴ *Id.* at 42

⁸⁵ *Id.*

⁸⁶ SDWISFED GPRA data (7/1/2012 to 6/30/2013); <http://water.epa.gov/scitech/datait/databases/drink/sdwisfed/pivottables.cfm>

Wisconsin) being made by domestic wells⁸⁷. Approximately 43 million people in the United States rely on domestic wells for their drinking water supply, making them an important vehicle for groundwater exposure⁸⁸.

EPA's surface water estimates also seem insufficiently protective, in that they are also based on models trained with non-targeted 2,4-D monitoring data. For surface water estimates, we are particularly concerned that the calculated estimates do not use corn growing conditions from one of the target states as a model input. The Tier II PRZM-EXAMS model the Agency uses for its acute exposure relies on corn grown under conditions found in Mississippi, which has different water content, soil loss, and dates of planting, emergence, and harvesting than corn grown in, for example, Illinois⁸⁹. Additionally, EFED surface water modeling revealed peak acute exposures of up to 4000 µg ae/L for some use scenarios and indicated that setback distances of up to 1500 feet were used in some calculations⁹⁰. Setback distances, or the distance a pesticide can be applied near a drinking water source, are specified on the pesticide label. EPA states that a 2,4-D Master Label was the source of its application assumptions⁹¹, but publically available copies of the Master Label do not include 2,4-D choline salt and the expanded⁹².

3. EPA does not clearly demonstrate that breast milk is adequately considered in dietary exposure for infants.

⁸⁷ Kenny, J.F., Barber, N.L., Hutson, S.S., Linsey, K.S., Lovelace, J.K., and Maupin, M.A., 2009, Estimated use of water in the United States in 2005: U.S. Geological Survey Circular 1344, Table 4A, p. 11; <http://pubs.usgs.gov/circ/1344/pdf/c1344.pdf>

⁸⁸ <http://www.usgs.gov/newsroom/article.asp?ID=2173#.U6OYTPlDWS0>

⁸⁹ see http://www.epa.gov/oppfed1/models/water/met_ms_corn.htm for MS corn and http://www.epa.gov/oppfed1/models/water/met_il_corn.htm for IL corn.

⁹⁰ U.S. EPA. Environmental Fate and Effects Division's Risk Assessment for the Reregistration Eligibility Document for 2,4-Dichlorophenoxyacetic Acid. See page 42 (<http://www.epa.gov/espp/litstatus/effects/24d/attachment-b.pdf>; accessed 06/25/2014)

⁹¹ *Id.* at 41.

⁹² <http://www.epa.gov/oppfed1/endorsement/litstatus/effects/redleg-frog/2-4-d/appendix-n.pdf>

In its human health risk assessment, EPA states that “toxicokinetic studies conducted in pregnant rats show that 2,4-D is transferred through maternal milk to the pups”⁹³, and has been shown to impact the nutritional content of the milk⁹⁴. Thus, maternal exposure to 2,4-D and subsequent transfer through breast milk may be a significant contributor to dietary 2,4-D exposure in infants. It is absolutely critical that EPA properly and adequately assess the levels of 2,4-D that could be passed to infants via both breast milk and formula (via water used to reconstitute formula and via the formula itself), and without transparent information to evaluate EPA assumptions, it is unclear that developing brains are sufficiently protected.

4. EPA has not appropriately accounted for the volatility of 2,4-D in its exposure risk calculations.

In its volatilization modeling and risk assessment evaluation of 2,4-D, EPA states that its field volatility study (i.e. its monitoring data) indicated that volatilization of 2,4-D from treated crops does occur and could result in bystander exposure to vapor phase 2,4-D⁹⁵. However, the Agency dismisses this data and relies upon modeling estimates derived from its Probabilistic Exposure and Risk model for FUMigants (PERFUM) instead. EPA’s modeling exercise indicates that airborne concentrations are “not of concern”⁹⁶.

It is not clear why EPA decided to reject monitoring data and use modeling estimates in its place. Again, the public is not provided adequate information to evaluate the Agency’s determination on this potentially critical exposure pathway. In fact, EPA sheds doubt on the

⁹³ U.S. EPA. 2,4-D. Human Health Risk Assessment for a Proposed Use of 2,4-D Choline on Herbicide-Tolerant Corn and Soybean. 2013. p.10.

⁹⁴ Sturtz N, Bongiovanni B, Rassetto M, Ferri A, de Duffard AME, Duffard R. Detection of 2,4-dichlorophenoxyacetic acid in rat milk of dams exposed during lactation and milk analysis of their major components. *Food Chem Toxicol.* 2006;44(1):8-16. doi:10.1016/j.fct.2005.03.012.

⁹⁵ U.S. EPA. 2,4-D. Human Health Risk Assessment for a Proposed Use of 2,4-D Choline on Herbicide-Tolerant Corn and Soybean. 2013. p. 34.

⁹⁶ *Id.*

modeling results, stating that some information “could be excluded” in its volatilization models given “limited information available and a lack of intentional statistical design to quantitatively evaluate [factors that could potentially affect the emission rates and off-site transport of 2,4-D]”⁹⁷. However, EPA does not make clear in its proposal which information it is excluding. As a consequence, it is impossible to determine whether the Agency used reasonable worst-case assumptions and/or adequately protective cut off figures in its probabilistic estimation. In addition, volatilization models should include estimates or uncertainty factors for additional off-gassing emissions, with particular concern for additional flux associated with use of 2,4-D later in the growing season (potential for mid-to-late July⁹⁸ for corn and mid-to-late June for soy⁹⁹), increased use and temperature factors associated with climate change¹⁰⁰, and should include location-based, worst-case scenario weather information for the proposed states in the PERFUM model to ensure that the highest risk estimates are used. From the public information available, it does not appear that EPA has taken the higher frequencies of application later in the season (at warmer temperatures) into account with its modeling.

5. EPA has used invalid assumptions in determining the exposure risk estimates for 2,4-D spray drift.

In its assessment of the potential for population exposure from spray drift, EPA inappropriately bases its analysis on the “premise of compliant applications” in accordance with

⁹⁷ *Id.*

⁹⁸ <http://www.sdstate.edu/ps/extension/crop-mgmt/corn/upload/Corn-growth-stage-day-and-GDU-calendar10.pdf> and <http://www.sdstate.edu/ps/extension/crop-mgmt/corn/upload/Corn-growth-stage-day-and-GDU-calendar10.pdf>; last visited June 15, 2014.

⁹⁹ <http://www.extension.umn.edu/agriculture/soybean/soybean-growth-and-development-information-for-replant-decisions/>; last visited June 17, 2014.

¹⁰⁰ Ziska LH. Increasing Minimum Daily Temperatures Are Associated with Enhanced Pesticide Use in Cultivated Soybean along a Latitudinal Gradient in the Mid-Western United States. *PLoS one*. 2014;9(2):e98516. doi:10.1371/journal.pone.0098516.

label restrictions¹⁰¹. As we have raised in prior NRDC comments (APPENDIX B)¹⁰², EPA does not collect user testing data to evaluate whether applicators understand and routinely implement the control measures that would limit spray drift. The presence of 2,4-D in homes¹⁰³ and the environment suggest either that non-compliant applications are occurring or that the labels are insufficiently protective. EPA's assumption of compliant application falls far short of a reasonable worst-case assessment of harm that would be caused by a variety of very common problems such as poor user understanding of the local factors that influence spray drift (e.g., wind speed and meteorological conditions), poor worker training, and a host of additional real-world problems that lead to spray drift exposures. In the absence of data to support its compliant application assumption, EPA should assume a reasonable worst-case scenario of non-compliance in its calculations of drift and volatilization.

Additionally, EPA estimates drift based on an existing *turf* drift assessment, incorrectly concluding that “[i]f 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 exposure¹⁰⁴”.

The increased exposure to Enlist Duo will occur through an increased *frequency* of application, not necessarily an increased application rate. By again neglecting to account for increased frequency of application inherent in the proposed uses of Enlist Duo, EPA misses

¹⁰¹ U.S. EPA. 2,4-D. Human Health Risk Assessment for a Proposed Use of 2,4-D Choline on Herbicide-Tolerant Corn and Soybean. 2013. See Table 4.5.4.1, p. 35.

¹⁰² Sass J, Comments on two draft guidance documents describing how off-site spray drift will be evaluated for ecological and human health risk assessments for pesticides. April 30, 2014. EPA-HQ-OPP-2013-0676

¹⁰³ Morgan MK, Sheldon LS, Thomas KW, et al. Adult and children's exposure to 2,4-D from multiple sources and pathways. *J Expo Sci Environ Epidemiol*. 2008;18(5):486-494. doi:10.1038/sj.jes.7500641.

¹⁰⁴ U.S. EPA. 2,4-D. Human Health Risk Assessment for a Proposed Use of 2,4-D Choline on Herbicide-Tolerant Corn and Soybean. 2013. See Table 4.5.4.1, p. 35.

additional windows of exposure that are the heart of the matter. While 2,4-D application is limited to 1.5 lb ae/acre/year on turf, Enlist Duo seeks approval for an application rate of 3 lb ae/acre/season. Increased frequency of exposure, particularly over large geographic areas (Figure 1), could be detrimental to the health and well-being of pregnant women and children.

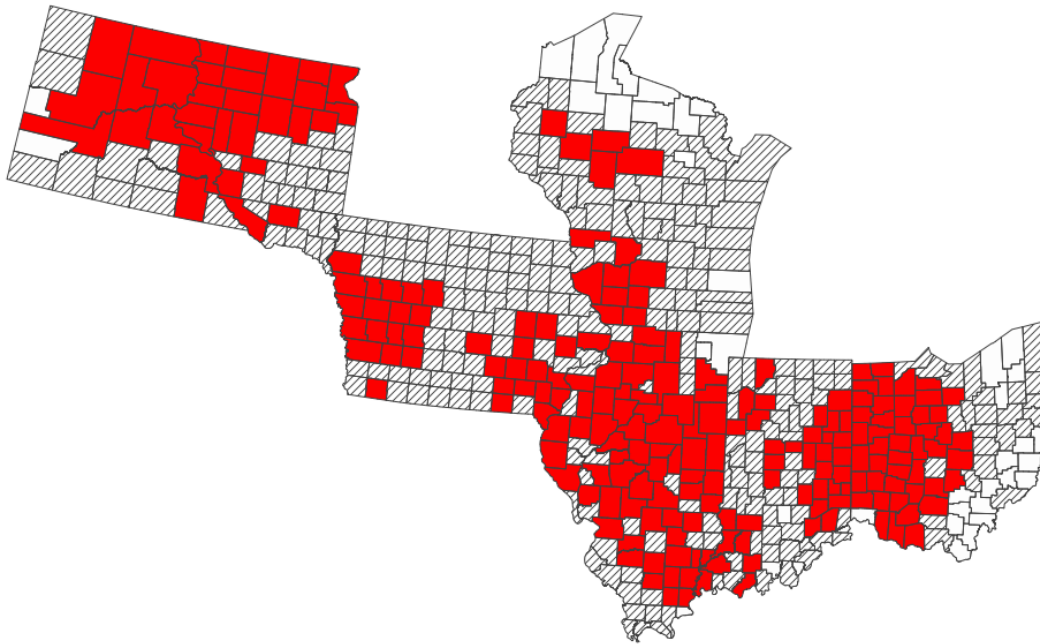


Figure 1. Potential areas of geographic expansion of 2,4-D with Enlist Duo registration. Counties mapped in red represent areas with more than 10,000 lbs of 2,4-D usage in 2011 (data from USGS 2011 ; ref 1). Counties mapped in hatched lines represent counties with more than 10,000 pounds of glyphosate usage in 2011 (data from USGS 2011; ref 1). Enlist Duo™ (a combination of 2,4-D and glyphosate) could significantly expand the use of 2,4-D in the cross-hatched areas.

6. EPA must use a minimum of the statutorily required FQPA tenfold safety factor to protect infants and children from the toxic effects of 2,4-D.

EPA is required to use a 10X safety factor “for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.”¹⁰⁵ EPA may use a different safety factor “*only if*, on the basis of reliable data, such margin will be safe for infants and children.”¹⁰⁶

¹⁰⁵ 21 U.S.C. § 346a(b)(2)(C)

¹⁰⁶ *Id.*

In the proposed registration of 2,4-D, EPA contends that the FQPA safety factor can be reduced from 10X to 1X because the “[t]he toxicity database is complete and adequate to assess safety for infants and children”¹⁰⁷. As we illustrated in our discussion of thyroid toxicity, the 1-generation study EPA relied on to determine thyroid effects did not determine a NOAEL for 2,4-D. The increased susceptibility of offspring to 2,4-D toxicity, the ability of 2,4-D to bind the thyroid, androgen, estrogen, and arylhydrocarbon receptors in *in vitro* Tox21 assays, human epidemiology demonstrating thyroid effects, and the uncertainty of the shape of the dose curve alone, justify the retention of, at a minimum, the statutorily-presumed children’s 10X uncertainty factor to be protective of pregnant women, infants, and children.

In addition to specific thyroid-related effects, the peer-reviewed publication record contains several additional studies that are relevant to adverse effects on fetal development and hormone regulation, including (but not limited to):

- Kooijman R, Devos S, Hooghe-Peters E. Inhibition of *in vitro* cytokine production by human peripheral blood mononuclear cells treated with xenobiotics: Implications for the prediction of general toxicity and immunotoxicity. *Toxicology in Vitro*. 2010;24(6):1782-1789. doi:10.1016/j.tiv.2010.07.007.
- Stebbins-Boaz B, Fortner K, Frazier J, et al. Oocyte maturation in *Xenopus laevis* is blocked by the hormonal herbicide, 2,4-dichlorophenoxy acetic acid. *Molecular Reproduction and Development*. 2004;67(2):233-242. doi:10.1002/mrd.10396.
- Cavieres MF, Jaeger J, Porter W. Developmental toxicity of a commercial herbicide mixture in mice: I. Effects on embryo implantation and litter size. *Environmental Health Perspectives*. 2002;110(11):1081-1085.
- Pochettino AA, Bongiovanni B, Duffard RO, Evangelista de Duffard AM. Oxidative stress in ventral prostate, ovary, and breast by 2,4-dichlorophenoxyacetic acid in pre- and postnatal exposed rats. *Environmental Toxicology*. 2013;28(1):1-10. doi:10.1002/tox.20690.
- Ferri A, Duffard R, Sturtz N, de Duffard AME. Iron, zinc and copper levels in brain, serum and liver of neonates exposed to 2,4-dichlorophenoxyacetic acid. *Neurotoxicology and Teratology*. 2003;25(5):607-613. doi:10.1016/S0892-0362(03)00075-8.

¹⁰⁷ U.S. EPA. 2,4-D. Human Health Risk Assessment for a Proposed Use of 2,4-D Choline on Herbicide-Tolerant Corn and Soybean. 2013. See page 14

- Greenlee AR, Ellis TM, Berg RL. Low-dose agrochemicals and lawn-care pesticides induce developmental toxicity in murine preimplantation embryos. *Environmental Health Perspectives*. 2004;112(6):703-709. doi:10.1289/ehp.6774.

The published literature, as well as the thyroid effects mentioned above, provide multiple streams of evidence that warrant a 10X FQPA uncertainty factor necessary to protect the health of pregnant mothers, infants, and children.

Additionally, immense uncertainty remains in the exposure risk estimates calculated by EPA. As stated in our exposure estimate sections above, EPA lacks considerable data to accurately estimate exposure to 2,4-D from the diet (including food and water contributions), breast milk, volatilization, and spray drift sources for pregnant women, infants, and children, and thus must rely on reasonable worst case estimations. These additional uncertainties provide an additional clear rationale for retaining, at a minimum, the 10X FQPA children's protection uncertainty factor.

Thus, EPA must retain, at a minimum, the statutorily-presumed FQPA 10x uncertainty factor to take into account potential pre-and post-natal toxicity and completeness of the data with respect to infants and children.

IV. CONCLUSION

Glyphosate and 2,4-D, the two herbicides in Enlist Duo, pose serious environmental and health effects. EPA must consider these effects in its review of Enlist Duo, including the effects of glyphosate on the monarch butterfly.

NRDC reserves the right to supplement this petition based on new information.

Respectfully submitted,



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APPENDIX A



Comments of the Natural Resources Defense Council on Dow Agroscience's Applications to Register New Uses for 2,4-D

EPA-HQ-OPP-2011-0835

June 22, 2012

The Natural Resources Defense Council (NRDC) is a national, non-profit environmental organization of lawyers, scientists, and other professionals. NRDC presents these comments on behalf of our 1.3 million members and online activists. NRDC does not have any financial interest in the topic of these comments.

On August 19, 2009, Dow Agroscience (Dow) petitioned the U.S. Department of Agriculture (USDA) for a determination of non-regulated status of its DAS-40278-9 corn, which has been genetically engineered to be tolerant to the pesticide 2,4-D.¹ As part of the application, Dow claimed that it planned to submit metabolism and residue data and proposed labeling to EPA for 2,4-D to be used on the DAS-40278-9 corn. NRDC strongly opposed Dow's petition to the USDA for deregulation of DAS-40278-9 corn (and will oppose Dow's pending DAS-68416-4 soybean petition for deregulation).

On May 23, 2012, the U.S. Environmental Protection Agency (EPA) published a notice that Dow had submitted three new use pesticide applications for 2,4-D to be used on corn and soybean crops that have been genetically modified to be tolerant to 2,4-D. NRDC submits these comments with respect to these new use applications as identified in 77 Fed. Reg. 30524 (May 23, 2012):

- Registration Number and Registration File Symbol: 62719-640 and 62719-AUO. Active ingredients: 2,4-D choline salt and glyphosate. Proposed Classification/Use: Enlist AAD-1 Corn (Trait Code: DAS-40278-9).
- Registration File Symbol: 62719-AGO. Active ingredient: 2,4-D choline salt. Proposed Classification/Use: Enlist AAD-1 Corn (Trait Code: DAS-40278-9).
- Registration File Symbol: 62719-AUU. Active ingredient: 2,4-D choline salt. Proposed Classification/Use: Enlist AAD-12 Soybeans (Trait Code: DAS-68416-4).

¹ Since its original submission, the application was revised on December 16, 2009, April 30, 2010 and April 12, 2011.

Without information about these new use applications for 2,4-D, NRDC is concerned about any expanded use of 2,4-D. Based on our concerns about 2,4-D in general and the expected increase of 2,4-D use if these genetically modified crops are deregulated by USDA, NRDC opposes these Dow applications for new uses of 2,4-D.

EPA must conduct a thorough risk assessment, taking into account the consequences of USDA approving both DAS-40278-9 corn and DAS-68416-4 soybeans. At a minimum, NRDC requests that before EPA makes a final decision on the new use applications, the agency should publish all the underlying risk assessments and proposed decision and provide a sufficient comment period of at least 90 days for the public. To date, EPA has provided scant information about these three applications to the public, and none of the information provides substantive details about the proposed new uses. Furthermore, there has been a great public display of concern about this new crop and the use of 2,4-D (more than 300,000 people submitted comments opposing Dow's application for deregulated status of its genetically modified DAS-40278-9 corn). Combined, these two factors underscore EPA's responsibility to provide a second comment period for these new use applications.

Human Health Concerns

A total of about 70 million pounds of 2,4-D are used annually for both agriculture and urban applications, with a little more than half (about 40 million pounds) used for agriculture.² Humans are exposed to 2,4-D through both dermal contact and ingestion of contaminated food and water. Residues remain on crops treated with 2,4-D, and the herbicide enters surface water and groundwater, ultimately contaminating drinking water supplies.³

In urban areas, 2,4-D is the most frequently applied herbicide for outdoor home-and-garden applications, and it is detected at above 1 parts per billion in 11 percent of samples from streams and shallow groundwater in urban areas, according to U.S. Geological Survey water monitoring data.⁴

2,4-D drifts from the point of application and becomes widely distributed, exposing populations distant from the site of application to its harmful effects. One study, for instance, found that 2,4-D residues were detectable in 83 percent of urban household dust samples in North Carolina and 98 percent of homes in Ohio, despite the fact that 2,4-D use was reported at just one of the 135 homes inspected.⁵ The herbicide is often tracked into homes, where it may persist for months on indoor carpets, leaving children who crawl or play on floors disproportionately vulnerable to 2,4-D exposure and accompanying risks.⁶

² USGS (2006). United States Geological Survey, *The Quality Of Our Nation's Waters—Pesticides In The Nation's Streams And Ground Water, 1992–2001*. Chapter 4, page 60, Fig 4-3. <http://pubs.usgs.gov/circ/2005/1291/>

³ USGS (2006). <http://pubs.usgs.gov/circ/2005/1291/>

⁴ USGS (2006). Chapter 4, Page 52.

⁵ Morgan MK, Sheldon LS, Thomas KW, Egeghy PP, Croghan CW, Jones PA, Chuang JC, Wilson NK. Adult and children's exposure to 2,4-D from multiple sources and pathways. *J Expo Sci Environ Epidemiol*. 2008 Sep;18(5):486-94

⁶ Nishioka MG, Lewis RG, Brinkman MC, Burkholder HM, Hines CE, Menkedick JR. Distribution of 2,4-D in air and on surfaces inside residences after lawn applications: comparing exposure estimates from various media for young children. *Environ Health Perspect*. 2001 Nov;109(11):1185-91

Studies in humans have reported associations between exposure to 2,4-D and non-Hodgkin's lymphoma, a cancer of the white blood cells (lymphocytes).⁷ This finding is consistent with other studies finding that 2,4-D increases lymphocyte replication in exposed farmworkers,⁸ and that 2,4-D formulations are cytotoxic and mutagenic in cell tests.^{9 10} For example, in human lymphocytes, 2,4-D causes chromosome breakage and abnormal cells.¹¹ In 2010, according to the National Cancer Institute, approximately 65,540 people in the United States were diagnosed with non-Hodgkin's lymphoma. The incidence of this disease in the United States has increased to about double the rate seen in the 1970s, even when adjusted for population growth and aging.¹² 2,4-D is likely to be responsible for a fraction of cases of non-Hodgkin's lymphoma each year, although it is difficult to quantify the exact numbers.

Even a recent 2011 study conducted by Dow Chemical of the cancer incidence among its own 2,4-D production workers reported a statistically significant elevation in respiratory cancers, mainly mesothelioma by 3.79-fold above background.¹³

Many animal studies show that 2,4-D exhibits hormone-disrupting activity and affects the function of the neurotransmitters dopamine and serotonin.¹⁴ Interference with hormones and neurotransmitters can cause serious and lasting effects during fetal and infant development, including birth defects, neurological damage, and interference with reproductive function. Human studies support the results of the animal studies. Male farm sprayers exposed to 2,4-D have lower sperm counts and more spermatid abnormalities compared to men who are not exposed to this chemical.¹⁵ In Minnesota, higher rates of birth defects have been observed in wheat-growing areas of the state with the highest use of 2,4-D and other herbicides of the same

Marcia G. Nishioka et al., Measuring Lawn Transport of Lawn-Applied Herbicide Acids from Turf to Home: Correlation of Dislodgeable 2,4-D Turf Residues with Carpet Dust and Carpet Surface Residues, 30 ENVTL. SCI. & TECH. 3313 (1996).

⁷ Miligi L, Costantini AS, Veraldi A, Benvenuti A; WILL, Vineis P. Cancer and pesticides: an overview and some results of the Italian multicenter case-control study on hematolymphopoietic malignancies. *Ann N Y Acad Sci* 1076:366-77, 2006.

⁸ Figgs LW, Holland NT, Rothmann N, Zahm SH, et al. Increased lymphocyte replicative index following 2,4-dichlorophenoxyacetic acid herbicide exposure. *Cancer Causes Control* 11(4):373-80, 2000.

⁹ Zeljezic D, Garaj-Vrhovac V. Chromosomal aberrations, micronuclei and nuclear buds induced in human lymphocytes by 2,4-dichlorophenoxyacetic acid pesticide formulation. *Toxicology* 200:39-47, 2004.

¹⁰ Holland NT, et al., Micronucleus frequency and proliferation in human lymphocytes after exposure to herbicide 2,4-dichlorophenoxyacetic acid in vitro and in vivo. *Mutat Res* 521(1-2):165-78, 2002.

¹¹ Zeljezic D, Garaj-Vrhovac V. Chromosomal aberrations, micronuclei and nuclear buds induced in human lymphocytes by 2,4-dichlorophenoxyacetic acid pesticide formulation. *Toxicology* 200:39-47, 2004.

¹² Howlader N, Noone AM, Krapcho M, Neyman N, Aminou R, Waldron W, Altekruse SF, Kosary CL, Ruhl J, Tatalovich Z, Cho H, Mariotto A, Eisner MP, Lewis DR, Chen HS, Feuer EJ, Cronin KA, Edwards BK (eds). SEER Cancer Statistics Review, 1975-2008, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2008/, based on November 2010 SEER data submission, posted to the SEER web site, 2011.

¹³ Burns, C.; Bodner, K.; Swaen, G.; Collins, J.; Beard, K.; Lee, M. Cancer Incidence of 2,4-D Production Workers. *Int. J. Environ. Res. Public Health* 2011, 8, 3579-3590

¹⁴ Pochettino AA, Bongiovanni B, Duffard RO, Evangelista de Duffard AM. Oxidative stress in ventral prostate, ovary, and breast by 2,4-dichlorophenoxyacetic acid in pre- and postnatal exposed rats. *Environ Toxicol.* 2011 Mar 3.

Stürtz N, Jahn GA, Deis RP, Rettori V, Duffard RO, Evangelista de Duffard AM. Effect of 2,4-dichlorophenoxyacetic acid on milk transfer to the litter and prolactin release in lactating rats. *Toxicology.* 2010 Apr 30;271(1-2):13-20.

Stürtz N, Deis RP, Jahn GA, Duffard R, Evangelista de Duffard AM. Effect of 2,4-dichlorophenoxyacetic acid on rat maternal behavior. *Toxicology.* 2008 May 21;247(2-3):73-9.

¹⁵ Lerda D, Rizzi R. Study of reproductive function in persons occupationally exposed to 2,4-D. *Mutation Research* 262:47-50, 1991.

class.¹⁶ This increase was most pronounced among infants who were conceived in the spring, the time of greatest herbicide use. A larger study in agricultural counties in Minnesota, Montana, North Dakota, and South Dakota found significant increases in malformations of the circulatory and respiratory systems, especially among infants conceived between April and June in wheat-growing counties.¹⁷ In the same study, infant deaths from birth defects among males were significantly elevated.

Increased Use of 2,4-D

Estimates suggest that the use of 2,4-D could increase between 5 to 30 fold within the next decade as a result of deregulation of DAS 40278-9 corn, alone.^{18 19} The USDA's environmental assessment of Dow's petition to deregulate DAS-40278-9 corn states that the cultivation of that corn might result in a broader use of 2,4-D on corn, and nearly every outside analysis concludes that the introduction of staple crops resistant to 2,4-D will lead to an increase in 2,4-D use nationwide.²⁰ The increase in 2,4-D use from the deregulation of genetically-modified soybeans will likely push that number even higher.

EPA Must Incorporate the Increased Use of 2,4-D In The Risk Assessment

Among other problems, EPA's current approval of 2,4-D does not account for the increase in 2,4-D use that is predicted to occur with the introduction of 2,4-D tolerant DAS 40278-9 corn and other 2,4-D tolerant crops. This significant increase in the amount of 2,4-D that will be released into the environment should dramatically change EPA's assessment of 2,4-D's eligibility for continued registration.

When EPA finalized the 2,4-D Reregistration Eligibility Determination (RED) in 2005, USDA had not yet received any petitions for deregulation of 2,4-D resistant crops. The RED, thus, does not incorporate any of the potential adverse impacts of a significantly higher use of 2,4-D, nationally. As such, in light of the DAS 40278-9 corn petition and pending DAS-68416-4 soybean petition for deregulation at USDA, EPA must include at least the following considerations in its risk assessment, which were not considered in the RED:

¹⁶ Garry VF, Schreinemachers D, Harkins ME, et al. Pesticide applicers, biocides, and birth defects in rural Minnesota. *Environ Health Perspect* 104:394-399, 1996.

¹⁷ Schreinemachers DM. Birth malformations and other adverse perinatal outcomes in four U.S. wheat-producing states. *Environ Health Perspect* 111(9):1259-1264, 2003.

¹⁸ The estimate for a potential 5 fold increase in 2,4-D use is based on the following assumptions and calculations. The National Agricultural Statistics Services (NASS) indicates that as recently as 2010, farmers used approximately 1/3 lb per acre per application of 2,4-D, which is a fraction of the maximum label rate of 2 lbs per acre per application. Dow has indicated that, to be effective when used with DAS 40278-9 corn, growers need to apply 1 to 2 lbs per acre of 2,4-D. This will cause increase the per field use of 2,4-D, even though the label rate may not change. The change in actual application rates would increase the use of 2,4-D by 3-6 fold. The data also show that 2,4-D is used on approximately 10 percent of corn fields. Conservative, rough estimates suggest that 20-30 percent of corn fields will adopt DAS 40278-9 corn and use 2,4-D. This suggests a 2-3 fold increase in 2,4-D use based on the increased percentage of corn fields that had not previously, but will now be using 2,4-D. Taking the most conservative assumptions, at a minimum, we can expect at least a 5 fold increase in 2,4-D use due to DAS 20478-9 corn.

¹⁹<http://www.centerforfoodsafety.org/projected-increase-in-24-d-use-with-introduction-of-24-d-resistant-corn-through-2019-benbrook2012/>

²⁰ APHIS, Draft Environmental Assessment at 80, 85, 100

- Increased direct exposure from drift to people who live downwind of areas planted with DAS 40278-9 corn and genetically modified soybean crops;
- Aggregate impact on wildlife, water quality, and air quality from the dramatic increased use of 2,4-D both on a per field basis and on a regional basis; and
- Risk to applicators from the increased exposure to 2,4-D due to increased overall application amounts.

Combining all the increased exposures that are likely to occur, the existing risk from the household exposures to weed and feed products, and the indirect exposures through residue or garden soil contamination, EPA is likely to find that the risk will be substantial and that these new uses cannot be approved.

Such a finding could affect the registration of 2,4-D in many ways, including whether 2,4-D would be approved for use on DAS 40278-9 corn, DAS-68416-4 soybean, and any other 2,4-D tolerant crops that Dow may be developing. In addition, USDA relies heavily on EPA's RED regarding the human health effects rather than conduct its own determination in the environmental assessment. Because USDA has put the burden on EPA to determine whether there will be adverse impacts to the environment from deregulating Dow's DAS 40278-9 corn, EPA must conduct an assessment that considers the impacts from the predicted increase in 2,4-D use. Such an updated assessment will significantly impact USDA's environmental assessment of DAS-40278-9 corn – and the pending environmental assessment of soybean crops that are genetically modified to be tolerant to 2,4-D (and any other crops that are in the pipeline.)

Among others, EPA must consider the impact that the increased use of 2,4-D will have on the following exposures as explained in more detail below: worker, drinking water, and residential exposures.

Worker Exposure

In its discussion of worker safety, USDA states that while “in 2005, 2,4-D was applied on less than 8% of corn acreage,” in the United States, “[i]t is conceivable that the cultivation of DAS-40278-9 corn could result in a broader use of 2,4-D on corn.”²¹ However, as with glyphosate, the application of which increased substantially following the deregulation of “Roundup Ready” staple crops, the application of 2,4-D is almost certain to expand. USDA suggests that the effect on worker safety will be negligible, reasoning that “[i]n situations where the maximum total annual application is reached, worker exposure to 2,4-D would be similar to that which currently occurs in those farms where 2,4-D currently is applied to corn at the maximum annual rate.”²² Dow has noted that the target application rate for 2,4-D on DAS 40278-9 corn will be the same as the current maximum label rate for 2,4-D on corn (1 lb/acre). However, EPA's RED uses the average application rate – rather than the maximum application label rate – to evaluate the intermediate term exposure for the occupational handler exposure assessment. The average application rate used by EPA is one-half of the maximum label rate, and therefore, a change in the actual application rate to meet the target rate indicated by Dow would increase the overall exposure to workers. Therefore, EPA must account for the likelihood that the maximum total

²¹ Id. at 100.

²² Id. at 3

annual quantity of 2,4-D will be applied following the deregulation of DAS-40278-9 corn and DAS-68416-4 soybean, as well as the increase in the total number of workers who will be exposed to 2,4-D. EPA must account for the effect that the increased use of 2,4-D will have on workers' exposures in considering these three new use applications.

Drinking Water Exposure

According to EPA's October 27, 2011 Human Health Risk Assessment for the proposed establishment of tolerances and registration of new uses of 2,4-D choline, the Health Effects Division states that "[t]he previous drinking water assessment [from the 2005 RED] will not be affected by the use of 2,4-D choline on AAD-1 corn [DAS 40278-9 corn], as the use patterns have not changed for field corn."²³ EPA's drinking water assessment of 2,4-D was based, in part, on the estimated environmental concentration based on monitoring data and modeling. Since this assessment was conducted in 2005, before Dow petitioned to deregulate DAS 40278-9 corn, it did not account for the significant increase in 2,4-D use that is expected to occur. An increase in 2,4-D use will mean an increase in the 2,4-D that could contaminate surface water and drinking water. This will affect the modeling and estimated environmental concentration of 2,4-D. As such, EPA must conduct a new drinking water assessment as part of its dietary exposure and risk from drinking water and take into account the predicted increase in 2,4-D use from this new use on 2,4-D resistant corn and soybeans.

Residential Exposure

According to EPA's October 27, 2011 Human Health Risk Assessment for the proposed establishment of tolerances and registration of new uses of 2,4-D choline, "No changes to residential exposures will occur as a result of the use on tolerant corn."²⁴ However, there are considerable concerns about the ability of 2,4-D to drift long distances. For example, according to a North Dakota State University, "very fine particles [of 2,4-D] can drift 367 yards to a few miles with only a 3 miles per hour wind."²⁵ Combined with the estimates of increased use of 2,4-D as a result of these new crops, it is reasonable to expect that residential exposures will also increase, for those populations who live nearby areas where 2,4-D will be sprayed on these new crops. Even in situations where drift concentrations are low, the combined exposure from drift and household uses could be significant and must be evaluated. EPA must account for this increased exposure in its risk assessment for these new uses.

²³ Memorandum dated October 27, 2011 from Alexandra LaMay to Michael Walsh, re: 2,4-D: Petition for the Establishment of a New Formulation of 2,4-D Choline on Herbicide Tolerant Field Corn Containing the Aryloxyalkanoate Dioxygenase-1 (ADD-1) Gene, p 10.

²⁴ Id.

²⁵ Alan G. Dexter Herbicide Spray Drift, available at <http://www.ag.ndsu.edu/pubs/plantsci/weeds/a657w.htm>, last visited June 22, 2012.

In conclusion, EPA must ensure that it conducts a full risk assessment of these 2,4-D new uses taking into account the increased use of 2,4-D and the resulting increase in exposures that will likely occur with the adoption of genetically modified corn and soybeans that are tolerant to 2,4-D. NRDC continues to oppose the expanded use of 2,4-D.

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APPENDIX B



NATURAL RESOURCES DEFENSE COUNCIL
THE EARTH'S BEST DEFENSE

Comments from the NRDC on two draft guidance documents describing how off-site spray drift will be evaluated for ecological and human health risk assessments for pesticides

EPA-HQ-OPP-2013-0676

DUE APR 30, 2014

These comments are supported by:

- Alaska Community Action on Toxics – Pamela Miller
- CATA - The Farmworker Support Committee/El Comité de Apoyo a los Trabajadores Agrícolas – Nelson Carrasquillo
- Empire State Consumer Project – Judy Braiman
- Farmworker Association of Florida – Jeannie Economos
- Healthy Schools Network – Claire Barnett
- Maryland Pesticide Network – Ruth Berlin

The Natural Resources Defense Council (NRDC) is a national, non-profit environmental organization of lawyers, scientists, and other professionals. NRDC presents these comments on behalf of our 1.3 million members and online activists. NRDC does not have any financial interest in the topic of these comments.

These comments are on the following documents:

EPA-HQ-OPP-2013-0676-0001; FR Notice

EPA-HQ-OPP-2013-0676-0002; Guidance on Modeling Offsite Deposition of Pesticides Via Spray Drift for Ecological and Drinking Water Assessments (November 1, 2013)

EPA-HQ-OPP-2013-0676-0003; Residential Exposure Assessment Standard Operating Procedures. Addenda 1: Consideration of Spray Drift

EPA-HQ-OPP-2013-0676-0004; Use of AgDRIFT and AGDISP in OPP Risk Assessments

OVERALL COMMENTS ON THE MODELS

OPP should evaluate the AgDRIFT and AGDISP models according to CREM recommendations.

OPP should show how it has followed the recommendations and guidance of the EPA Council for Regulatory Environmental Modeling ([CREM](#)) to evaluate the model uncertainties, limitations, and appropriate applications using the CREM model evaluation tools. OPP should make this analysis publicly accessible. On the EPA website, the basic description of CREM states that, "Given the crucial role that models play in informing regulatory decision making, the EPA established the Council for Regulatory Environmental Modeling (CREM) in 2000 in an effort to improve the quality, consistency and transparency of the models for environmental decision making." EPA established CREM for the purpose of evaluating environmental models. CREM makes the following recommendations for the use of models:

Use of models by the EPA should be to fill in data gaps when trying to set protective regulations, but not to overturn observations from laboratory, environmental monitoring, epidemiologic, or other relevant scientific studies.

Models can be highly subjective, and therefore correspondence from models developed by different sectors should be considered. Results from models are similar to a critical review of the overall scientific literature, in that they incorporate the results of many studies to generate an overall summary of the data. As such, models can be highly subjective, depending on the bias of the sponsor and any financial interests they may have in the regulations that may result. The scientific journals have recognized this reality, and many have strict guidelines against allowing financial interested parties to write scientific review papers.

The underlying assumptions that are used to build the model framework, and are used to define the parameters of the model, should be stated. We suggest that thorough documentation be provided of the underlying assumptions that are used to build the model framework, and are used to define the parameters of the model. Model parameters are terms in the model that are fixed during a model run or simulation, but can be changed in different runs to conduct sensitivity analysis or calibrate the model. Parameters can be quantities estimated from sample data to characterize a statistical population, or known mathematical constants.

Any known limitations in the model should be stated, and thorough documentation should be provided.

Appropriate uses, and inappropriate uses, of the model should be stated, and thorough documentation should be provided.

Results of uncertainty and sensitivity analysis and validation tests should be provided. Sensitivity analysis evaluates the effects of changes in input values or assumptions on a model's results. Uncertainty analysis investigates the effects of database uncertainties, uncertainty associated with model parameter assumptions, uncertainty regarding appropriate application of the model, and other potential sources of error in the model. Structural uncertainty in the model can be addressed by comparing the ability of different model frameworks to model the same data sets, resulting in a quantitative range of uncertainty. If such comparisons have been done, these results should be documented. Comparing the ability of a model to handle multiple data sets,

and comparing multiple models to handle the same data sets can test the uncertainty associated with a model. The resulting quantitative range of uncertainty should be documented.

Variability results from the inherent randomness of certain input parameters, such as fluctuations in seasonal conditions or genetic variances among populations. Variability in model parameters is largely dependent on the extent to which input data has been aggregated. While variability may not be able to be reduced, it should be characterized and represented to the public and stakeholders.

Model corroboration describes all the methods, both qualitative and quantitative, for evaluating the degree to which a model corresponds to reality. Any tests for model corroboration that have been performed should be documented, along with the results.

Application niche of the model should be stated. The application niche for a particular model is the set of conditions under which the use of the model is scientifically defensible.

Proprietary models must be extremely well documented, when used. EPA legally may not rely on a proprietary model without providing substantial detail about its built-in assumptions and calculation methodologies. As the D.C. Circuit has held, "EPA has undoubted power to use predictive models so long as it explains the assumptions and methodology used in preparing the model and provides a complete analytic defense should the model be challenged."¹ In so doing, EPA can keep proprietary data confidential, but must provide enough information about the underlying facts supporting its decision to the public to show that it has engaged in reasoned decision making.² We support the CREM recommendations that proprietary models be accompanied by comprehensive, publicly available documentation that describes the conceptual and theoretical basis for the model, the process used to evaluate the model, and access to input and output data such that the public can replicate results derived from the model.³

If OPP has evaluated the AgDRIFT and AGDISP models using CREM parameters, where can the public find this information? If OPP has not evaluated the models using CREM parameters, why not? Will OPP do this in a publicly transparent way, providing thorough documentation of its review?

The need to make EPA regulatory decisions as transparent as possible, and to allow others to reproduce EPA calculations and derivation of numbers, is essential to elevating the public confidence in EPA assessments. All models used to inform regulatory decisions should be accompanied by comprehensive, publicly available documentation that describes the conceptual and theoretical basis for the model, the process used to evaluate the model, and access to input and output data such that the public can replicate results derived from the model.

¹ *Appalachian Pwr. Co. v. EPA*, 249 F.3d 1032, 1052 (D.C. Cir. 2001) (internal punctuation and quotations omitted).

² See *NRDC v. Thomas*, 805 F.2d 410, 418 n.13 (D.C. Cir. 1986) (rejecting challenge to confidential data where EPA "combine[d] the data from the confidential reports . . . and plot[ted] them on a graph that was made part of the public record . . . then discussed the plotted data at some length").

³ The Council for Regulatory Environmental Modeling. Draft Guidance on the development, evaluation, and application of regulatory environmental models. November, 2003.

http://www.epa.gov/osp/crem/library/CREM%20Guidance%20Draft%202012_03.pdf

SPECIFIC COMMENTS ON THE MODELS

The following comments are specific to the EPA Guidance on Modeling Offsite Deposition of Pesticides Via Spray Drift for Ecological and Drinking Water Assessments.

EPA should not presume negligible spray drift in the absence of reliable evidence to support its presumption. Lines 84-88 – EPA states that it assumes that spray drift is negligible for those application methods and materials for which it does not have data, including applications of dry materials, drip chemigation, and for applications with hand held or back pack sprayers. It seems highly likely that applications with these methods will result in some spray drift, and without reliable data one way or the other EPA should not assume that drift is “negligible”. For example, hand spray guns allow the applicator to alter both the spray pressure and the droplet size, both of which can alter drift potential. Hand spray guns can deliver a high-pressure stream to treat trees and shrubs, which seems likely to lead to off-site drift. Is EPA in the process of collecting these data and making it public? If not, what is the basis for EPA’s decision to presume negligible spray drift from these methods?

Line 159: EPA should require that any changes to the input parameters be clearly and publicly noted, along with a statement showing exactly how this alters the output, and whether it makes the output more or less protective of the environment and human health.

Figure 3: EPA provides guidance to compare the amount of spray drift to a calculated Level of Concern (LOC). However, the guidance should also prevent spray drift that lead to damage to crops, damage to fish or wildlife or their habitat (even if the LOC is not exceeded), or illness in humans and domesticated animals. In addition, EPA’s guidance should prevent a situation in which adverse outcomes can reasonably be anticipated, such as an application that might drift onto a school yard, whether or not any children are present at the time of the application. Spray drift exposures that are in excess of a tolerance, water quality criterion, maximum contaminant level, or other appropriate regulatory benchmark should also be prevented. For example, currently, Indiana regulations state: “A person may not apply a pesticide in a manner that allows it to drift from the target site in sufficient quantity to cause harm to a non-target site.” “Sufficient Quantity to Cause Harm” means an amount of pesticide that results in any of the following:

- (A) Pesticide residues in excess of tolerances or standards
- (B) Documented health, illness, stunting, deformation, discoloration; or other effects that are detrimental to the non-target site.

This level of prevention is more stringent than the weak and limited consideration of LOC exceedances only.

The following comments are specific to the EPA Guidance on Residential Exposure Assessment Standard Operating Procedures

The paucity of toxicity data on inhalation exposures, the effects of simultaneous exposures to multiple pesticides, and the variability among different people in their sensitivity to pesticide exposure makes it impossible for EPA to definitively determine the extent of potential adverse effects from spray drift. In addition, epidemiological studies showing statistically significant adverse effects on humans are routinely omitted from risk assessments. This calls into question the validity of the toxicological endpoints selected by EPA. People living close to pesticide application sites and/or working with

pesticides have significantly higher exposures than the average person and drift controls should protect these people as well.

OVERALL COMMENTS ON SPRAY DRIFT

Chemical trespass should be prevented

Any amount of chemical that drifts away from the application site and makes its way into other fields, including organic fields, homes, residential gardens and yards, schools, or workplaces is potentially problematic and should be regulated as such. Neither the registrants nor EPA know the long-term effects of exposure to small amounts of spray drift many times per year, year after year, to many different chemicals. It is impossible to say that harm will not occur from low levels of off-target spray drift that may land near schools, yards, parks and homes. Many types of harm that have been linked to chemical exposures may take time to manifest as something recognizable as harm, such as cancer, Parkinson's disease, or birth defects (for examples, see Grandjean and Landrigan 2014; Roberts and Karr, 2012).^{4 5} In light of these unknowns, EPA should not endorse any level of off-target pesticide particle movement as acceptable.

The idea of accepting toxic drift as inevitable takes a narrow view of pest control. There are many ways to prevent toxic spray drift from impinging on neighboring properties, most notably by use of biological and cultural pest control methods wherever possible, by restricting the use of spray or blower technologies in the application of pesticides, by using the wind to ensure that off-target areas are not contaminated with pesticide spray, and by using substantial buffer zones around target areas. Neighboring properties should not be required to accept any level of chemical trespass.

Buffer Zone Protections for Pesticide Sprays Adjacent to Organic Farms

EPA, working together with the USDA, should institute and enforce standards adequately protecting organic farms from pesticide drift of applications on adjacent property and should incorporate such standards into the current Guidances. Alternatively, EPA should immediately publish a separate Draft Guidance governing spray adjacent to organic farms. Organic farmers impacted by chemical drift bear heightened financial losses due to the special nature and premium prices of their crops. Reports and news articles demonstrate these impacts occur often, but compensation is not easily obtained.⁶ Organic farms can lose their organic status for several years after such events occur. Currently, the burden falls on organic farmers to establish buffer zones to protect their land from exposure to chemical pesticides. It is more reasonable to require buffer zones of those using these hazardous chemicals to ensure their actions do not in any way impact those around them, including organic farmers.

⁴ Grandjean P, Landrigan PJ. Neurobehavioural effects of developmental toxicity. *Lancet Neurol.* 2014 Mar;13(3):330-338. doi: 10.1016/S1474-4422(13)70278-3. Epub 2014 Feb 17. Review.

⁵ Roberts JR, Karr CJ; Council On Environmental Health. Pesticide exposure in children. *Pediatrics.* 2012 Dec;130(6):e1765-88. doi: 10.1542/peds.2012-2758. Epub 2012 Nov 26. Erratum in: *Pediatrics.* 2013 May;131(5):1013-4.

⁶ See, e.g., Food and Water Watch comments submitted to this docket, *Appellate court: Santa Cruz organic dill grower has right to sue neighboring farm for 'pesticide drift'*, San Jose Mercury News, December 22, 2010, found at http://www.mercurynews.com/central-coast/ci_16923749?nclick_check=1, and *Pesticide Drift on an Iowa Farm Is Focus of Feb. 25 Webinar*, Michigan Farmer, February, 22, 2014, found at <http://farmprogress.com/story-pesticide-drift-iowa-farm-focus-feb-25-webinar-9-109150>.

At a minimum, pesticide applicators should be required to take the steps outlined by the Purdue University Extension service.⁷ Those steps include making a proactive determination whether and where organic farms are located adjacent to the spray area, and updating that determination on a regular basis. Wind speed and direction should be carefully monitored throughout the spray application. Additionally, EPA/USDA could establish an online buffer calculator or app to show what added buffers are necessary in particular meteorological conditions and when no spray is allowed at all. Such an online calculator/app is currently available in Canada and could be used as a template.⁸

EPA should test the efficacy of its labels

EPA does not currently conduct user testing of labels to observe whether or not the intent of EPA's control measures is understandable by applicators. To assess label effectiveness as a means of communicating important safety and use information, it would be necessary for EPA to carry out statistically valid field surveys that observe applicator interpretation and understanding of pesticide label instructions. It is difficult to anticipate the myriad ways that people can misinterpret a statement until you've actually observed their behavior and queried their understanding. One only has to note the range of mistakes people make in the application of pesticides and the associated adverse effects to see the inadequacy of the current approach that assumes perfect understanding of pesticide labels.

Penalties are an important disincentive for non-compliance

We agree that education and training are important components of a program to reduce drift. We also point out that substantial penalties for violations are an important component of a program to ensure applicator compliance and should be incorporated into US EPA's enforcement program.

Drift Reduction Technology should be mandated

Advances in DRT is a promising way to reduce spray drift over the long run. EPA's DRT project is intended to increase the adoption of DRTs by developing a standardized evaluation process so that incentives can be developed through government programs and through acknowledgement on pesticide labels. The adoption of new technologies will occur more rapidly if there are appropriate incentives for use, and disincentives for failures. EPA should conduct an assessment of the efficacy of those technologies and the economic impacts of their adoption, as a demonstration of the technology verification protocol under development. We are also concerned that EPA is incentivizing the use of new technologies to spray in conditions (wind speed, as an example) that currently exceed recommended standards, or to allow use of higher application rates than would otherwise be permitted, or to reduce the width of a required buffer zone. This is unacceptable and would almost certainly lead to even more harm from drift than we currently have now because it would be abused to push the limits of conditions under which applications could legally be made.

EPA should truth-test its drift reduction recommendations with real-world data and evidence.

EPA should strengthen the collection, use, and public availability of information regarding real world effects of its regulatory approaches, especially labeling, including: 1) collecting objective monitoring data of water quality and other environmental receptors, 2) information on enforcement actions by state regulatory agencies, 3) incident databases (including both proper use and misuse incidents), and 4) assessments of users' understanding of label statements. EPA should particularly emphasize the

⁷ Elizabeth Maynard, Bryan Overstreet, and Jim Riddle, *Driftwatch: Watch Out for Pesticide Drift and Organic Production*, Purdue University, 2012, found at <https://www.extension.purdue.edu/extmedia/HO/DW-1-W.pdf>.

⁸ See at <http://www.hc-sc.gc.ca/cps-spc/pest/agri-commerce/drift-derive/calculator-calculatrice-eng.php>.

collection of data that are valid, robust, and publicly available. EPA should also work with stakeholders to identify and resolve information technology issues that might impede the collection of these types of data. By strengthening the use of these additional sources of information, the workgroup intends for EPA to evaluate, first, whether the data demonstrate that existing regulatory requirements are being successful in preventing harm from spray drift, as anticipated when EPA imposed them. In doing so, EPA should consider how the information not only sheds light on EPA assessments of individual pesticide chemicals but also what it indicates about the overall impact of pesticide use. Second, if the analysis of this information indicates that harm is occurring, EPA should attempt to discern the reasons that the existing regulatory requirements have failed to produce the expected levels of protection.

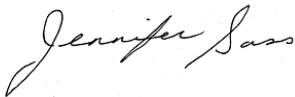
Avoid direct exposure to people from spray drift

EPA should require at least 24-hour advance written notification of all residents, workers and property owners within 1/4 mile of the application site so they may take action to protect themselves and their families from potential harm. Information provided should include anticipated date and time of application, name of the pesticide product, a list of active ingredients and other "inert" ingredients, and a copy of the Material Safety Data Sheet (MSDS) for the pesticide product(s) being sprayed.

EPA should not disregard volatilization of pesticide in its definition of spray drift.

EPA specifically defines spray drift as not including pesticide movement by volatility (FR Notice at 4691, Section I.D) However, attempts to reduce harm from off-site airborne pesticide movement through management of spray drift alone will be inadequate to address the issue of harm from drift. Volatilization drift is a major component of drift for volatile and semi-volatile pesticides (vapor pressure > 10⁻⁶ mm Hg) that contributes substantially to human and wildlife exposures and harm through inhalation. With a few exceptions, EPA does not yet routinely evaluate bystander inhalation exposures from volatilization in the risk assessments, except for fumigant pesticides and pesticides used in ULV applications for mosquito control. For some pesticides and some populations, volatilization is the primary source of exposure. In many cases, volatilization drift has caused serious harm to people.⁹ In monitoring studies conducted by the California Air Resources Board and Department of Pesticide Regulation¹⁰ and PANNA,¹¹ concentrations have been measured above levels of toxicological concern for acute, sub-chronic, and/or chronic/cancer toxicity, determined by comparison of estimated doses received from inhalation to doses EPA designates as Levels of Concern in recent FQPA risk assessments.

Thank you for the opportunity to present these comments.



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⁹ California Department of Pesticide Regulation Pesticide Illness Surveillance Program, <http://www.cdpr.ca.gov/docs/whs/pisp.htm>.

¹⁰ California Department of Pesticide Regulation Toxic Air Contaminant Program, Monitoring Reports, <http://www.cdpr.ca.gov/docs/emppm/pubs/tac/tacstdys.htm>.

¹¹ Drift Catcher Results, Pesticide Action Network North America, <http://www.panna.org/campaigns/driftCatcherResults.html>.