



CENTER FOR
FOOD SAFETY

2,4-D: New Use on Herbicide-Tolerant Corn and Soybean
Environmental Protection Agency, Mailcode 28221T
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Docket No. EPA-HQ-OPP-2014-0195

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Comments to EPA on EPA's Proposed Registration of Enlist Duo Herbicide Containing 2,4-D and Glyphosate for New Uses on Herbicide-Tolerant Corn and Soybean

The Center for Food Safety (CFS) hereby submits the following comments, including the attached scientific analysis in Appendix A, on the U.S. Environmental Protection Agency's (EPA's) proposed new registration of Dow Agrosciences' (Dow's) Enlist Duo herbicide, which contains the active ingredient 2,4-dichlorophenoxyacetic acid (2,4-D) and glyphosate, for proposed new uses on corn and soybean crops that have been genetically engineered to resistant the application of 2,4-D and glyphosate.

CFS is a national, nonprofit public interest and environmental advocacy organization working to protect human health and the environment by curbing the use of harmful food production technologies. In furtherance of this mission, CFS uses legal actions, groundbreaking scientific and policy reports, books and other educational materials, and grassroots campaigns, on behalf of its more than 500,000 members. CFS is a recognized national leader on the issue of GE organisms and pesticides, and has worked on improving their regulation and addressing their impacts continuously since the organization's inception in 1997.

Dow's proposed registration of Enlist Duo herbicide (GF-2726, EPA File Symbol 6217-AUO) is an end-use product containing 24.4% 2,4-D choline salt and 22.1% glyphosate,¹ with proposed uses on Dow's Enlist™ AAD-1 Corn, DAS-40278-9) (2,4-D resistant GE corn) and Enlist™ AAD-12 Soybean, DAS-68416-4 (2,4-D resistant GE soy) (collectively 2,4-D resistant GE corn and soybean or Enlist corn and soybean), which are sold under the same trademark name Enlist™. Dow has petitioned the Animal Plant Health and Inspection Service (APHIS) of the U.S. Department of Agriculture to deregulate its Enlist™ 2,4-D resistant corn and soybean.²

The comments submitted by CFS herein also incorporate by reference and supplement

¹ CFS uses the phrases "Enlist Duo Herbicide" and "2,4-D choline salt" interchangeably to refer to the proposed product for registration.

² See APHIS, 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, Draft Environmental Impact Statement—2013 (Jan. 2013).

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the detailed legal and scientific comments and supporting reference materials and studies that CFS submitted at earlier stages of this agency proposal, specifically, the 2012 notice of new use registration issued by EPA. CFS also incorporate by reference the many detailed comments and member comments previously submitted to EPA's ongoing registration review of the active ingredient 2,4-D.

CFS will not duplicate and repeat comments that it has already submitted numerous times, nor the detailed critiques and demands for lawful compliance and proper scientific analysis that EPA has yet to answer, address, or explain. Rather, these comments will incorporate previously unaddressed points and add to them with further deficiencies in EPA's proposed registration. In sum, EPA's proposed registration of 2,4-D choline salt for use on 2,4-D resistant corn and soybean violates all applicable statutes. EPA's assessment underestimates the true costs of the proposed registration, relies on unenforceable mitigation measures and voluntary stewardship programs, and is replete of unreliable assumptions and uncertainties. EPA has not made the requisite finding, mandated under FIFRA, to approve the proposed registration of 2,4-D choline salt on 2,4-D resistant GE corn and soybean. To the contrary, EPA's assessment demonstrates that the proposed registration of 2,4-D choline salt for use on 2,4-D resistant corn and soybean would result in unreasonable adverse effects to the environment, to the detriment of human health, sensitive species, the environment, and U.S. agriculture.

RELEVANT LEGAL STANDARDS

The Federal Insecticide, Fungicide, and Rodenticide Act

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to regulate the registration, use, sale, and distribution of pesticides in the United States. FIFRA defines pesticides broadly to include herbicides—"any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccants."³ Under FIFRA, EPA is "charged to consider the effects of pesticides on the environment."⁴

Pursuant to FIFRA, EPA oversees both initial registration of an active ingredient as well as any new uses of the registered active ingredient of a pesticide. FIFRA mandates that prior to approving any pesticide registration and any new uses of the pesticide, EPA consider the "impacts on human health, occupational risks, and environmental risks"⁵ of the proposed pesticide formulation and its proposed uses. FIFRA "protects human health and prevents environmental harms from pesticides" by requiring EPA to conduct a cost-benefit analysis of the pesticides.⁶ Under the Act, EPA cannot register the pesticide unless EPA concludes that the proposed new use "will not generally cause unreasonable adverse effects on the environment" when "perform[ing] its intended function" and "when used in accordance with widespread and commonly recognized practice."⁷ FIFRA defines "unreasonable adverse effects on the

³ 7 U.S.C. § 136(u)(2).

⁴ *Fairhurst v. Hagener*, No. CV-03-67-BU-SHE, 2004 U.S. Dist. LEXIS 30161, at *49 (D. Mont. Mar. 24, 2004).

⁵ EPA, Overview of Risk Assessment in the Pesticide Program (May 9, 2012), at http://www.epa.gov/pesticides/about/overview_risk_assess.htm.

⁶ *Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005).

⁷ 7 U.S.C. § 136a(c)(5).

environment” as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”⁸ The Act defines “environment” broadly to include “water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.”⁹ In sum, FIFRA’s broad statutory definition of the phrase “unreasonable adverse effects on the environment” mandates that EPA consider all economic, social and environmental risks, including risks that are interrelated and indirect results of the proposed registration, in the agency’s review of a proposed registration.

Section 3(c) of FIFRA states that a manufacturer must submit an application to register the use of a pesticide.¹⁰ Section 3(c) of FIFRA outlines two types of pesticide use registrations: unconditional or conditional.¹¹ Under Section 3(c)(5) of FIFRA, EPA shall register a pesticide if the agency determines that the pesticide “will perform its intended function without unreasonable adverse effects on the environment” and that “when used in accordance with widespread and commonly recognized practice[,] it will not generally cause unreasonable adverse effects on the environment.”¹² Alternatively, where there are data gaps and missing information, EPA can register a pesticide with conditions (conditional registration) under Section 3(c)(7) of FIFRA “for a period reasonably sufficient for the generation and submission of required data,” but only if EPA also determines that the conditional registration of the pesticide during that time period “will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.”¹³

FIFRA also mandates that, as part of the registration of a pesticide and its proposed uses, EPA shall classify the pesticide and its use as either “general use” or “restricted use.”¹⁴ Under FIFRA, EPA must classify a pesticide and its proposed use as “restricted use” if “the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator.”¹⁵

The culmination of the registration process is EPA’s approval of a label for the pesticide, including use directions and appropriate warnings on safety and environmental risks. It is a violation of FIFRA for any person to sell or distribute a “misbranded” pesticide.¹⁶ A pesticide is misbranded if the “labeling accompanying it does not contain directions for use which ... if complied with ... are adequate to protect health and the environment.”¹⁷

The Federal Food, Drug, and Cosmetic Act

⁸ 7 U.S.C. § 136(bb) (emphasis added).

⁹ 7 U.S.C. § 136(j).

¹⁰ 7 U.S.C. § 136a(c)(1); 40 C.F.R. § 152.42.

¹¹ 7 U.S.C. § 136a(c)(5), (7).

¹² 7 U.S.C. § 136a(c)(5).

¹³ 7 U.S.C. § 136a(c)(7)(C).

¹⁴ 7 U.S.C. § 136a(d)(1)(A).

¹⁵ 7 U.S.C. § 136a(d)(1)(C).

¹⁶ 7 U.S.C. § 136j(a)(1)(E).

¹⁷ 7 U.S.C. § 136(q)(1)(F).

The Federal Food, Drug, and Cosmetic Act (FFDCA)¹⁸ prohibits the introduction of “adulterated” food into interstate commerce.¹⁹ The Act requires that where use of a pesticide will result in any pesticide residue being left on food, the EPA must either set a “tolerance” level for the amount of allowable pesticide residue that can be left on the food, or set an exemption of the tolerance requirement.²⁰ The tolerance or exemption requirements apply to raw agricultural commodities such as DAS-402780-9 corn and DAS-68416-4 soybeans.²¹

The FFDCA mandates EPA to “establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the EPA Administrator determines that the tolerance is safe”.²² For a tolerance level to be “safe,” the statute requires EPA determine “that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.”²³ “Aggregate exposure” includes not only dietary exposure through food consumption, but also exposure from all nonoccupational sources, including “exposures through water and residential uses,” as well as the cumulative effects of the particular pesticide’s residues “and other substances that have a common mechanism of toxicity.”²⁴ The Act further requires that, in determining the “safe” tolerance level, EPA must specifically consider potential routes of exposure to infants and children, and apply additional margin of safety for the pesticide residue and other sources of exposure to ensure that the tolerance level will be safe for infant and children.²⁵

Endangered Species Act

As recognized by the Supreme Court, the ESA is “the most comprehensive legislation for the preservation of endangered species ever enacted by any nation.”²⁶ The ESA’s statutory scheme “reveals a conscious decision by Congress to give endangered species priority over the ‘primary missions’ of federal agencies.”²⁷ Federal agencies are obliged “to afford first priority to the declared national policy of saving endangered species.”²⁸

Section 7(a)(2) of the ESA requires every federal agency to consult the appropriate federal fish and wildlife agency—Fish and Wildlife Service (FWS), in the case of land and freshwater species and the National Marine Fisheries Service (NMFS) in the case of marine species—to “insure” that the agency’s actions are not likely “to jeopardize the continued

¹⁸ 21 U.S.C. § 301 *et seq.*

¹⁹ 21 U.S.C. § 331.

²⁰ 21 U.S.C. § 346a(1).

²¹ 21 U.S.C. § 321(r) defines “raw agricultural commodities” as “any food in its raw or natural state, including all fruits that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing.”

²² 21 U.S.C. § 342a(2)(A) (emphasis added); *see also* 40 C.F.R. § 180.1(f).

²³ 21 U.S.C. § 346a(2)(A)(ii).

²⁴ 21 U.S.C. § 346a; *see Natural Res. Def. Council v. Whitman*, No. C 99-03701-WHA, 2001 WL 1221774 (N.D. Cal. Nov. 7, 2001).

²⁵ 21 U.S.C. § 346a(c).

²⁶ *Tenn. Valley Authority v. Hill*, 437 U.S. 153, 180 (1978).

²⁷ *Id.* at 185.

²⁸ *Id.*

existence” of any listed species or “result in the destruction or adverse modification” of critical habitat.²⁹ The ESA’s implementing regulations broadly define agency action to include “all activities or programs of any kind authorized, funded or carried out ... by federal agencies,” including the granting of permits and “actions directly or indirectly causing modifications to the land, water or air.”³⁰ A species’ “critical habitat” includes those areas identified as “essential to the conservation of the species” and “which may require special management considerations or protection.”³¹

To facilitate compliance with section 7(a)(2)’s prohibitions on jeopardy and adverse modification, the ESA requires each federal agency that plans to undertake an action to request information from the expert agency “whether any species which is listed or proposed to be listed [as an endangered species or a threatened species] may be present in the area of such proposed action.”³² If FWS/NMFS advises the agency that listed species or species proposed to be listed may be present, the agency must then prepare a biological assessment for the purpose of identifying any such species that are likely to be affected by the proposed agency action.³³

If, based on a biological assessment, an agency determines that its proposed action may affect any listed species and/or their critical habitat, the agency generally must engage in formal consultation with FWS/NMFS.³⁴ At the end of the formal consultation, FWS/NMFS must provide the agency with a “biological opinion” detailing how the proposed action will affect the threatened and endangered species and/or critical habitats.³⁵ If FWS/NMFS concludes that the proposed action will jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat, the biological opinion must outline “reasonable and prudent alternatives” to the proposed action that would avoid violating ESA section 7(a)(2).³⁶

Pending the completion of formal consultation with the expert agency, an agency is prohibited from making any “irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures.”³⁷

Migratory Bird Treaty Act

The Migratory Bird Treaty Act (MBTA) implements the obligations of the U.S. under several international treaties and conventions for the protection of migratory birds.³⁸ The MBTA mandates that proposed projects must avoid the take of migratory birds entirely and must

²⁹ 16 U.S.C. § 1536(a)(2); *see also* 50 C.F.R. § 402.01(b).

³⁰ 50 C.F.R. § 402.02 (emphasis added).

³¹ 16 U.S.C. § 1532(5)(A).

³² 16 U.S.C. § 1536(c)(1); *see also* 50 C.F.R. § 402.12(c).

³³ *Id.*

³⁴ 50 C.F.R. § 402.14.

³⁵ 16 U.S.C. § 1536(b); 50 C.F.R. § 402.14.

³⁶ 16 U.S.C. § 1536(b)(3)(A).

³⁷ 16 U.S.C. § 1536(d).

³⁸ 16 U.S.C. § 701.

minimize the loss, destruction, and degradation of migratory bird habitat.³⁹ The vast majority of U.S. native birds are protected under the MBTA, even those that do not participate in international migrations.⁴⁰ Under the MBTA, “[n]o person may take, possess, import, export, transport, sell, purchase, barter, or offer for sale, purchase, or barter, any migratory bird, or the parts, nests, or eggs of such bird except as may be permitted under the terms of a valid permit.”⁴¹

COMMENTS SUMMARY

As analyzed in detail in the attached Appendix A, EPA’s proposed registration of 2,4-D choline salt on Dow’s 2,4-D resistant GE corn and soybean, two crops that are specifically engineered to resist the application of Dow’s 2,4-D, marks a significant departure from existing use patterns of 2,4-D on existing varieties of corn and soybean. The novelty of the proposed new use on the two most widely planted agricultural crops in the United States demands that EPA carefully consider the “economic, social, and environmental costs” associated with the proposed new uses in its risk assessment.⁴² EPA cannot approve the proposed registration of 2,4-D choline salt on 2,4-D resistant GE corn and soybean if the agency’s assessment reveals that the proposed registration and uses may result in unreasonable adverse effect on the environment. EPA must also ensure that “there is a reasonable certainty that no harm to humans, including sensitive populations, will result from aggregate exposure” to 2,4-D.⁴³ EPA’s current assessment fails to meet these standards. To the contrary, EPA’s assessment demonstrates that the use of the proposed registration would result in unreasonable adverse effect on the environment. EPA must conduct a new risk assessment before moving forward with the proposed approval of Enlist Duo Herbicide for use on 2,4-D resistant GE corn and soybean.

I. EPA’s Assessment Underestimates the True Costs of the Proposed Registration of Enlist Duo 2,4-D Choline Salt for Use on 2,4-D Resistant Corn and Soybean, Which Far Outweigh the Claimed Benefits of EPA’s Proposed Approval.

As explained in detail in the attached appendix A, EPA ignores the true costs of the proposed use approval on human health, U.S. agriculture, and the environment, by underestimating the significant change in use patterns of 2,4-D that will result from the proposed registration of Enlist Duo herbicide for use on 2,4-D resistant, GE corn and soybean. EPA’s assessment also underestimates the potential adverse effects of registering Enlist Duo herbicide by limiting its assessment to 2,4-D only, despite the fact that the Enlist Duo herbicide also consists of another active ingredient, glyphosate, and various undisclosed inert ingredients. Not only is EPA’s assessment narrowly focused on 2,4-D, the agency also based the majority of its assessment using other formulations of 2,4-D rather than the 2,4-D choline salt being considered in the proposed registration. Similarly, EPA’s risk assessment fails to adequately address the toxicity of the metabolites and degradates of 2,4-D. EPA’s risk assessment thus entirely fails to assess the potential adverse effects stemming from the actual formulation of 2,4-D choline salt product being proposed for use on 2,4-D resistant GE corn and soybean.

³⁹ *Id.* § 701–12.

⁴⁰ *See* 50 C.F.R. § 10.13.

⁴¹ *Id.* § 21.11.

⁴² 7 U.S.C. § 136(bb).

⁴³ 21 U.S.C. § 346a.

As explained in detail in the attached Appendix A, EPA's assessment also completely ignores numerous interrelated costs to the environment and U.S. agriculture from the proposed registration of 2,4-D choline salt on 2,4-D resistant GE corn and soybean. EPA identifies weed resistance to 2,4-D as a significant risk, but disregards the cost of weed resistance on U.S. agriculture and the environment by relying on a voluntary industry stewardship program. EPA also acknowledges that drift of the proposed 2,4-D choline salt is a reality, yet disregards this significant risk without any analysis to the significant economic damage to U.S. agriculture and the environment from 2,4-D drift. EPA also disregards out of hand harms from the proposed new use of 2,4-D choline salt to honey bees and pollinators, as well as other beneficial organisms, and the cumulative impacts harm to such vital species may have on U.S. agricultural production. Finally, EPA entirely fails to analyze the interrelated economic and social costs of approving the proposed pesticide for use specifically on crops genetically engineered to withstand their very application, discussed in detail in the attached Appendix A and below, at Section II.

Thus, EPA's risk assessment ignores the true costs of proposed registrations of 2,4-D choline salt on human health, U.S. agriculture and the environment, in violation of FIFRA's mandate that EPA consider the effects of the proposed registration by critically comparing the costs and benefits of the proposed agency action.

II. EPA Fails to Consider the Interrelated Economic and Social Costs of Approving 2,4-D Choline Salt, an Integral Part to the Introduction and Adoption of 2,4-D Resistant GE Crop System.

EPA's risk assessment is fundamentally flawed because the agency entirely failed to address the interrelated economic and social costs of the agency's proposed approval. EPA acknowledges that the proposed use on 2,4-D resistant crops is "a new use pattern for the 2,4-D component" of the proposed 2,4-D choline salt formulation, but fails to assess and consider the interrelated economic and social costs of approving the pesticide component of the new 2,4-D GE regime. EPA's approval of the proposed use of 2,4-D choline salt on corn and soybean genetically engineered to withstand the application of 2,4-D would continue and exasperate the current trend of herbicide use, the development of weed resistance, the risk of transgenic contamination and their associated economic and social harms to U.S. farms, the threat to U.S. organic industry, the elimination of non-GE choice for domestic and international consumers, and further the concentration of the seed market.

Transgenic Contamination

EPA entirely fails analyze the likelihood of harm from transgenic contamination of 2,4-D resistant GE corn and soybean. The term "transgenic contamination" refers to the unintended comingling of GE crops with non-GE crops. Transgenic contamination "can occur through pollination of non-genetically engineered plants by genetically engineered plants or by the

mixing of genetically engineered seed with natural or non-genetically engineered seed.”⁴⁴ Transgenic contamination may occur through a variety of other pathways, including: seed spillage, seeds remaining in seed cleaning and other farm equipment, volunteer growth, cross-pollination not just by wind, but by insect or animal, post-harvest mixing in the grain-handling system, weather events, and simple human error.

In the Union of Concerned Scientist (UCS) report, “*Gone to Seed*,” UCS found that about 50% or more of the certified non-GE corn, canola, and soybean seed has been contaminated with transgenes.⁴⁵ The level of contamination was typically far greater than the minimum levels that can be detected. “*Gone to Seed*” demonstrated that the frequency and levels of contamination of soybean seed was found to be about as high as for corn. Soybeans are largely self-pollinating (do not pollinate other soybean plants’ flowers very often), while corn is highly out-crossing. Therefore, the contamination of soybean seed is likely to be largely from causes other than cross-pollination. Such causes could include seed mixing or human error, and the contamination suggests that these sources may be at least as important as cross-pollination, and must also be analyzed.

In another report, “*A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops*,” UCS enlisted the assistance of several academic experts in agricultural sciences to determine whether GE pharmaceutical-producing crops could be kept out of food. This report demonstrates how difficult this is, even for pharmaceutical crops that would be grown on small acreage and under stringent confinement. The authors of this report examined confinement methods, such as field separation, cleaning of farm equipment, segregation of seed, and others, and found that it would still be difficult to ensure the absence of contamination.⁴⁶

Another route of contamination that is unpredictable, but likely over time, is human error. Two academic ecologists address this in a peer-reviewed paper, and conclude that contamination by GE crops due to human error or other means has occurred numerous times, and is likely to continue to occur. This paper documents many instances where GE crops are known to have contaminated non-GE crops or food.⁴⁷ Thus, transgenic contamination through human error and human behavior, such as composting, exchanging seeds, or mislabeling seeds, must be addressed in an EIS.

Past Contamination Episodes

Past contamination episodes from GE crops, specifically the past contamination incident with GE StarLink corn, further illustrate why contamination is an impact that must be adequately

⁴⁴ *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007), at *5, *aff’d*, 541 F.3d 938 (9th Cir. 2008).

⁴⁵ M. Mellon and J. Rissler, Union of Concerned Scientists, *Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply* (2004).

⁴⁶ David Andow et al., Union of Concerned Scientists, *A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops* (Dec. 2004).

⁴⁷ M. Marvier and R. Van Acker, *Can Crop Transgenes be Kept on a Leash?* 3 *Frontiers in Ecology and the Env’t.* 95-100 (2005).

considered in an EIS here. Transgenic contamination is widespread and has been documented around the world.⁴⁸ A report from an environmental organization documented 39 cases in 2007 and more than 200 in the last decade.⁴⁹ Contamination incidents have not been limited to a single crop or region; corn, rice, canola and other crops have all been contaminated by transgenes

The StarLink corn contamination showed how much damage a GE-crop can do to the agricultural economy. StarLink is a variety of corn genetically engineered to produce the Cry9C insecticidal toxin to kill certain corn pests.⁵⁰ Due to the concerns of leading allergists advising the EPA that this toxin might cause food allergies, the EPA approved StarLink in 1998 only for animal feed and industrial uses such as ethanol production, but not for human consumption. EPA had a binding agreement with the developer of StarLink, Aventis CropScience. According to this agreement, all Aventis-affiliated seed dealers would sell StarLink corn seed to farmers only if the farmers would agree to the following conditions: 1) plant a buffer strip 660 feet wide around StarLink corn plots to mitigate cross-fertilization of neighboring corn fields; and 2) segregate StarLink corn and buffer strip corn for distribution only to non-food channels.⁵¹ Aventis CropScience assured the EPA that with these measures it could keep StarLink out of the human food supply.

StarLink corn was grown for only three years, from 1998 to 2000, on at most 341,000 acres, or 0.43% of total U.S. corn acreage (year 2000).⁵² Despite the limited acreage planted in StarLink, and the conditions attaching to its cultivation, testing initiated by public interest groups and subsequently conducted by the U.S. Food and Drug Administration (FDA) found that over

⁴⁸ See, e.g., *New Study Finds GM Genes in Wild Mexican Maize*, NEW SCIENTIST, Feb. 21, 2009; Rex Dalto *Modified Genes Spread to Local Maize: Findings Reignite Debate over Genetically Modified Crops*, 456 NATURE 7219, 149 (2008); Inst. for Nutrition and Food Tech. (INTA), *Chile Enters the List of Countries Contaminated with GMOs: A Report from INTA Has Detected Transgenic Contamination of Maize in the Fields of Central Chile* (Oct. 22, 2008), available at <http://www.nwrae.org/content/chile-enters-list-countries-contaminated-gmos-0>; Graeme Smith, *Illegal GM Crops Found In Scotland*, HERALD, Sept. 13, 2008; Elizabeth Rosenthal, *Questions on Biotech Crops with No Clear Answers*, N.Y. TIMES, June 6, 2006; *Gene Flow Underscores Growing Concern over Biotech Crops*, ASSOCIATED PRESS, Sept. 22, 2004; Andrew Pollack, *Can Biotech Crops Be Good Neighbors?*, N.Y. TIMES, Sept. 26, 2004; Lyle F. Friesen et al., *Evidence of Contamination of Pedigreed canola (Brassica napus) Seedlots in Western Canada with Genetically Engineered Herbicide Resistance Traits*, 95 AGRON. J. 1342-1347 (2003); Simon Jeffery, *Rogue genes: An Unauthorised Strain of GM Crops Has Been Found Across England and Scotland.*, GUARDIAN, Aug. 16, 2002; Alex Roslin, *Modified Pollen Hits Organic Farms: Genetically Altered Strains Spread by Wind*, TORONTO STAR, Sept. 30, 2002; Fred Pearce, *The Great Mexican Maize Scandal*, NEW SCIENTIST 2347, June 15, 2002.

⁴⁹ GREENPEACE INT'L. *GM CONTAMINATION REGISTER REPORT 2007* (Feb. 28, 2008), available at <http://www.greenpeace.org/international/press/reports/gm-contamination-register-2007>; see also Carey Gillam, U.S. Organic Food Industry Fears GMO Contamination, REUTERS NEWS SERV., Mar. 12, 2008, available at <http://www.reuters.com/article/idUSN1216250820080312>.

⁵⁰ For the following discussion of StarLink, see Bill Freese, Friends of the Earth, *The StarLink Affair*, (July 2001), available at www.foe.org/safefood/starlink.pdf (last accessed July 11, 2011).

⁵¹ **EPA Cry9C Fact Sheet, Biopesticide Fact Sheet: *Bacillus thuringiensis* subspecies *tolworthi* Cry9C Protein and the Genetic Material Necessary for Its Production in Corn (006466)** (Nov. 2000).

⁵² SAP StarLink, FIFRA Scientific Advisory Panel to the EPA, *Assessment of Additional Scientific Information Concerning StarLink Corn*, SAP Report No. 2001-09 (from meeting on July 17/18, 2001).

300 corn products in grocery stores around the country were contaminated with StarLink. The USDA found StarLink contaminating 9-22% of grain samples.⁵³

The extent of the contamination is startling when one considers that StarLink never represented more than 0.43% of U.S. corn acreage. While post-harvest mixing was responsible for much of the contamination, there is also abundant evidence that popcorn, sweet corn, white corn and seed corn stocks were also contaminated with StarLink.⁵⁴ These latter findings strongly suggest that StarLink pollen blown by the wind fertilized conventional corn, despite the 660-foot border strip requirement. In fact, a USDA-sponsored testing program for seed companies that had never been licensed to grow StarLink found that nearly one-fourth of these seed firms (71 of 288) had some corn lines that tested positive for StarLink. USDA had to buy back nearly 450,000 units of StarLink-contaminated seed corn at a cost of several million dollars to prevent further spread of StarLink in future years. Tainted seed dated anywhere from production year 1997 to 2001.⁵⁵ The estimated overall cost of this major contamination debacle to Aventis CropScience, StarLink's developer, as well as farmers and the food industry, has been estimated at \$1 billion.⁵⁶

Recent contamination events in other crops illustrate how difficult it is to prevent contamination at detectable and economically important levels. Of particular interest is the recent contamination of rice by the unapproved GE LL601 "LibertyLink" rice. This type of GE rice was grown only in limited-acreage field tests, rather than on a commercial scale, and under the regulatory auspices of APHIS, which includes confinement requirements. It had not been grown at all for several years when contamination of the U.S. rice supply was detected at low levels that have nonetheless caused great economic harm to the U.S. rice industry. At least one identified source of contamination by LL601 occurred at Louisiana State University (LSU), where one of the scientists in charge has claimed that they exceeded APHIS confinement recommendation considerably, but still experienced contamination.⁵⁷ Despite an extensive investigation, USDA was unable to determine exactly how the contamination occurred.⁵⁸

In late 2010, contamination stemming from a 2005 field trial of Roundup Ready Bentgrass was discovered in Ontario, Oregon, four miles from the field trial location in Idaho.⁵⁹ Five years later, contamination is widespread and rampant, covering an estimated 27 square miles. The experimental GE grass, developed by Scotts Company and Monsanto, was field

⁵³ A. Shadid, *Genetically engineered corn appears in one-tenth of grain tests*, *Boston Globe*, May 3, 2001. Shadid, A. "Testing shows unapproved, altered corn more prevalent than thought," *Boston Globe*, May 17, 2001.

⁵⁴ Press Release, USDA, *USDA purchases Cry9C affected corn seed from seed companies*, (June 15, 2001), formerly accessible at: www.usda.gov/news/releases/2001/06/0101.htm; A. Hovey, *StarLink protein found in other crops*, *Lincoln Star Journal*, Mar. 29, 2001.

⁵⁵ Bill Freese, *Friends of the Earth, The StarLink Affair*, (July 2001), available at www.foe.org/safefood/starlink.pdf (last accessed July 11, 2011).

⁵⁶ *Tests to Detect Allergens in Altered Foods Fall Short*, ST. LOUIS POST-DISPATCH, June 12, 2002.

⁵⁷ G. Vogel, *Tracing the transatlantic spread of GM rice*, 313 *Science* 1714 (2006).

⁵⁸ USDA, REPORT OF LIBERTY LINK RICE INCIDENTS 1 (2007), available at www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf.

⁵⁹ Mitch Lies, *GMO bentgrass found in Eastern Oregon*, CAPITAL PRESS, Nov. 9, 2010, available at <http://www.capitalpress.com/oregon/ml-gmo-bentgrass-111210>.

tested in Oregon in trials that had ended over five years earlier.⁶⁰ The field trials were successfully challenged in litigation against USDA for its failure to comply with the National Environmental Policy Act in assessing them.⁶¹ During that litigation, EPA scientists found the GE grass had escaped the trial, cross-pollinated with wild varieties and was growing in a protected national grassland over twelve miles away.⁶² USDA fined Scotts \$500,000⁶³ in 2007 and presumed the issue resolved, until the shocking discovery of new populations again growing in the wild over five years later.⁶⁴ The expert wildlife agency FWS, in the most recent draft of a Biological Opinion on the effects of Roundup Ready Bentgrass, prepared pursuant to the ESA, also noted another contamination incident: the escape of GE Roundup Ready Sugar Beets into potting soil being sold to the public. FWS noted, the “[r]ecent escape of G[enetically] M[odified] sugar beets into compost sold to homeowners illustrates the potential for products to move outside of their intended market. Sugar beets are . . . wind pollinated and were thought to be well controlled by the growers using the product. Despite best management practices, escape of the transgenes occurred.”⁶⁵ (In 2010, after APHIS engaged in consultation FWS under the ESA’s Section 7 consultation mandate, FWS concluded that allowing Roundup Ready bentgrass’ commercialization would likely cause the extinction of two endangered plants in Oregon because the engineered bentgrass would spread the transgenic resistance to wild relatives, which would then take over the species’ critical habitat and be impossible to eradicate.⁶⁶).

Courts have found these and other contamination incidents sufficient evidence of the likelihood of contamination. “The Court finds it significant that there have been instances in which genetically engineered corn, cotton, soybean and rice have mixed with and contaminated the conventional crops.”⁶⁷ The “significance” of these events is further evidence that 2,4-D resistance can cause significant impacts through contamination, whether via gene flow or other pathways. These impacts must be analyzed in an EIS.

Market Rejection of Contaminated Organic and Conventional GE-Sensitive Products

EPA also ignores the potential impacts on organic farming and conventional farming from contamination by 2,4-D resistant corn. The example of rice farmers’ huge financial loss due to market rejection of LL601-contaminated rice is illustrative.⁶⁸ Affected rice farmers were forced to sue Bayer CropScience, the developer of LL601, in an effort to recover their losses. In response to a petition from Bayer CropScience, APHIS subsequently deregulated LL601, but did nothing to redress the economic harms to rice farmers. Rather than accept responsibility for the

⁶⁰ *Id.*

⁶¹ *ICTA*, 473 F.Supp.2d at 28.

⁶² *ICTA*, 473 F.Supp. at 21; Jay R. Reichman, et al., *Establishment of Transgenic Herbicide-Resistant Creeping Bentgrass (Agrostis solonifera L.) in Nonagronomic Habitats*, MOLECULAR ECOLOGY (2006).

⁶³ Christopher Doering, *Scotts to Pay \$500,000 Fine over Biotech Bentgrass*, REUTERS, Nov. 26, 2007, available at <http://www.reuters.com/article/2007/11/27/us-scotts-usda-idUSN2643698720071127>.

⁶⁴ Mitch Lies, *Coba Presses Scotts for Bentgrass Plan*, CAPITAL PRESS, Feb. 10, 2011, available at <http://www.capitalpress.com/oregon/ml-coba-letter-021111>.

⁶⁵ FWS, *Draft Biological Opinion, Roundup Ready Bentgrass* (2010) (included in references submitted with comments).

⁶⁶ *Id.*

⁶⁷ See, e.g., *Sugar Beets I*, 2010 WL 964017, at *2.

⁶⁸ R. Weiss, *Gene-altered profit-killer*, *Washington Post*, Sept. 21, 2006.

episode, Bayer CropScience blamed farmers and an “Act of God” for the contamination episode.⁶⁹ Just months later, still another unapproved GE rice variety developed by Bayer CropScience, LL604, was found contaminating a popular variety of conventional rice sold to farmers as seed rice (Clearfield 131). APHIS responded by issuing several emergency action notifications to distributors of Clearfield 131 to halt sales of the contaminated seed rice.⁷⁰ As a result, rice farmers in the South experienced a severe shortage of seed rice for the 2007 season.⁷¹ APHIS conducted an investigation into the contamination episodes, but was unable to determine precisely how they occurred.⁷² Courts have subsequently found Bayer negligent in every bellwether case, with total damages estimated at a billion dollars.⁷³ The litigation was eventually settled in part for \$750 million dollars.⁷⁴

The genetic engineering of papaya in Hawaii (no other country in the world grows it) has also resulted in widespread contamination⁷⁵ and huge losses in export income to papaya growers there, and reduced prices, due to rejection of the GE papaya overseas.⁷⁶ U.S. corn exporters lose about \$300 million per year in exports due to European Union rejection of engineered corn.⁷⁷ Similarly, the potential approval in the U.S. of GE wheat would cause major disruptions in the global wheat economy, because foreign markets in Japan, Italy, France, Norway, South Korea, Taiwan, Egypt, the Philippines, Algeria, China, Indonesia, Malaysia and Thailand would reject contaminated wheat.⁷⁸ An assessment by an agricultural economist from Iowa State University revealed that if transgenic wheat were to be commercialized, U.S. wheat growers would lose between 43% and 52% of their total exports, resulting in a net loss in the price paid to farmers of between 32% and 35%.⁷⁹ Finally, the recent approval of Roundup Ready alfalfa is likely to significantly damage the U.S.’s approximately \$200 million a year alfalfa hay and seed export

⁶⁹ R. Weiss, *Firm Blames Farmers, ‘Act of God’ for Rice Contamination*, *Washington Post*, Nov. 22, 2006.

⁷⁰ USDA APHIS. *Statement by Dr. Ron DeHaven regarding APHIS hold on Clearfield CL131 long-grain rice seed*, Mar. 5, 2007. http://www.aphis.usda.gov/newsroom/content/2007/03/ge_riceseed_statement.shtml (last accessed July 7, 2011).

⁷¹ D. Bennett, *Arkansas’ emergency session on CL 131 rice*, Delta Farm Press, March 1, 2007.

⁷² USDA, *Report of LibertyLink Rice Incidents*, Oct. 2007, available at <http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf> (last accessed July 11, 2011).

⁷³ See, e.g., *In re Genetically Modified Rice Litigation*, 666 F.Supp.2d 1004 (E.D. Mo. Oct. 9, 2009); *In re Genetically Modified Rice Litigation*, 2009 WL 4801399 (E.D. Mo. Dec. 9, 2009).

⁷⁴ Andrew Harris and David Beasley, *Bayer Agrees to Pay \$750 Million to End Lawsuits Over Gene-Modified Rice*, Bloomberg News, July 1, 2011, available at <http://www.bloomberg.com/news/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.html>

⁷⁵ MELANIE BONDERA & MARK QUERY, HAWAII SEED, HAWAII PAPAYA: GMO CONTAMINATED 11-13, (2006) (finding that after the 1998 deregulation of PRSV resistant papaya, within six years contamination rates as high as 50% were found on the island of Hawaii); HAWAII SEED, FACING HAWAII’S FUTURE, HARVESTING ESSENTIAL INFORMATION ABOUT GMOS 44 (2006).

⁷⁶ GREENPEACE INT’L, THE FAILURE OF GE PAPAYA IN HAWAII (May 2006), available at <http://www.greenpeace.org/international/press/reports/FailureGEPapayainHawaii>

⁷⁷ Pew Initiative on Food and Biotechnology, *US v. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food* (2005) at 3-4.

⁷⁸ *Cost of Genetically Engineered Plants: Hearing before the Subcomm. on Domestic Policy of the H. Comm. on Oversight and Gov’t Reform*, 110th Cong. 7 (Mar. 13, 2008) (Statement of Todd Leake, Conventional and GE grain grower).

⁷⁹ *Id.*

market; many foreign importers will shift to other sources due to the high risk of contamination in the United States.⁸⁰

EPA also ignores the cost to organic and specialty crop producers to reduce the risk of transgenic contamination. Organic and specialty growers bear completely the onerous burden of reducing the risk of contamination, through changes to their production practice, imposition of buffer zones, and testing and certification of the purity of their products. Contamination of organic feed threatens entire organic industries, beyond producers of organic corn and soybean but also to organic dairy and livestock producers that rely on such organic feed.

Impacts on the Public's and Farmers Fundamental Right to Choose and Contamination's Environmental Component

Beyond the often severe economic harm to farmers and the loss of choice for farmers and consumers, transgenic contamination is first and foremost an environmental harm.⁸¹ The economic effects are an interrelated, direct result of the initial impact on the environment: “the alteration of a plant specie’s [*sic*] DNA through the transmission of the genetically engineered gene to [non-engineered plants].”⁸² Thus, as the Supreme Court held, the “injury has an environmental as well as an economic component.”⁸³ The loss of biodiversity due to contamination, and the potential elimination or reduction of conventional and organic varieties of corn is environmental injury.⁸⁴

Further, harm to organic production systems is also harm to the environment, because organic is an environmentally sustainable production system, in sharp contrast with transgenic crop systems. Consumers choose organic products in large part because organic agriculture is an ecologically beneficial agricultural model.⁸⁵ Organic agriculture results in healthier, more productive soils; elimination of synthetic pesticide and fertilizer use and associated adverse impacts; and increased biodiversity through a holistic production management system. Indeed, the very definition of organic production is a system that integrates “cultural, biological, and

⁸⁰ See *Roundup Ready Alfalfa FEIS*, at 58-59, 169-170, App. R at R-3, R-14 to R-15 (2011).

⁸¹ *Geertson Seed Farms*, 2007 WL 518624, at *9 (“An action which potentially eliminates or least greatly reduces the availability of a particular plant—here, non-engineered alfalfa—has a significant effect on the human environment.”).

⁸² *Id.* at *8 (“Here, the economic effects on the organic and conventional farmers of the government’s deregulation decision are interrelated with, and, indeed, a direct result of, the effect on the physical environment; namely, the alteration of a plant specie’s DNA through the transmission of the genetically engineered gene to organic and conventional alfalfa.”); *id.* at 11 (“As the Court explained, *supra*, however, economic interests that are interrelated with natural or physical environmental effects fall within NEPA’s zone of interests. The alfalfa farmer plaintiffs’ potential economic injury arises directly from the environmental impact of APHIS’s decision to deregulate Roundup Ready alfalfa.”).

⁸³ *Monsanto*, 130 S.Ct. at 2756 (“Respondents now seek injunctive relief in order to avert the risk of gene flow to their crops—the very same effect that the District Court determined to be a significant environmental concern for purposes of NEPA. The mere fact that respondents also seek to avoid certain economic harms that are tied to the risk of gene flow does not strip them of prudential standing.”).

⁸⁴ *Geertson Seed Farms*, 2007 WL 518624, at *9 (“An action which potentially eliminates or least greatly reduces the availability of a particular plant—here, non-engineered alfalfa—has a significant effect on the human environment.”).

⁸⁵ See, e.g., Organic Trade Association, *Consumer Profile Facts*, <http://www.ota.com/organic/mt/consumer.html>.

mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.”⁸⁶ These ecological benefits lie at the core of the organic industry and drive consumer choices.

Seed Market Concentration

EPA also entirely fails to address the interrelated impact on seed market compensation that stems from its proposed approval of 2,4-D choline salt use on 2,4-D resistant GE corn and soybean. Seed companies have aggressively undermined independent researchers’ ability to fully investigate their patented crops’ performance.⁸⁷ Research and development suffer from seed market concentration. Seed companies often want the right to approve all publications, which researchers find unreasonable. This chills research on GE crops.

Research and development is not the only area that suffers from seed market concentration. The privatization and concentration of the world’s seed supply is a serious and continuously evolving problem, compounded with each new GE crop deregulation. “It is estimated that the top ten seed corporations around the globe hold 49-51% of the commercial seed market, and the top ten agro-chemicals control 84% of the agrochemicals market. Likewise, all genetically modified (GM) seeds are bio-patented by multinational corporations and 13 commercial corporations own 80% of the GM food market.”⁸⁸

The increased seed market concentration has already made it hard for farmers to purchase conventional corn and soy seeds.⁸⁹ With increased seed market concentration, the once diverse selection of conventional seed is disappearing. As a result, farmers are forced to purchase GE seed and with that pay hefty technology fees.

The Department of Justice has noticed the effects. In August of 2009, it announced that it would investigate anticompetitive conduct in the seed industry, the recent ability to patent seed having led to unprecedented seed industry concentration. Major seed companies set out to acquire ownership of, or control over, smaller firms, leading to the number of corn seed producers dropping from over 300 to merely a handful of large firms able to muster the capital for genetic manipulation through laboratory operations. The commercialization of the 2,4-D choline salt for use on Dow’s 2,4-D resistant corn and soybean will influence Dow’s control over seed process and market consolidation. The general public is adversely affected, as increased seed prices are reflected in the cost of food.

⁸⁶ 7 C.F.R. § 205.2 (2011).

⁸⁷ *Sugar Beets I*, Huber Decl., ¶¶ 17-18 (April 13, 2010); Emily Waltz, *Under Wraps*, 27 *Nature Biotechnology* 880, 882 (2009).

⁸⁸ Yamuna Ghale and Bishnu Raj Upreti, *Concentration and Monopolisation of Seed Market: Impact on Food Security and Farmer’s Rights in Mountains*, available at http://docs.google.com/viewer?a=v&q=cache%3A3CPrhC0TuVIJ%3Awww.mtnforum.org%2Frs%2Fol%2Fcounter_docdown.cfm%3FfID%3D2056.pdf+seed+market+concentration&hl=en&gl=us&sig=AHIEtbTwpX0MzR5HZZ8CUBA8qoWofinQvw&pli=1.

⁸⁹ CFS, *Monsanto v. US Farmers*, Jan. 13, 2005, available at <http://truefoodnow.files.wordpress.com/2009/12/cfsmonsantovsfarmerreport1-13-05.pdf>.

As noted in the Legal Standards section above, in considering the proposed registration, EPA must consider all “economic, social, and environmental costs and benefits for the use of” the proposed 2,4-D choline salt. EPA recognizes that the agency’s approval of 2,4-D choline salt use on 2,4-D resistant corn and soybean will facilitate the use of 2,4-D on existing and future GE corn and soybean crop acreage, yet fails to consider the numerous interrelated economic and social costs of the agency’s proposed approval. EPA must consider these interrelated risks in its assessment of the proposed 2,4-D choline salt use on 2,4-D resistant corn and soybean.

III. EPA Fails to Adequately Assess the Risks Posed by the Proposed Registration of Enlist Duo to Farmers, Pesticide Applicators, and Other Exposed Populations

Under FIFRA, EPA cannot approve a proposed registration or proposed use if there would be “unreasonable adverse effects on the environment” from the pesticide use, defined as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.” The proposed registration would pose unreasonable risks to farmers, pesticide applicators and other exposed populations. In the context of the Enlist Duo assessment, EPA has ignored or summarily dismissed key epidemiology studies linking 2,4-D exposure to cancer and Parkinson’s disease, among other conditions; ignored a study pointing to potentially serious health impacts from exposure to 2,4-D and glyphosate, but to neither used alone; ignored numerous “incident” reports of health harms from exposure to 2,4-D, including several deaths, that are otherwise known to the Agency; failed to integrate this evidence of human harm with findings from highly artificial, registrant-conducted, animal studies; and failed to generate or obtain reliable information on the serious issue of 2,4-D-related dioxin contamination of 2,4-D formulations and the environment, as explicitly requested by CFS in prior comments. These assessment failures make it imperative that EPA reject the proposed registration, and postpone any decision until adequate analysis is undertaken in the context of EPA’s 2,4-D registration review.

IV. EPA’s Assessment Demonstrates that the Proposed Registration of Enlist Duo 2,4-D Choline Salt for Use on 2,4-D Resistant Corn and Soybean May Result in Unreasonable Adverse Effects on the Environment.

EPA’s proposed registration is unlawful because the agency’s own risk assessment identifies numerous potential risks to human health and the environment. As discussed in detail in the attached appendix, EPA’s Proposed Registration document and the agency’s Ecological Risk Assessment identified numerous potential risks to species and the environment from the proposed registration of 2,4-D choline salt on 2,4-D resistant GE corn and soybean. As explained in the attached appendix, EPA’s risk assessment estimated levels of exposure that far exceed the agency’s acceptable risk quotient for several animal species and plants, including crops that are significant to U.S. agriculture. Similarly, EPA’s risk assessment acknowledges weed resistance as an adverse effect to the proposed use of 2,4-D choline salt on 2,4-D resistant corn and soybean.

Yet, EPA summarily dismissed such risks, concluding without any supporting data that any such adverse risks to wildlife and plants may be mitigated with a 30-foot buffer zone. As explained in detail in the attached appendix, EPA’s risk assessment and proposed approval is

flawed because EPA bases its conclusion that the proposed approval would not result in unreasonable adverse effect on the environment by relying on unsubstantiated mitigation measures and voluntary stewardship programs, EPA's assessment does not provide any support on (1) the agency's conclusion that the buffer zone would adequately reduce or mitigate the risks to wildlife and plants and (2) the agency's assumption that the 30-foot buffer zone requirement would be followed. EPA's repeated reliance on unanalyzed, uncertain mitigation measures to do away with the unreasonable adverse effects of the proposed registration violates the agency's duty under FIFRA.

Moreover, as explained in detail in the attached appendix, EPA's proposed registration is also unlawful in light of EPA's duties under FIFRA and the FFDCA to consider the aggregate harm from exposure to 2,4-D. As explained in detail in the attached appendices, EPA's assessment of risk from human exposure to 2,4-D is legally deficient because the agency relied on flawed assumptions, ignored critical medical literature, and applied the wrong safety factor in its modeling and analyses.

Finally, EPA's proposed approval is also unlawful because, despite the identification of numerous risks stemming from the proposed uses of 2,4-D choline salt on 2,4-D resistant GE corn and soybean and the agency's admission that mitigation measures such as buffer zones and mitigation measures are necessary, EPA has not indicated that the agency will approve the proposed registration and use as a "restricted use", in violation of the agency's duty under FIFRA.⁹⁰ In reevaluating the risks associated with the proposed 2,4-D choline salt use on 2,4-D resistant GE corn and soybean, the agency must also consider the proper classification of the proposed registration.

III. EPA's Assessment of the Impacts to Threatened and Endangered Species from the Proposed Registration of Enlist Duo 2,4-D Choline Salt for Use on 2,4-D Resistant Corn and Soybean Is Legally Deficient.

As explained in detail in the attached appendix, EPA's assessment of risks to federally listed threatened and endangered species and its "no effect" finding is legally deficient. EPA should reassess the potential effects on threatened and endangered species, and consult the expert FWS/NMFS agencies as required under Section 7 of the ESA.

IV. EPA's Assessment Neglects Any Potential Impacts on Migratory Birds.

As explained in the attached appendix, EPA's assessment acknowledged that the proposed registration of 2,4-D choline salt on 2,4-D resistant corn and soybean poses potential risks to avian species, yet EPA failed to properly consider and disclose its obligations to migratory birds, never even mentioning its responsibilities under the MBTA. The MBTA prohibits the take of migratory birds entirely and mandates that the loss, destruction, and degradation of migratory bird habitat must be minimized. If approved, 2,4-D choline salt would be used in fields visited by hundreds of species of birds protected under the MBTA. Rather than determining whether the proposed use of 2,4-D choline salt on 2,4-D resistant GE corn and

⁹⁰ See 7 U.S.C. § 136a(d).

soybean would have adverse effects on species protected under the MBTA, EPA simply ignores this significant issue. EPA must cure this defect by conducting a new risk assessment.

V. EPA's Proposed Registration Is Flawed and Premature in Light of the Ongoing Registration Review of 2,4-D.

As explained in the attached appendix, EPA is in the process of the agency's registration review of 2,4-D, whereby EPA critically examines 2,4-D in light of the latest science on its human toxicity, and to collect and evaluate data to assess the dioxin-related concerns in light of the Agency's ongoing review of dioxin toxicity. The ongoing registration review also involves a detailed assessment of use patterns, without which human health and other risks cannot be adequately evaluated. The proposed registrations would enable vastly increased use of 2,4-D, and undoubtedly open the door to off-label use of many other 2,4-D formulations; shift use of 2,4-D to considerably later in the season, with attendant increase in drift-related crop injury; would shift usage of 2,4-D in a manner that is highly likely to foster rapid evolution of 2,4-D resistance in weeds, with consequent harms to the environment and human health from increased herbicide use; may pose serious risks to non-target organisms via 2,4-D residues and metabolites, including 2,4-DCP and conjugates; threaten biodiversity through increased damage to field-edge habitats; and threaten endangered species and their critical habitat. For these reasons, EPA should defer any decision on the proposed registrations until it has completed its registration review of 2,4-D.

CONCLUSION

For the reasons described above and discussed in detail in the attached Appendix A, we request EPA to comply with FIFRA, FFDCFA, MBTA, and the ESA by critically considering the unreasonable adverse effects stemming from the change in use patterns of 2,4-D under Dow's proposed new use registration of 2,4-D choline salt applications on 2,4-D resistant GE corn and soybeans.

Submitted by,
Center for Food Safety