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Office of Pesticide Programs
U.S. Environmental Protection Agency
Mailcode 28221 T
1200 Pennsylvania Ave, NW
Washington, DC 20460

Re: Evaluation of 2,4-D Choline Salt Herbicide on Enlist Corn, Soybeans, and Cotton.
Docket Number: EPA-HQ-OPP-2016-0594

Dear Sir/Madam,

We are writing to express our disagreement with the U.S. Environmental Protection Agency's (EPA) recent decision to approve the registration of the chemical cocktail Enlist Duo. This new product registration will include uses for genetically engineered (GE) corn, soybean and cotton. EPA believes that Enlist Duo will "have a significant impact to weed management." To this end, EPA is proposing to expand Enlist Duo's registered uses to an additional 19 states.

At the crux of this amended assessment is the claim of "synergy" made by the registrant. The registrant, Dow AgroSciences, filed patent applications for Enlist Duo at the U.S. Patent Office claiming "synergy," which EPA had not evaluated. EPA states that it has since received data that does not support synergism between the glyphosate and 2,4-D combination. Specifically, EPA states, "Enlist Duo does not show any increased toxicity to plants and is therefore not of concern."[1] And while EPA's four page assessment on the matter, "*2,4-D Choline: Review of Seedling Emergence and Vegetative Vigor Terrestrial Plant Studies for the Formulated Product Enlist Duo,"* discusses the vegetation studies reviewed for synergistic effects, the agency did not conduct reviews for synergism in non-plant species - a critical risk uncertainty which cannot be ignored.

As we have mentioned in previous comments to the agency regarding Enlist Duo, the scientific literature makes it clear that 2,4-D is highly toxic, as it is linked to numerous adverse health effects, including increased risk of birth defects, reduced sperm counts, increased risk of

[1] EPA News Release November 1, 2016. EPA Re-affirms Decision on Enlist Duo for GE Crops and Proposes to Amend the Registration. https://www.epa.gov/pesticides/epa-re-affirms-decision-enlist-duo-ge-crops-and-proposes-amend-registration

non-Hodgkin lymphoma, Parkinson's disease, and endocrine disruption.[2] EPA has itself identified in this assessment certain chronic endpoints, including developmental toxicity and neurotoxicity, where effects have been reported in laboratory organisms. As evidenced with other GE crops, the use of 2,4-D-tolerant crops will simultaneously increase 2,4-D use in the environment, leading to unreasonable adverse risks that EPA must consider before allowing an unprecedented increase in 2,4-D use. We believe that, since 2,4-D is highly toxic, an expansion of uses is not appropriate, given weak label recommendations, and increased exposure to the public.

Enlist Duo "Synergy" Concerns

EPA has stated that it has conducted an evaluation of synergism label claims made by the registrant. Data on these claims were submitted to the U.S. Patent and Trademark Office, but were not known to the agency for the initial registration. The agency notes that the information to support the patent applications were based on "visual observations of weed control and injury," and not directly applicable to the EPA's quantitative risk assessment process for plants. Subsequently, EPA requested and received data that met agency protocols, which find that "the combination of 2,4-D choline and glyphosate in Enlist Duo does not show any increased toxicity to plants and is therefore not of concern."[3]

However, in reviewing the rest of EPA's assessment, it is unclear whether assessment of synergy was conducted for other organisms. Even though prompted by label claims of synergy for certain plant species, the fact remains that other non-target organisms, including humans, can and will be exposed to a chemical mixture that has not been properly evaluated. The current risk assessment document has assessed risks based on the 2-4-D choline salt only for mammals, birds, and other required organisms. It does not appear that assessments, based on exposure to both glyphosate and 2,4-D choline, have been conducted to properly assess whether synergistic effects can occur in non-plant organisms.

Thus far, the Enlist Duo assessment is an assessment of the 2,4-D choline salt and not a proper assessment of the actual formulated product, which contains two active ingredients. This presents uncertainties and data gaps in the assessment, which we believe are unacceptable.

2,4-D Tolerance Assessments

Theoretically, tolerance limits help ensure that pesticide applications do not exceed federal application rates, and that the human population is not exposed to residues that can adversely impact health. These set limits must be based on human health data and should not be amended without complete information, or to simply accommodate a new use pattern.

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[2] Beyond Pesticides comments to Docket Number EPA-HQ-OPP-2014-0195. June 2014.
[3] USEPA. 2016. 2,4-D Choline: Review of Seedling Emergence and Vegetative Vigor Terrestrial Plant Studies for the Formulated Product Enlist Duo. Office of Chemical Safety and Pollution Prevention. Washington DC.

Previously, EPA stated that the maximum residues in field trial data for 2,4-D choline did not exceed the current 2,4-D tolerances on commodities, and has therefore not issued any new tolerances.[4] Now EPA states, "Permanent tolerances for 2,4-D are established under 40 CFR 180.142" and "confirms that residues associated with this proposed decision are safe within the context of the safety standards of section 408 of FFDCA." According to the agency, these assessments were conducted using modeling software.

With recent media reports documenting glyphosate residues in various foods,[5] it will only be a matter of time before unacceptable 2,4-D residues are detected. But given the toxicity of 2,4-D and the adverse human health impacts associated with exposures, we urge EPA to safeguard the nation's food supply by not approving 2,4-D application in soybean and corn production.

Assessment of Drift

The major marketing spin for Enlist Duo is the promise that the choline salt of 2,4-D is significantly less volatile than other forms of 2,4-D. EPA's information regarding this is based on a field study submitted by the registrant that is still "preliminary."[6,7] The vapor pressure for the 2,4-D acid is $1.4x10^{-7}$mmHg, DMA salt: $1x10^{-7}$mmHg, and EHE salt: $3.6x10^{-6}$mmHg, while that of 2,4-D choline salt is not provided, but EPA concludes that its volatility flux rate is lower than the EHE and DMA salts.[8] However, it is still not clear what field conditions existed during the study reviewed by EPA, e.g. temperature, soil moisture content etc., and so this data does not provide meaningful information, and has not been independently corroborated.

Volatility is dependent on several environmental conditions, including temperature and humidity. The vapor pressure of the 2,4-D acid ($1.4x10^{-7}$mmHg) indicates that 2,4-D has relatively low volatility, but historical evidence of 2,4-D drift and damage to non-target sites demonstrates that the chemical can, in fact, enter the atmosphere (volatilize) and travel significant distances (drift). Thus, claims of the 2,4-D choline salt's comparatively lower volatility has limited application to real world experience, given different environmental and application variables that play a part in whether the chemical will remain on site or travel off site. In this 2016 document, EPA notes that the field study "suggests that volatilization of 2,4-D choline salt from treated crops does occur and could result in bystander exposure to vapor phase 2,4-D

[4] USEPA. 2011. 2,4-D. Summary of Analytical Chemistry and Residue Data for Use of 2,4-D Choline in/on Herbicide Tolerant Field Corn Containing the Aryloxyalkanoate Dioxygenase-1 (ADD-1) Gene. Office of Pesticide Programs. Washington DC.
[5] Food Democracy Now! and The Detox Project. 2016. Glyphosate: Unsafe on Any Plate, https://s3.amazonaws.com/media.fooddemocracynow.org/images/FDN_Glyphosate_FoodTesting_Report_p2016.pdf.
[6] USEPA. 2013. EFED Environmental Risk Assessment of Proposed Label for Enlist (2,4-D Choline Salt), New Uses on Soybean with DAS 68416-4 (2,4-D Tolerant) and Enlist (2,4-D + Glyphosate Tolerant) Corn and Field Corn. Environmental Fate and Effects Division. Washington DC.
[7] USEPA. 2016. Proposed Registration Decision of Enlist Duo Herbicide. Office of Pesticide Programs. Washington DC.
[8] Ibid.

choline salt," however, EPA quickly dismisses this by saying modeling data show that airborne levels are not a concern. We have pointed out to the agency that local climate and topographical conditions are important contributing factors for drift. For instance, conditions in the Northwest are markedly different than those in the Southwest, and it is expected that drift in different areas will depend on local conditions. However, current modeling approaches for assessing pesticide drift do not take these factors into consideration. Further, according to the Enlist Duo label, EPA is leaving it up to the applicator to evaluate all factors and make "appropriate adjustments" in applying the product. It is clear that the agency does not have a full understanding of local, real-world factors influencing drift, which is troubling given the dramatic expansion of Enlist Duo to 19 additional states in the south, east and western U.S.

2,4-D drift has long been a known problem to off-site locations, endangered species, and non-target crops. Many forms of 2,4-D volatilize above 85°F[9] and 2,4-D drift has been known to damage tomatoes, grapes, and other plants. Drift can injure plants half a mile or more from the application site, and concentrations 100 times below the recommended label rates have been reported to cause injury to grapes. [10] In addition to non-target plants, 2,4-D drift can impact species listed under the *Endangered Species Act* (ESA). In 2011, the National Marine Fisheries Service (NMFS) identified 2,4-D as likely to jeopardize all listed salmonid, based on current registration and label directions.[11] While 2,4-D acid degrades fairly quickly in soils, it is relatively persistent in anaerobic aquatic environments (half-life ranges from 41 to 333 days).[12] Non-target plants in these areas and others are therefore also at risk. Likewise, 2,4-D is toxic to aquatic plants, and is more toxic to vascular plants than to non-vascular plants. Claims that the 2,4-D choline salt is somehow safer for the environment due to its supposed lower volatility, which allegedly makes it less prone to drift, are yet to be independently substantiated. Moreover, the surfactants and solvents added to commercial mixtures, like that of Enlist Duo, can substantially alter volatility. The environmental conditions contributing to volatility and movement of the 2,4-D choline salt formulation off the target site, as cited above, have not been adequately addressed by EPA.

Enlist Duo Label

There is an expectation that EPA label use restrictions for Enlist Duo will mitigate the potential (non-target) risks from exposure. But, pesticide product label directions have been shown to have no effect on decreasing spray drift. EPA has stated that Enlist Duo's label spray drift mitigations "would reduce exposures off site to levels well below the agency's level of concern." These mitigation measures include 30-foot in-field buffers, applications nozzle

[9] Hales, R. 2010. Herbicide Injury a Problem on Plants. Colorado State University Cooperative Extension.
[10] Ball, D.A, Parker, R, et al. 2004. Preventing Herbicide Drift and Injury to Grapes. Oregon State University Extension Service.
[11] NMFS. 2011. Endangered Species Act Section 7 Consultation Biological Opinion: 2,4-D, Triclopyr, Diuron, Linuron, Captan, and Chlorothalonil. National Marine Fisheries Service.
[12] USEPA. 2005. 2,4-D RED Facts. Available at http://www.epa.gov/oppsrrd1/REDs/factsheets/24d_fs.htm.

restrictions, and a 24-hour rainfast period to reduce runoff. These are not novel mitigation measures and are not effective in reducing non-target impacts from drift.

Most of the information to mitigate against non-target exposures are vague, unrealistic and unenforceable. For instance, for non-target crops the label states, "At the time of application, the wind cannot be blowing toward adjacent commercially grown tomatoes and other fruiting vegetables (EPA crop group 8), cucurbits (EPA crop group 9), grapes and cotton without the Enlist trait." But by EPA's own admission, volatilization from treated crops does occur for the choline salt, where residues can arguably then move off-site depending on local conditions. Additionally, wind speeds and direction may change throughout the day making it possible that these nearby crops can be impacted. These real-world occurrences go ignored by the agency, as reflected by the language currently approved for the label.

As we have indicated in previous comments to the agency, pesticide spray drift, especially when it comes to a known bad actor like 2,4-D, is an inevitable consequence of pesticide use. Unfortunately, non-targets sites, crops and organisms will always be a risk from drift exposure, despite mitigation measures and label recommendations, which have not proven to be completely successful. In light of 2,4-D's high toxicity and history of non-target damage, we urge the agency to reconsider expanding the uses of this chemical.

Mitigating Resistant Weeds

The proliferation of glyphosate-resistant weeds presents an ever-growing economic concern to farmers, since widespread distribution of hard-to-control weeds has the potential to cause significant economic losses. Unfortunately, an over dependence on chemical controls has resulted in the overwhelming selection of weeds resistant to the very same chemicals used to control them. Scientists have advised against the dependence on herbicides, and advocate for the use of crop rotations and the rotation to non-GE crops.[13] Therefore, introducing another chemical cocktail to combat resistant weeds is not a suitable solution to the problems facing farmers. It is inevitable that the introduction of 2,4-D GE crops and increased use of 2,4-D will result in 2,4-D resistant weeds. Already, 28 species across 16 plant families have evolved resistance to the synthetic auxin herbicides, the mode of action to which 2,4-D belongs, with 16 known to be resistant specifically to 2,4-D.[14] Experts have already predicted that with the introduction of herbicide-tolerant genes, plants carrying multiple resistances will become common after commercial release of genetically modified organisms.[15]

Currently, EPA is requiring herbicide resistance management plans for products used in GE crop systems. Recommendations include scouting fields, monitoring for resistance, and

[13] Culpepper, A. S. 2006. Glyphosate-Induced Weed Shifts. *Weed Technology*, 20(2), 277–281.
[14] Egan JF, Maxwell BD, Mortensen DA, et al. 2011. 2,4-Dichlorophenoxyacetic acid (2,4-D)-resistant crops and the potential for evolution of 2,4-D-resistant weeds. Proc Natl Acad Sci. 108(11): E37.
[15]Eastham, K., and Sweet, J. 2002 Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer. Assessing the Impact of GM Plants (AIGM) programme for the European Science Foundation and the European Environment Agency Environmental issue report.

reporting resistance incidents. But these measures are built around continued application of the pesticide product. Retrofitting resistance safeguards to a system that remains dependent of chemical inputs guarantees the continued proliferation of weed resistance.

EPA acknowledges, to some extent, that resistance is inevitable in these cropping systems and has proposed a five-year limited registration for Enlist Duo "so that any unexpected weed resistance issues that may result from the proposed uses can be addressed before granting an extension or the EPA can allow the registration to terminate if necessary." While EPA may believe it is being conservative and precautious, we believe that the only way to safeguard against the onset of 2,4-D resistance is to NOT APPROVE the registration of Enlist Duo or any other 2,4-D product. Instead, EPA should conduct its pesticide registration review under the unreasonable adverse effects standard of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) with a critique of the reasonableness of pesticide use and exposure, given the availability of less toxic or non-chemical alternatives. In this case, the agency must incorporate an analysis of farmers who incorporate more non-chemical weed control practices, including crop-rotation, cultural, biological and mechanical controls, as well as sustainable integrated pest management strategies that do not include prophylactic applications of pesticides. In so doing, the agency would fulfill its statutory obligation to determine the acceptability of the identified risks, as well as the uncertainties associated with its risk calculations.

Conclusion

Following our 2014 comments regarding Enlist Duo, we are again urging the agency against approval of this product. EPA believes the benefits to farmers from Enlist Duo outweigh the risks, but EPA has not fully considered all the environmental costs, including the cost of tackling increased 2,4-D resistant weeds, crop and non-target damages from uncontrolled drift, as well as unanswered questions regarding synergy in non-plant species. U.S. agriculture should be moving away from 2,4-D, as we have with older, more toxic pesticides (organophosphates, organochlorines). 2,4-D has a well-documented history of environmental contamination and adverse human health effects. As a result, 2,4-D and Enlist Duo should not be a solution for burgeoning resistant weeds. EPA must go back and take a look at other non-chemical solutions for addressing weed resistance and work with applicable stakeholders to transition American agriculture away from 2,4-D.

Again we urge EPA not to approve the registration of Enlist Duo.

Respectfully,

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