Message

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Sent: 6/27/2025 6:05:00 PM
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Subject: Letter to MAHA Commission from CropLife America with Policy Recommendations for August 12 Strategy
Attachments: Final CLA Policy Recommendations ltr MAHA Commission.pdf

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Dear MAHA Commissioners and Executive Director:

As the principal organization representing the United States innovators, producers, and distributors of pesticide products, CropLife America (CLA) is committed to working with you and members of the MAHA Commission to advance our shared goals of promoting children's health and ensuring that pesticide regulatory decisions are based on gold-standard science. We thank you for the opportunity for an open dialogue to achieve our shared goal of a healthier America.

In the attached letter, CLA offers 17 recommendations for policy topics the Commission should include regarding pesticides in the MAHA Strategy due August 12, based on topics raised in the Initial Assessment of May 22.

CLA looks forward to further opportunities to engage with the Commission in advance of the August Strategy's release and are ready to provide more detailed information on any of the topics addressed in this letter. We will follow up in approximately one week to find a time to meet with your team to further discuss our recommendations.

Kind regards,

Alexandra Dunn

Alexandra Dapolito Dunn, Esq.
President and CEO
CropLife America
4201 Wilson Boulevard, Suite 700
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CropLife ☆AMERICA☆

June 27, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary, U.S. Department of Health and Human Services
Chair, Make America Healthy Again Commission
200 Independence Avenue, S.W.
Washington, DC 20201

Submitted via e-mail to: Hannah Anderson, Deputy Chief of Staff for Policy

Dear Secretary Kennedy:

As the principal organization representing the United States (U.S.) innovators, producers, and distributors of pesticide products, CropLife America (CLA) is committed to working with you and members of the Make America Health Again (MAHA) Commission (Commission) to advance our shared goals of promoting children's health and ensuring that pesticide regulatory decisions are based on gold-standard science. We thank you for the opportunity for an open dialogue to achieve our shared goal of a healthier America.

In Section I of our letter, we are pleased to provide CLA's recommendations for policy topics the Commission should include regarding pesticides in the MAHA Strategy due August 12 (August Strategy), based on the topics raised in the MAHA Initial Assessment (Assessment) released May 22.[1] In Section II, CLA raises some concerns with the Assessment's reliance on flawed studies, incomplete references from the extensive body of scientific literature on pesticide safety, and unsupported claims that could undermine public confidence in the regulatory policies governing pesticide safety and consequently the domestic food supply.

CLA looks forward to further opportunities to engage with the Commission in advance of the August Strategy's release and are ready to provide more detailed information on any of the topics addressed in this letter. We may also supplement this letter with additional recommendations as we continue dialogue with the agricultural community, the Commission, and other stakeholders. We will follow up in approximately one week to find a time to meet with your team to further discuss our recommendations.

[1] The MAHA Report - The White House

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I. Ongoing Pesticide Activities and Innovations that Complement the Commission's Goals and Should be Referenced in the August Strategy

A. Pesticides are Vital to Children's Access to a Nutritious, Diverse, and Balanced Diet

CLA shares the Commission's goal of expanding access to and maintaining the affordability of fresh fruits, vegetables, and whole grains for American children. Pesticides are a part of all types of agricultural production systems, including conventional and organic, which are critical tools in a large toolbox that help American farmers to provide a safe, abundant, nutritious, and affordable food supply.

CLA recommends that in the August Strategy, the Commission specifically state that an agricultural production system that includes pesticides is vital to growing the fresh fruits, vegetables, whole grains, and animal protein that make up the nutritious diet that will support the health outcomes sought by the Commission. The Commission should consider observing in the August Strategy that without pesticide use in agricultural systems, there would be an estimated 78% loss of fruit production, 54% loss of vegetable production, and 32% loss of cereal (grains) production.[2] If the Commission's findings or recommendations were to have the effect of constraining American farmers' access to these important tools, food production would shift abroad and fruit and vegetable prices would increase substantially, putting healthy domestic options out of reach for millions of American families.

B. Pesticides Protect Children from Pest-Borne Disease

CLA recommends that in the August Strategy, the Commission state that responsibly regulated pesticides are critical to control ticks, mosquitoes, rodents, and other pests that spread diseases that can affect children.[3] Such diseases include Lyme disease, West Nile virus, Zika virus, and microbial infections. Household pests such as cockroaches can trigger or aggravate children's asthma and allergies – two of the chronic children's health conditions called out in the Assessment (page 9). The August Strategy provides the Commission with an opportunity to raise awareness and acknowledge that pesticides help to control these pests and are therefore protecting public health and, specifically, children's health.

C. EPA's Robust Risk and Science Based Pesticide Review System

CLA appreciates that the Assessment recognizes that EPA "has a robust risk-based approach that considers hazard and exposure for assessing the risks of … pesticides, to human health and the environment." (Assessment at 37). **CLA recommends that in the August**

[2] Agriculture Development, Pesticide Application and Its Impact on the Environment - PMC
[3] Pesticides, Disease Vectors and Public Health | US EPA

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Strategy, the Commission reiterate the robust, respected process used by EPA to review pesticides before and after regulation. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (later supplemented by the Federal Food, Drug, and Cosmetic Act [FFDCA]), no pesticide may be sold for use in the U.S. unless the U.S. Environmental Protection Agency (EPA or Agency) has approved it based on extensive scientific studies and data, which are independently evaluated by Agency experts across many scientific disciplines. EPA follows comprehensive and well-documented risk assessment processes developed over decades, which include internal cross-disciplinary peer review.

Pesticides registered for use as part of agricultural systems are thoroughly reviewed by governmental food, health, and environmental scientists to ensure they pose no unreasonable risk when used as directed and "a reasonable certainty that no harm will result from" exposure to pesticide residues on food. The test guidelines the EPA requires for these studies and models that are used to inform regulatory risk assessments are subject to extensive public scrutiny and independent scientific peer review before they are adopted.[4]

In addition to EPA's extensive internal scientific expertise, the Agency consults with external and independent experts to address novel or complex scientific questions. For example, EPA regularly convenes Scientific Advisory Panels (SAPs) under Section 25(c) of FIFRA, comprised of biologists, statisticians, toxicologists, and other specific experts to transparently provide independent scientific advice and to scrutinize proposed regulatory decisions on a range of health and safety issues.[5] EPA also obtains independent input from healthcare providers, academics, scientists, and other stakeholders on the Children's Health Protection Advisory Committee,[6] the Human Studies Review Board,[7] and the Pesticide Program Dialogue Committee.[8]

The net result of this legal and procedural framework is that our nation's science-based pesticide testing and risk assessment process is recognized as the gold standard globally.

D. Legally Mandated and Routine Pesticide Safety Review

CLA recommends that the Commission's August Strategy reference EPA's continual work to ensure pesticide safety. The Agency is required to re-evaluate each registered pesticide product and its registered uses every 15 years under FIFRA 3(g) to ensure that the pesticide satisfies current scientific standards.

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[4] OCSPP-TestGuidelines_MasterList-2019-09-24.docx
[5] FIFRA Scientific Advisory Panel | US EPA
[6] Children's Health Protection Advisory Committee (CHPAC) | US EPA
[7] Human Studies Review Board | US EPA
[8] Pesticide Program Dialogue Committee (PPDC) | US EPA

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Regarding the three pesticides specifically mentioned in the Assessment (*See* Assessment at pages 38, 45), **the Commission's August Strategy should state that EPA has scheduled registration review decisions for chlorpyrifos in 2025, and for atrazine and glyphosate in 2026.** These are among the over 200 pesticides for which EPA has scheduled registration review decisions, representing a major dedication and prioritization of EPA's finite scientific resources.[9]

E. EPA Procedures are Specifically Designed to Consider Children's Exposures

CLA recommends that the Commission's August Strategy explicitly state that EPA's pesticide review process comprehensively addresses the unique exposure pathways and developmental vulnerabilities of children discussed in the Assessment and includes the context provided below.[10]

For example, in evaluating dietary exposure levels of pesticide residues, EPA considers the food consumption patterns of infants and children, including disproportionately high consumption of certain foods. EPA also considers that children consume water at different rates than adults on a body weight basis.

In addition to assessing dietary exposures, EPA's rigorous scientific assessments include all other potential exposure pathways in all settings, giving special attention to children's body size and behaviors throughout development to adulthood. EPA's risk assessments consider where children spend time in indoor and outdoor settings where they may be crawling, walking, grasping, and engaging in hand-to-mouth behaviors. While approximately 50 percent of non-agricultural locations may not be treated with pesticides at all, EPA assumes there is exposure potential at all locations, resulting in highly protective safety factors for products.

Regarding toxicity, EPA reviews extensive data for each pesticide regarding any potential negative health outcomes, including (but not limited to) developmental issues, cancer, neurotoxicity, metabolic changes, acute symptoms, thyroid issues, and immune impacts. EPA must then consider information regarding the special susceptibility of infants and children to chemical residues "including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." 21 U.S.C. 346a(b)(2)(C). Under federal law, EPA may apply an additional ten times (10X) safety factor specifically to account for children's increased neurological and developmental sensitivity. This results in setting allowable pesticide residue levels that may be ten times lower than the calculated safe level. As EPA risk assessment decisions are driven by the highest risk group, many of EPA's pesticide approval decisions and use restrictions are decided in the end by EPA's analysis of the potential exposures and vulnerabilities of children.

[9] https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions
[10] *E.g.*, US EPA - EPA's Risk Assessment Process: Staff Paper #44

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The Assessment raises scientific uncertainty regarding the potential effects of aggregate and cumulative chemical exposures. (Assessment at 39). For pesticides, the Food Quality Protection Act of 1996 (FQPA) specifically addresses these topics.[11] Under the FQPA, EPA developed sophisticated and comprehensive risk assessment approaches for evaluating aggregate pesticide exposures from all sources[12] and cumulative exposure to pesticides identified as having common mechanisms of toxicity.[13] Under its detailed guidance on conducting cumulative and aggregate risk assessment, developed after public comment and multiple SAP reviews, EPA established a scientific approach for evaluating multichemical, multi-pathway risks to better protect public health and sensitive subpopulations – particularly children.[14]

F. Testing Pesticides for Possible Endocrine Effects

CLA recommends that in the August Strategy, the Commission discuss the significant progress EPA has made to implement the Endocrine Disruptor Screening Program (EDSP) for pesticides. The Commission's interest in this topic is timely, given the culmination of scientific advancement that has allowed EPA to establish a process and prioritization for completing this important work. CLA continues to support EPA's implementation of the EDSP.

The FQPA directs EPA to screen and test pesticides to identify potential endocrine disruptors, and substantial scientific resources have been dedicated to developing EPA's EDSP. After years of cutting-edge scientific work to develop valid scientific methods for screening and testing conventional pesticide chemicals for potential endocrine effects, EPA reached a significant milestone in 2023, publishing a plan to prioritize determinations regarding potential human estrogen, androgen, and thyroid effects for conventional pesticides.[15] On December 12, 2024, EPA entered a settlement agreement providing for the implementation of the EDSP, committing EPA to various action items.[16] On January 3, 2025, the Northern District of California entered a consent decree, committing EPA to court-enforceable deadlines for EPA's plan to implement the EDSP.

In 2025, EPA issued pesticide call in notices ("data call-ins"), establishing deadlines for companies to provide additional data regarding the pesticides identified as high priority for endocrine review.[17] More progress will be made throughout 2025 and into 2026.

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[11] Summary of the Food Quality Protection Act | US EPA
[12] General Principles for Performing Aggregate Exposure and Risk Assessments for Pesticides | US EPA
[13] Cumulative Assessment of Risk from Pesticides | US EPA
[14] US EPA: Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity
[15] Endocrine Disruptor Screening Program Timeline | US EPA; EPA Rebuilds Endocrine Disruptor Screening Program to Better Assess Human Endocrine Effects of Pesticides | US EPA
[16] EPA Finalizes Settlement and Announces New Tracking Website for Endocrine Disruptor Screening Program Data Call-In Notices | US EPA
[17] Status of Endocrine Disruptor Screening Program Data Call-In (DCI) Notices for Group 1 Chemicals | US EPA

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G. Innovations in Pesticide Application Technology

CLA recommends that in the August Strategy, the Commission discuss how private-sector innovation can focus and help to ensure the meticulous application of pesticides through precision agriculture. The agricultural sector is actively investing in new approaches and technologies to allow ever more targeted and precise pesticide applications, which increase crop productivity and reduce the total amount of pesticides needed to protect those crops.[18]

Senator Deb Fischer recently reintroduced three items of legislation intended to facilitate these precision application investments.[19] The agricultural sector is also working on improving pesticide labeling to facilitate the incorporation of these precision application methods, including targeted drone applications, computer-assisted targeted spray technology,[20] robotic monitoring, and related innovations.

H. New Approach Methods (NAMs) and Precision Toxicology

CLA supports the Commission's recommendation in the Assessment regarding developing testing methods for pesticides and other chemicals that do not use animals – known as New Approach Methods or (NAMs). (*See* Assessment at 72, Next Steps #9). Advancing NAMs is a topic of common interest to EPA, agricultural stakeholders, and non-governmental entities. **CLA recommends that in the August Strategy, the Commission discuss NAMs in more detail.**

The increased sophistication of NAMs is rapidly advancing through the work of scientists across academic institutions, governmental agencies, and the agricultural sector. Today, some hazards, like skin irritation, can be tested reliably through NAMs, while more complex effects are not yet reliably testable through NAMs. CLA agrees that more research is needed to support the development and validation of animal testing alternatives. Discussion of these points in the August Strategy would be appropriate.

CLA also supports the Commission including in the August Strategy a strong discussion of precision toxicology, as referenced in the Assessment. (*Id.* #10). Precision toxicology is the use of detailed "whole picture" biological information (*e.g.,* changes in gene expression profiles that are related to adversity). The rapid increase in large-scale biological data generation through genomic techniques has transformed biological research. The detailed information offered by these techniques can be especially useful in identifying the toxicological mechanism, which can play a significant role in determining whether a health effect observed in animal tests could be relevant to humans.

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[18] Precision Tech Ag Professional - CropLife

[19] https://www.fischer.senate.gov/public/index.cfm/2025/5/fischer-reintroduces-precision-ag-package

[20] See & Spray™ Customers See 59% Average Herbicide Savings in 2024 – CropLife Magazine (by Meister Media, unrelated to CLA)

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Substantial data processing is required to make this information useful, and even slight changes in this processing phase can significantly impact the results. Additionally, for precision toxicology approaches to be applied to human health, the disease or health effect being evaluated must be understood on a molecular level, which is often not the case. While work remains to standardize precision toxicology data generation, processing, and interpretation before it can be applied in regulatory decision making, CLA is committed to advancing this process with stakeholders.

I. Supporting USDA's Pesticide Data Program

CLA recommends that in the August Strategy, the Commission supports continuing USDA's Pesticide Data Program (PDP). The PDP is a national pesticide residue monitoring program that "produces the most comprehensive pesticide residue database in the U.S." and emphasizes the testing of "those commodities highly consumed by infants and children."[21] EPA relies on PDP data and USDA food consumption models to provide the children's diet information necessary for reliable pesticide risk assessments.[22] The Assessment cites PDP data that found that 99% of tested food samples were compliant with EPA residue limits. (Assessment at 45).

PDP's work helps EPA and other agencies make informed regulatory decisions, supports public confidence in the U.S. food supply, and facilitates the global marketing of U.S. agricultural products. In 2024 alone, the U.S. exported $176 billion in agricultural goods, significantly reducing the trade deficit, and reflecting the trust that global regulators and consumers place in American safety and quality systems.

J. Funding EPA's Office of Pesticide Programs and its Reduced Risk Pesticide Registration Program

CLA recommends that in the August Strategy, the Commission support Congressional funding of EPA's Office of Pesticide Programs (OPP) at the Pesticide Registration Improvement Act (PRIA) 5 statutory level of $166M. OPP employs the scientists and regulators who implement EPA's comprehensive pesticide risk assessment processes discussed in Sections C and E, the reevaluation program discussed in Section D, and the EDSP program discussed in Section F. Pesticide companies pay application and maintenance fees to EPA under PRIA,[23] however these fees account for about one-third of the costs of

[21] Pesticide Data Program | Agricultural Marketing Service
[22] US EPA - EPA's Risk Assessment Process: Staff Paper #44 at 6, 11.
[23] Application fees are due when the application is submitted, and the amount does not vary based on the outcome of EPA's review.

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operating EPA's pesticide regulatory program.[24] The remaining two-thirds are funded through annual appropriations by Congress which have regularly fallen short.

Adequate OPP funding at statutorily mandated levels is essential to allow EPA to timely complete its ongoing scientific safety review of existing pesticides, and to continue to implement initiatives like the EDSP. The scientific and regulatory innovations identified as desirable in the Assessment (*e.g.*, Page 39), require EPA engagement, review, and approval, placing further demands on OPP's already-limited resources.

CLA recommends that in the August Strategy, the Commission reference the importance of supporting OPP's Reduced Risk Program. This program provides an expedited review process for pesticides that are assessed as meeting reduced risk criteria, allowing them to be registered and available to users more quickly. Reviewing and approving reduced risk product applications puts additional strain on OPP staff, as they involve convening a Reduced Risk Committee, reviewing comparative risk data, and other supporting information to determine eligibility for such status. If reduced risk status is granted, OPP conducts the complete pesticide risk assessment and regulatory approval process on an expedited basis. In past years, OPP funding decreases have limited EPA's full implementation of the Reduced Risk Program.

Other innovations like those identified above (*e.g.*, precision agriculture, NAMs, precision toxicology) hold significant promise. But to be successful, these new methods require the dedication of OPP resources necessary for scientific review and approval prior to their application in order to inform regulatory decision making. **The August Strategy should include a strong call for support for the statutorily mandated OPP funding so that EPA's robust regulation of pesticides can continue and the Agency can also facilitate the innovations identified in the Assessment and sought by the Commission.**

K. Funding for State Pesticide Programs

CLA recommends that in the August Strategy, the Commission support funding for state pesticide programs. Federal funding is a critical element to ensure education across each state on the proper handling and use of pesticides, which helps to protect children. Reductions in federal assistance to state pesticide programs could have significant unintended consequences on children and public health.

States are both co-regulators and stakeholders in the regulation of pesticides. States play a critical role first in carrying out educational programs to help ensure proper use of pesticides. Second, they take necessary enforcement actions when pesticides are not used according to the label.

[24] US EPA - FY 2023 Pesticide Registration Improvement Act (PRIA) Annual Report.

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All EPA registered pesticides also must be registered in each state before they can be used in that state. As each state pesticide program has developed in its own manner, the states coordinate and exchange best practices and experiences with one another through a variety of professional forums. EPA and USDA are very engaged in supporting the capacity of state programs. **The Commission should recognize in the August Strategy the key role of states in advancing training on proper pesticide use and management, as well as the exchange of knowledge.**

II. Unfounded Scientific Claims and Unreliable References in the Assessment

A. Industry-Conducted Studies

The Commission's critique of industry-conducted studies (Assessment at 45-46) does not apply to pesticide studies for the reasons discussed here. First, core scientific data used to support EPA pesticide risk assessments and registration must conform to globally harmonized, peer-reviewed study guidelines, designed to ensure the quality, validity, and integrity of pesticide data. The conduct of such studies must also comply with rigorous Good Laboratory Practice (GLP) standards, established in EPA regulations at 40 C.F.R. Part 160.

Second, GLP standards impose detailed requirements for the personnel, facilities, equipment, and practices of pesticide testing facilities, including maintenance of an independent quality assurance unit, standards for equipment, requirements for handling test substances and samples, and extensive recordkeeping and reporting requirements. Facilities that conduct pesticide studies are subject to inspection by EPA and other officials, including laboratories outside the United States, and violations may be subject to civil and criminal penalties. Over several decades of EPA pesticide regulation, there have been only a few instances of significant data quality issues at commercial pesticide laboratories, and in those instances EPA reviewers and inspectors were able to promptly identify and remedy them.[25] These procedures and requirements ensure unbiased study designs and reliable, high-quality data.

Also unwarranted and unsupported is the Assessment's concern that "publication bias" could limit the publication of "unfavorable results" regarding pesticides. (Assessment at 46). Under Section 6(a)(2) of FIFRA, adverse effect information possessed by a pesticide registrant must be timely submitted to EPA, including unfavorable results from a scientific study, or incidents of alleged harmful effects from product use.[26] EPA's review is not limited to industry submissions, but also considers other scientifically relevant and reliable studies and information in scientific literature regarding a given pesticide. The data submitted to EPA concerning each pesticide product, and EPA's review process, are globally recognized as gold standard science.

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[25] *E.g.*, EPA Halts Acceptance of Data for Pesticide Registration from a Non-compliant Laboratory

[26] Incident Reporting by Pesticide Manufacturers/ Registrants | US EPA

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B. Unsupported Claims and Unreliable References in the Assessment

As the Commission moves forward towards the August Strategy, CLA recommends that it draws its conclusions exclusively from a weight-of-the-evidence evaluation of the entire body of high-quality science and data regarding agricultural systems and pesticide use. The Commission should avoid reliance on misleading, and outlier studies. Such studies will undermine public confidence and lead to misguided federal and state policies to restrict agricultural systems used to prevent pest-borne diseases and could limit farmers' tools to provide a safe, abundant, and affordable food supply.

A weight-of-the-evidence approach is consistent with EPA's established pesticide risk assessment process, and President Trump's recent Executive Order 14303 "Restoring Gold Standard Science." 90 Fed. Reg. 22601, 22603 (May 29, 2025).[27]

CLA is concerned that while acknowledging that the "American food system is safe" (Assessment at 16), the Assessment includes misleading and unfounded claims regarding exposure to chemicals including pesticides. The presence of one or more pesticides detected in food and feed residues does not translate to risk without evaluation of the amount and type of exposure and the toxicological characteristics of the substance. Epidemiology studies, for example, are typically observational, and it is notoriously difficult to derive reliable evidence regarding risk based on a statistical association from such studies. In general, a single study suggesting a correlation does not establish causation, and confounding variables are common.

Several of the Assessment's original references have been updated. **CLA recommends that the Commission remove reference to this study regarding "possible health effects" of glyphosate as it was rejected by a federal court as junk science.** ***In re Roundup Prods. Liab. Litig.*****, 737 F.Supp. 3d 898, 900 (N.D. Cal. 2024) (addressing Zhang et. al., cited in the Assessment on page 45, n. 305).**

[27] "When scientific or technological information is used to inform agency evaluations and subsequent decision-making, employees shall apply a 'weight of scientific evidence' approach."

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III. Conclusion

CLA shares the Commission's goal of improving the health of American children, including by increasing the availability of a nutritious, diverse, and balanced diet, which will help to advance overall children's health.

We are pleased to offer the preceding recommendations in response to the Commission's request for specific policy suggestions. We believe each suggestion is concrete, practical, relevant, consistent with law, and aligned with the Commission's vision.

CLA looks forward to discussing our letter with members of the Commission and other stakeholders as the August Strategy is developed, through the Commission's promised inclusive and transparent process and through meetings that we convene as CLA. As mentioned above, CLA may supplement this letter with additional recommendations as we continue our dialogue with the agricultural community, the Commission, and other stakeholders.

We are proud to be part of the agricultural system in the U.S. that helps our farmers offer the healthiest, most abundant, and most affordable food in the world. As noted on the first page, we will follow up in one week to find a time to meet with your team to further discuss our recommendations.

Sincerely,



Alexandra Dapolito Dunn, Esq.
President and CEO
CropLife America

cc: Vincent Haley, Assistant to the President for Domestic Policy – Executive Director
Brooke Rollins, Secretary of Agriculture
Scott Turner, Secretary of Housing and Urban Development
Linda McMahon, Secretary of Education
Douglas Collins, Secretary of Veterans Affairs
Lee Zeldin, Administrator of the Environmental Protection Agency

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Russell Vought, Director of the Office of Management and Budget
Stephen Miller, Assistant to the President and Deputy Chief of Staff for Policy
Dr. Kevin Hassett, Director of the National Economic Council
Dr. Stephen Miran, Chairman of the Council of Economic Advisers
Michael Kratsios, Director of the Office of Science and Technology Policy
Dr. Martin Makary, Commissioner of Food and Drugs
Dr. Jayanta Bhattacharya, Director of the National Institutes of Health

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Message

From: Jeff Blackwood [jblackwood@croplifeamerica.org]
Sent: 6/30/2025 4:52:29 AM
To: Bridgforth, Turner [Bridgforth.Turner@epa.gov]
Subject: CLA letter to MAHA Commission
Attachments: 6.27.2025 CLA Policy Recommendations ltr MAHA Commission.pdf

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Hi Turner,

Here is the letter CropLife sent to the Secretary Kennedy and the MAHA Commission last Friday sharing policy recommendations to consider in preparation for its August 12 strategy. Our press release is here.

Alex Dunn and I would like to meet with you next week to discuss this and other matters. Do you have any time on July 9 or 10 for us to come meet in person?

Thanks and best,
-Jeff

Jeff Blackwood
Vice President, Government Relations
202-604-3771



CropLife ☆AMERICA☆

June 27, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary, U.S. Department of Health and Human Services
Chair, Make America Healthy Again Commission
200 Independence Avenue, S.W.
Washington, DC 20201

Submitted via e-mail to: Hannah Anderson, Deputy Chief of Staff for Policy

Dear Secretary Kennedy:

As the principal organization representing the United States (U.S.) innovators, producers, and distributors of pesticide products, CropLife America (CLA) is committed to working with you and members of the Make America Health Again (MAHA) Commission (Commission) to advance our shared goals of promoting children's health and ensuring that pesticide regulatory decisions are based on gold-standard science. We thank you for the opportunity for an open dialogue to achieve our shared goal of a healthier America.

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[1] The MAHA Report - The White House

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I. Ongoing Pesticide Activities and Innovations that Complement the Commission's Goals and Should be Referenced in the August Strategy

A. Pesticides are Vital to Children's Access to a Nutritious, Diverse, and Balanced Diet

CLA shares the Commission's goal of expanding access to and maintaining the affordability of fresh fruits, vegetables, and whole grains for American children. Pesticides are a part of all types of agricultural production systems, including conventional and organic, which are critical tools in a large toolbox that help American farmers to provide a safe, abundant, nutritious, and affordable food supply.

CLA recommends that in the August Strategy, the Commission specifically state that an agricultural production system that includes pesticides is vital to growing the fresh fruits, vegetables, whole grains, and animal protein that make up the nutritious diet that will support the health outcomes sought by the Commission. The Commission should consider observing in the August Strategy that without pesticide use in agricultural systems, there would be an estimated 78% loss of fruit production, 54% loss of vegetable production, and 32% loss of cereal (grains) production.[2] If the Commission's findings or recommendations were to have the effect of constraining American farmers' access to these important tools, food production would shift abroad and fruit and vegetable prices would increase substantially, putting healthy domestic options out of reach for millions of American families.

B. Pesticides Protect Children from Pest-Borne Disease

CLA recommends that in the August Strategy, the Commission state that responsibly regulated pesticides are critical to control ticks, mosquitoes, rodents, and other pests that spread diseases that can affect children.[3] Such diseases include Lyme disease, West Nile virus, Zika virus, and microbial infections. Household pests such as cockroaches can trigger or aggravate children's asthma and allergies – two of the chronic children's health conditions called out in the Assessment (page 9). The August Strategy provides the Commission with an opportunity to raise awareness and acknowledge that pesticides help to control these pests and are therefore protecting public health and, specifically, children's health.

C. EPA's Robust Risk and Science Based Pesticide Review System

CLA appreciates that the Assessment recognizes that EPA "has a robust risk-based approach that considers hazard and exposure for assessing the risks of … pesticides, to human health and the environment." (Assessment at 37). **CLA recommends that in the August**

[2] Agriculture Development, Pesticide Application and Its Impact on the Environment - PMC
[3] Pesticides, Disease Vectors and Public Health | US EPA

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Strategy, the Commission reiterate the robust, respected process used by EPA to review pesticides before and after regulation. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (later supplemented by the Federal Food, Drug, and Cosmetic Act [FFDCA]), no pesticide may be sold for use in the U.S. unless the U.S. Environmental Protection Agency (EPA or Agency) has approved it based on extensive scientific studies and data, which are independently evaluated by Agency experts across many scientific disciplines. EPA follows comprehensive and well-documented risk assessment processes developed over decades, which include internal cross-disciplinary peer review.

Pesticides registered for use as part of agricultural systems are thoroughly reviewed by governmental food, health, and environmental scientists to ensure they pose no unreasonable risk when used as directed and "a reasonable certainty that no harm will result from" exposure to pesticide residues on food. The test guidelines the EPA requires for these studies and models that are used to inform regulatory risk assessments are subject to extensive public scrutiny and independent scientific peer review before they are adopted.[4]

In addition to EPA's extensive internal scientific expertise, the Agency consults with external and independent experts to address novel or complex scientific questions. For example, EPA regularly convenes Scientific Advisory Panels (SAPs) under Section 25(c) of FIFRA, comprised of biologists, statisticians, toxicologists, and other specific experts to transparently provide independent scientific advice and to scrutinize proposed regulatory decisions on a range of health and safety issues.[5] EPA also obtains independent input from healthcare providers, academics, scientists, and other stakeholders on the Children's Health Protection Advisory Committee,[6] the Human Studies Review Board,[7] and the Pesticide Program Dialogue Committee.[8]

The net result of this legal and procedural framework is that our nation's science-based pesticide testing and risk assessment process is recognized as the gold standard globally.

D. Legally Mandated and Routine Pesticide Safety Review

CLA recommends that the Commission's August Strategy reference EPA's continual work to ensure pesticide safety. The Agency is required to re-evaluate each registered pesticide product and its registered uses every 15 years under FIFRA 3(g) to ensure that the pesticide satisfies current scientific standards.

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[4] OCSPP-TestGuidelines_MasterList-2019-09-24.docx
[5] FIFRA Scientific Advisory Panel | US EPA
[6] Children's Health Protection Advisory Committee (CHPAC) | US EPA
[7] Human Studies Review Board | US EPA
[8] Pesticide Program Dialogue Committee (PPDC) | US EPA

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Regarding the three pesticides specifically mentioned in the Assessment (*See* Assessment at pages 38, 45), **the Commission's August Strategy should state that EPA has scheduled registration review decisions for chlorpyrifos in 2025, and for atrazine and glyphosate in 2026.** These are among the over 200 pesticides for which EPA has scheduled registration review decisions, representing a major dedication and prioritization of EPA's finite scientific resources.[9]

E. EPA Procedures are Specifically Designed to Consider Children's Exposures

CLA recommends that the Commission's August Strategy explicitly state that EPA's pesticide review process comprehensively addresses the unique exposure pathways and developmental vulnerabilities of children discussed in the Assessment and includes the context provided below.[10]

For example, in evaluating dietary exposure levels of pesticide residues, EPA considers the food consumption patterns of infants and children, including disproportionately high consumption of certain foods. EPA also considers that children consume water at different rates than adults on a body weight basis.

In addition to assessing dietary exposures, EPA's rigorous scientific assessments include all other potential exposure pathways in all settings, giving special attention to children's body size and behaviors throughout development to adulthood. EPA's risk assessments consider where children spend time in indoor and outdoor settings where they may be crawling, walking, grasping, and engaging in hand-to-mouth behaviors. While approximately 50 percent of non-agricultural locations may not be treated with pesticides at all, EPA assumes there is exposure potential at all locations, resulting in highly protective safety factors for products.

Regarding toxicity, EPA reviews extensive data for each pesticide regarding any potential negative health outcomes, including (but not limited to) developmental issues, cancer, neurotoxicity, metabolic changes, acute symptoms, thyroid issues, and immune impacts. EPA must then consider information regarding the special susceptibility of infants and children to chemical residues "including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." 21 U.S.C. 346a(b)(2)(C). Under federal law, EPA may apply an additional ten times (10X) safety factor specifically to account for children's increased neurological and developmental sensitivity. This results in setting allowable pesticide residue levels that may be ten times lower than the calculated safe level. As EPA risk assessment decisions are driven by the highest risk group, many of EPA's pesticide approval decisions and use restrictions are decided in the end by EPA's analysis of the potential exposures and vulnerabilities of children.

[9] https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions
[10] *E.g.*, US EPA - EPA's Risk Assessment Process: Staff Paper #44

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The Assessment raises scientific uncertainty regarding the potential effects of aggregate and cumulative chemical exposures. (Assessment at 39). For pesticides, the Food Quality Protection Act of 1996 (FQPA) specifically addresses these topics.[11] Under the FQPA, EPA developed sophisticated and comprehensive risk assessment approaches for evaluating aggregate pesticide exposures from all sources[12] and cumulative exposure to pesticides identified as having common mechanisms of toxicity.[13] Under its detailed guidance on conducting cumulative and aggregate risk assessment, developed after public comment and multiple SAP reviews, EPA established a scientific approach for evaluating multichemical, multi-pathway risks to better protect public health and sensitive subpopulations – particularly children.[14]

F. Testing Pesticides for Possible Endocrine Effects

CLA recommends that in the August Strategy, the Commission discuss the significant progress EPA has made to implement the Endocrine Disruptor Screening Program (EDSP) for pesticides. The Commission's interest in this topic is timely, given the culmination of scientific advancement that has allowed EPA to establish a process and prioritization for completing this important work. CLA continues to support EPA's implementation of the EDSP.

The FQPA directs EPA to screen and test pesticides to identify potential endocrine disruptors, and substantial scientific resources have been dedicated to developing EPA's EDSP. After years of cutting-edge scientific work to develop valid scientific methods for screening and testing conventional pesticide chemicals for potential endocrine effects, EPA reached a significant milestone in 2023, publishing a plan to prioritize determinations regarding potential human estrogen, androgen, and thyroid effects for conventional pesticides.[15] On December 12, 2024, EPA entered a settlement agreement providing for the implementation of the EDSP, committing EPA to various action items.[16] On January 3, 2025, the Northern District of California entered a consent decree, committing EPA to court-enforceable deadlines for EPA's plan to implement the EDSP.

In 2025, EPA issued pesticide call in notices ("data call-ins"), establishing deadlines for companies to provide additional data regarding the pesticides identified as high priority for endocrine review.[17] More progress will be made throughout 2025 and into 2026.

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[11] Summary of the Food Quality Protection Act | US EPA
[12] General Principles for Performing Aggregate Exposure and Risk Assessments for Pesticides | US EPA
[13] Cumulative Assessment of Risk from Pesticides | US EPA
[14] US EPA: Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity
[15] Endocrine Disruptor Screening Program Timeline | US EPA; EPA Rebuilds Endocrine Disruptor Screening Program to Better Assess Human Endocrine Effects of Pesticides | US EPA
[16] EPA Finalizes Settlement and Announces New Tracking Website for Endocrine Disruptor Screening Program Data Call-In Notices | US EPA
[17] Status of Endocrine Disruptor Screening Program Data Call-In (DCI) Notices for Group 1 Chemicals | US EPA

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G. Innovations in Pesticide Application Technology

CLA recommends that in the August Strategy, the Commission discuss how private-sector innovation can focus and help to ensure the meticulous application of pesticides through precision agriculture. The agricultural sector is actively investing in new approaches and technologies to allow ever more targeted and precise pesticide applications, which increase crop productivity and reduce the total amount of pesticides needed to protect those crops.[18]

Senator Deb Fischer recently reintroduced three items of legislation intended to facilitate these precision application investments.[19] The agricultural sector is also working on improving pesticide labeling to facilitate the incorporation of these precision application methods, including targeted drone applications, computer-assisted targeted spray technology,[20] robotic monitoring, and related innovations.

H. New Approach Methods (NAMs) and Precision Toxicology

CLA supports the Commission's recommendation in the Assessment regarding developing testing methods for pesticides and other chemicals that do not use animals – known as New Approach Methods or (NAMs). (*See* Assessment at 72, Next Steps #9). Advancing NAMs is a topic of common interest to EPA, agricultural stakeholders, and non-governmental entities. **CLA recommends that in the August Strategy, the Commission discuss NAMs in more detail.**

The increased sophistication of NAMs is rapidly advancing through the work of scientists across academic institutions, governmental agencies, and the agricultural sector. Today, some hazards, like skin irritation, can be tested reliably through NAMs, while more complex effects are not yet reliably testable through NAMs. CLA agrees that more research is needed to support the development and validation of animal testing alternatives. Discussion of these points in the August Strategy would be appropriate.

CLA also supports the Commission including in the August Strategy a strong discussion of precision toxicology, as referenced in the Assessment. (*Id.* #10). Precision toxicology is the use of detailed "whole picture" biological information (*e.g.,* changes in gene expression profiles that are related to adversity). The rapid increase in large-scale biological data generation through genomic techniques has transformed biological research. The detailed information offered by these techniques can be especially useful in identifying the toxicological mechanism, which can play a significant role in determining whether a health effect observed in animal tests could be relevant to humans.

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[18] Precision Tech Ag Professional - CropLife

[19] https://www.fischer.senate.gov/public/index.cfm/2025/5/fischer-reintroduces-precision-ag-package

[20] See & Spray™ Customers See 59% Average Herbicide Savings in 2024 – CropLife Magazine (by Meister Media, unrelated to CLA)

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Substantial data processing is required to make this information useful, and even slight changes in this processing phase can significantly impact the results. Additionally, for precision toxicology approaches to be applied to human health, the disease or health effect being evaluated must be understood on a molecular level, which is often not the case. While work remains to standardize precision toxicology data generation, processing, and interpretation before it can be applied in regulatory decision making, CLA is committed to advancing this process with stakeholders.

I. Supporting USDA's Pesticide Data Program

CLA recommends that in the August Strategy, the Commission supports continuing USDA's Pesticide Data Program (PDP). The PDP is a national pesticide residue monitoring program that "produces the most comprehensive pesticide residue database in the U.S." and emphasizes the testing of "those commodities highly consumed by infants and children."[21] EPA relies on PDP data and USDA food consumption models to provide the children's diet information necessary for reliable pesticide risk assessments.[22] The Assessment cites PDP data that found that 99% of tested food samples were compliant with EPA residue limits. (Assessment at 45).

PDP's work helps EPA and other agencies make informed regulatory decisions, supports public confidence in the U.S. food supply, and facilitates the global marketing of U.S. agricultural products. In 2024 alone, the U.S. exported $176 billion in agricultural goods, significantly reducing the trade deficit, and reflecting the trust that global regulators and consumers place in American safety and quality systems.

J. Funding EPA's Office of Pesticide Programs and its Reduced Risk Pesticide Registration Program

CLA recommends that in the August Strategy, the Commission support Congressional funding of EPA's Office of Pesticide Programs (OPP) at the Pesticide Registration Improvement Act (PRIA) 5 statutory level of $166M. OPP employs the scientists and regulators who implement EPA's comprehensive pesticide risk assessment processes discussed in Sections C and E, the reevaluation program discussed in Section D, and the EDSP program discussed in Section F. Pesticide companies pay application and maintenance fees to EPA under PRIA,[23] however these fees account for about one-third of the costs of

[21] Pesticide Data Program | Agricultural Marketing Service
[22] US EPA - EPA's Risk Assessment Process: Staff Paper #44 at 6, 11.
[23] Application fees are due when the application is submitted, and the amount does not vary based on the outcome of EPA's review.

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operating EPA's pesticide regulatory program.[24] The remaining two-thirds are funded through annual appropriations by Congress which have regularly fallen short.

Adequate OPP funding at statutorily mandated levels is essential to allow EPA to timely complete its ongoing scientific safety review of existing pesticides, and to continue to implement initiatives like the EDSP. The scientific and regulatory innovations identified as desirable in the Assessment (*e.g.*, Page 39), require EPA engagement, review, and approval, placing further demands on OPP's already-limited resources.

CLA recommends that in the August Strategy, the Commission reference the importance of supporting OPP's Reduced Risk Program. This program provides an expedited review process for pesticides that are assessed as meeting reduced risk criteria, allowing them to be registered and available to users more quickly. Reviewing and approving reduced risk product applications puts additional strain on OPP staff, as they involve convening a Reduced Risk Committee, reviewing comparative risk data, and other supporting information to determine eligibility for such status. If reduced risk status is granted, OPP conducts the complete pesticide risk assessment and regulatory approval process on an expedited basis. In past years, OPP funding decreases have limited EPA's full implementation of the Reduced Risk Program.

Other innovations like those identified above (*e.g.*, precision agriculture, NAMs, precision toxicology) hold significant promise. But to be successful, these new methods require the dedication of OPP resources necessary for scientific review and approval prior to their application in order to inform regulatory decision making. **The August Strategy should include a strong call for support for the statutorily mandated OPP funding so that EPA's robust regulation of pesticides can continue and the Agency can also facilitate the innovations identified in the Assessment and sought by the Commission.**

K. Funding for State Pesticide Programs

CLA recommends that in the August Strategy, the Commission support funding for state pesticide programs. Federal funding is a critical element to ensure education across each state on the proper handling and use of pesticides, which helps to protect children. Reductions in federal assistance to state pesticide programs could have significant unintended consequences on children and public health.

States are both co-regulators and stakeholders in the regulation of pesticides. States play a critical role first in carrying out educational programs to help ensure proper use of pesticides. Second, they take necessary enforcement actions when pesticides are not used according to the label.

[24] US EPA - FY 2023 Pesticide Registration Improvement Act (PRIA) Annual Report.

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All EPA registered pesticides also must be registered in each state before they can be used in that state. As each state pesticide program has developed in its own manner, the states coordinate and exchange best practices and experiences with one another through a variety of professional forums. EPA and USDA are very engaged in supporting the capacity of state programs. **The Commission should recognize in the August Strategy the key role of states in advancing training on proper pesticide use and management, as well as the exchange of knowledge.**

II. Unfounded Scientific Claims and Unreliable References in the Assessment

A. Industry-Conducted Studies

The Commission's critique of industry-conducted studies (Assessment at 45-46) does not apply to pesticide studies for the reasons discussed here. First, core scientific data used to support EPA pesticide risk assessments and registration must conform to globally harmonized, peer-reviewed study guidelines, designed to ensure the quality, validity, and integrity of pesticide data. The conduct of such studies must also comply with rigorous Good Laboratory Practice (GLP) standards, established in EPA regulations at 40 C.F.R. Part 160.

Second, GLP standards impose detailed requirements for the personnel, facilities, equipment, and practices of pesticide testing facilities, including maintenance of an independent quality assurance unit, standards for equipment, requirements for handling test substances and samples, and extensive recordkeeping and reporting requirements. Facilities that conduct pesticide studies are subject to inspection by EPA and other officials, including laboratories outside the United States, and violations may be subject to civil and criminal penalties. Over several decades of EPA pesticide regulation, there have been only a few instances of significant data quality issues at commercial pesticide laboratories, and in those instances EPA reviewers and inspectors were able to promptly identify and remedy them.[25] These procedures and requirements ensure unbiased study designs and reliable, high-quality data.

Also unwarranted and unsupported is the Assessment's concern that "publication bias" could limit the publication of "unfavorable results" regarding pesticides. (Assessment at 46). Under Section 6(a)(2) of FIFRA, adverse effect information possessed by a pesticide registrant must be timely submitted to EPA, including unfavorable results from a scientific study, or incidents of alleged harmful effects from product use.[26] EPA's review is not limited to industry submissions, but also considers other scientifically relevant and reliable studies and information in scientific literature regarding a given pesticide. The data submitted to EPA concerning each pesticide product, and EPA's review process, are globally recognized as gold standard science.

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[25] *E.g.*, EPA Halts Acceptance of Data for Pesticide Registration from a Non-compliant Laboratory

[26] Incident Reporting by Pesticide Manufacturers/ Registrants | US EPA

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B. Unsupported Claims and Unreliable References in the Assessment

As the Commission moves forward towards the August Strategy, CLA recommends that it draws its conclusions exclusively from a weight-of-the-evidence evaluation of the entire body of high-quality science and data regarding agricultural systems and pesticide use. The Commission should avoid reliance on misleading, and outlier studies. Such studies will undermine public confidence and lead to misguided federal and state policies to restrict agricultural systems used to prevent pest-borne diseases and could limit farmers' tools to provide a safe, abundant, and affordable food supply.

A weight-of-the-evidence approach is consistent with EPA's established pesticide risk assessment process, and President Trump's recent Executive Order 14303 "Restoring Gold Standard Science." 90 Fed. Reg. 22601, 22603 (May 29, 2025).[27]

CLA is concerned that while acknowledging that the "American food system is safe" (Assessment at 16), the Assessment includes misleading and unfounded claims regarding exposure to chemicals including pesticides. The presence of one or more pesticides detected in food and feed residues does not translate to risk without evaluation of the amount and type of exposure and the toxicological characteristics of the substance. Epidemiology studies, for example, are typically observational, and it is notoriously difficult to derive reliable evidence regarding risk based on a statistical association from such studies. In general, a single study suggesting a correlation does not establish causation, and confounding variables are common.

Several of the Assessment's original references have been updated. **CLA recommends that the Commission remove reference to this study regarding "possible health effects" of glyphosate as it was rejected by a federal court as junk science.** ***In re Roundup Prods. Liab. Litig.*****, 737 F.Supp. 3d 898, 900 (N.D. Cal. 2024) (addressing Zhang et. al., cited in the Assessment on page 45, n. 305).**

[27] "When scientific or technological information is used to inform agency evaluations and subsequent decision-making, employees shall apply a 'weight of scientific evidence' approach."

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III. Conclusion

CLA shares the Commission's goal of improving the health of American children, including by increasing the availability of a nutritious, diverse, and balanced diet, which will help to advance overall children's health.

We are pleased to offer the preceding recommendations in response to the Commission's request for specific policy suggestions. We believe each suggestion is concrete, practical, relevant, consistent with law, and aligned with the Commission's vision.

CLA looks forward to discussing our letter with members of the Commission and other stakeholders as the August Strategy is developed, through the Commission's promised inclusive and transparent process and through meetings that we convene as CLA. As mentioned above, CLA may supplement this letter with additional recommendations as we continue our dialogue with the agricultural community, the Commission, and other stakeholders.

We are proud to be part of the agricultural system in the U.S. that helps our farmers offer the healthiest, most abundant, and most affordable food in the world. As noted on the first page, we will follow up in one week to find a time to meet with your team to further discuss our recommendations.

Sincerely,



Alexandra Dapolito Dunn, Esq.
President and CEO
CropLife America

cc: Vincent Haley, Assistant to the President for Domestic Policy – Executive Director
Brooke Rollins, Secretary of Agriculture
Scott Turner, Secretary of Housing and Urban Development
Linda McMahon, Secretary of Education
Douglas Collins, Secretary of Veterans Affairs
Lee Zeldin, Administrator of the Environmental Protection Agency

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Russell Vought, Director of the Office of Management and Budget
Stephen Miller, Assistant to the President and Deputy Chief of Staff for Policy
Dr. Kevin Hassett, Director of the National Economic Council
Dr. Stephen Miran, Chairman of the Council of Economic Advisers
Michael Kratsios, Director of the Office of Science and Technology Policy
Dr. Martin Makary, Commissioner of Food and Drugs
Dr. Jayanta Bhattacharya, Director of the National Institutes of Health

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Message

From: Erick Lutt [erick.lutt@bayer.com]
Sent: 6/30/2025 1:49:33 PM
To: Bridgforth, Turner [Bridgforth.Turner@epa.gov]
Subject: U.S. Supreme Court asks for views of Solicitor General in Durnell case

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

As a FYI, the U.S. Supreme Court today asked the Solicitor General to provide the Court with the views of the U.S. government in the *Durnell* case.

Copied below is Bayer's press release and a *Bloomberg Government* article on this development.

Please call if you have any questions.

Thanks,
Erick

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E-mail: erick.lutt@bayer.com

https://www.bayer.com/media/en-us/us-supreme-court-asks-for-views-of-solicitor-general-in-durnell-case/

June 30, 2025

U.S. Supreme Court asks for views of Solicitor General in Durnell case

Company expects decision on petition during beginning of the 2025-2026 Court session / Bayer continues its multipronged strategy to significantly contain the litigation by the end of 2026

Leverkusen, June 30, 2025 – The U.S. Supreme Court today asked the Solicitor General to provide the Court with the views of the U.S. government in the *Durnell* case, following a petition for a writ of certiorari by Bayer's indirect subsidiary Monsanto in April 2025.

"We see this request as an encouraging step and look forward to hearing the views of the government on FIFRA's federal preemption provision, which relies on language common to several federal laws that cover a number of industries," said Bayer CEO Bill Anderson. "The security and affordability of the food supply depend on companies' and farmers' ability to rely on decisions made by responsible federal regulatory authorities.

When courts permit companies to be punished under state law for following federal law, it makes companies like ours a prime target of the litigation industry and threatens farmers and innovations that patients and consumers need for their nutrition and health."

In its petition, the company argues that a split among federal circuit courts in the Roundup™ litigation warrants review and resolution by the country's top court. The 3rd Circuit Court of Appeals unanimously held in the *Schaffner* case that the Federal Insecticide Fungicide and Rodenticide Act (FIRFA) expressly preempted the plaintiff's state claims based on failure-to-warn theories. The 9th and 11th Circuits and Missouri's intermediate appellate court in *Durnell* have reached different conclusions on the preemption question and the petition argues that both state and federal courts require guidance that only the U.S. Supreme Court can provide. *Durnell* is the first case for which Monsanto has sought Supreme Court review since the *Schaffner* decision created a split among the federal circuit courts.

Once the Solicitor General provides its views, the Supreme Court will then make a decision on the company's petition during the 2025-2026 Court session. If the Court accepts the case, a decision on the merits could still happen during the Court's next session which ends in June 2026. A positive ruling on the central, cross-cutting issue in the Roundup™ litigation – whether federal law preempts claims based on state failure-to-warn theories – could help to largely contain this litigation.

In the past weeks, 18 organizations and coalitions, representing agriculture, legal thought leaders, U.S. manufacturers, scientific communities, and a broad swath of business leaders from across the nation, filed amicus briefs urging the Supreme Court to grant Monsanto's petition. The Chamber of Commerce wrote: "The stakes of this case, and others like it, are enormous … [I]f federal preemption is discarded in cases like this one, manufacturers will routinely face potentially crushing liability under state law for failing to give warnings that federal law forbids."

Several grower groups like the American Farm Bureau Federation wrote in their amici briefs: "Put simply, America's agricultural industry could not operate without glyphosate ... Immediate devastation will occur for agricultural operations and American food supply."

"The litigation industry is spending hundreds of millions of dollars targeting Monsanto for not providing warnings they allege are required under state law, even though the U.S. Environmental Protection Agency (EPA) and every other health regulator worldwide that has assessed the safety of glyphosate has found that it is safe to use and does not cause cancer," Anderson said.

Bayer remains committed to significantly containing the U.S. litigation by the end of 2026. To achieve this goal, the company will continue its multipronged strategy. The company supports regulatory measures that would reinforce the preemptive effect of the EPA's human health assessments and approved labeling for products registered under FIFRA). FIFRA already prohibits states from imposing 'any requirements for labeling or packaging in addition to or different from' those required under federal law. The company supports a petition filed by 11 state Attorneys General calling on the agency to strengthen its regulations and specify that state labeling requirements, which are different than those determined by the EPA, would render the product misbranded. This petition, which received broad industry support, is now under consideration by the EPA.

Building off the efforts of elected officials and farmers in Georgia and North Dakota, the company will continue to work with state and federal legislators, along with more than 360 grower and industry groups, to reinforce that compliance with federal labels is sufficient to meet state warning requirements, consistent with the uniformity provision of FIFRA.

The company has obtained favorable outcomes in 17 of the last 25 trials and will continue to try cases based on the overwhelming scientific support for glyphosate's safety. It will also consider resolving claims by settlements if the terms are in Monsanto's strategic interest.

Additional options under consideration include state and federal executive branch actions consistent with current FIFRA policy on preemption, and limiting or ending the sale of glyphosate-based products. Lastly, the company continues to assess other options that would help protect the company and its other products from the financial threats posed by the litigation industry and its ceaseless attacks on glyphosate-based products.

In October 2023, *Durnell* was tried in Missouri Circuit Court for the City of St. Louis and the jury returned a verdict in favor of the plaintiff. The jury found the company failed to warn of the product's risk and awarded 1.25 million U.S. dollar to the plaintiff, but it rejected all other claims and declined to award punitive damages. The company appealed the verdict in August 2024 and the Missouri Court of Appeals, Eastern District upheld the verdict in February 2025. Monsanto promptly filed a writ to transfer the case to the Missouri Supreme Court, and it declined review on April 1, making it ripe for U.S. Supreme Court review.

About Bayer
Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Bayer AG is a holding company with operating subsidiaries worldwide. References to "Bayer" or "the company" herein may refer to one or more subsidiaries as context requires.

Bloomberg Government

US Supreme Court Seeks Government's View on Roundup Verdict

By Jef Feeley / June 30, 2025 09:37AM ET / Bloomberg Government

The US Supreme Court signaled interest in Bayer AG's bid to stop thousands of lawsuits blaming its top-selling Roundup weedkiller for causing cancer, seeking the Trump administration's view on whether to hear the company's appeal of a $1.25 million verdict.

Bayer argues a 2023 Missouri state-court jury that sided with a man who blamed Roundup for his cancer shouldn't have weighed a claim that the company failed to properly warn consumers about the product's health risks. Bayer says such claims are preempted by federal law.

Bayer argues in its appeal that so-called "failure to warn" claims brought in state court were precluded by the US Food and Drug Administration's decision not to force Bayer to put a cancer warning on Roundup. The company hopes a ruling in its favor would shield it from more cancer suits.

Bayer — which already has paid out about $11 billion in verdicts and settlements in the seven-year Roundup litigation — still faces 67,000 suits claiming its glyphosate-based of Roundup causes cancer, according to its 2024 annual report. Bayer inherited the weedkiller in 2018 in its $63 billion Monsanto acquisition. It insists the product is safe.

Bayer's lawyers hope to persuade the justices that federal oversight of chemicals such as glyphosate should bar plaintiffs from seeking damages in state court over the company's alleged failure to warn about it health risks. Some large verdicts against Bayer and Monsanto have been based, in part, on failure-to-warn allegations.

The Supreme Court directed its request for input to US Solicitor General D. John Sauer, the Trump administration's top courtroom lawyer.

The case is Monsanto v. Durnell, 24-1068.

To contact the reporter on this story:
Jef Feeley in Wilmington, Delaware at jfeeley@bloomberg.net

To contact the editors responsible for this story:
Elizabeth Wasserman at ewasserman2@bloomberg.net
Steve Stroth

BGOV Health Care Breaking News

Edit this alert

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Message

From: Alexandra Dunn [adunn@croplifeamerica.org]
Sent: 7/10/2025 2:01:43 PM
To: Atkinson, Emily [Atkinson.Emily@epa.gov]
CC: Jay Ivey [jivey@croplifeamerica.org]; Bridgforth, Turner [Bridgforth.Turner@epa.gov]; Jeff Blackwood [jblackwood@croplifeamerica.org]; Maggie Kelly [mkelly@croplifeamerica.org]
Subject: RE: Meeting with Administrator Zeldin or Deputy Administrator Fotouhi on MAHA on July 16 or 17 with CropLife America Leaders
Attachments: EPA Meeting Information Form 7.9.25.docx

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Hi Emily,

Here is the form for the meeting next week. Let me know what is next!

Alexandra Dapolito Dunn, Esq.
President and CEO
CropLife America
4201 Wilson Boulevard, Suite 700
Arlington, VA 22203
Phone: 202-872-3850
Cell: 703-848-5687
Email: adunn@croplifeamerica.org



From: Atkinson, Emily <Atkinson.Emily@epa.gov>
Sent: Wednesday, July 9, 2025 10:44 AM
To: Alexandra Dunn <adunn@croplifeamerica.org>
Cc: Jay Ivey <jivey@croplifeamerica.org>
Subject: FW: Meeting with Administrator Zeldin or Deputy Administrator Fotouhi on MAHA on July 16 or 17 with CropLife America Leaders

Hi Alex,

Administrator Zeldin has delegated this request to Deputy Administrator Fotouhi.

It looks like we could fit this in as a 30 minute in person meeting on Wednesday, July 16 at 11:00am.

Let me know if this could work with your schedule.

Thank you!
Emily

Emily Atkinson
Special Assistant
Office of the Deputy Administrator
U.S. Environmental Protection Agency
202-564-1850
atkinson.emily@epa.gov

From: Alexandra Dunn <adunn@croplifeamerica.org>
Sent: Wednesday, July 2, 2025 7:25 AM
To: Atkinson, Emily <Atkinson.Emily@epa.gov>; Amidon, Eric <Amidon.Eric@epa.gov>
Cc: Voyles, Travis <voyles.travis@epa.gov>; Bridgforth, Turner <Bridgforth.Turner@epa.gov>; Carpenter, Wesley <Carpenter.Wesley@epa.gov>; Jay Ivey <jivey@croplifeamerica.org>; Bolen, Derrick <bolen.derrick@epa.gov>
Subject: Meeting with Administrator Zeldin or Deputy Administrator Fotouhi on MAHA on July 16 or 17 with CropLife America Leaders

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Good morning Eric and Emily,

I am pleased to reach out to let you know that the CropLife America Board of Directors, Officers, and Federal Affairs leaders will be in Washington, DC on July 16 and 17 to discuss the forthcoming August 12 MAHA Commission policy strategy. We recently sent the attached letter to Administrator Zeldin and copied Assistant Deputy Administrator Voyles and Agricultural Adviser Bridgforth with 17 policy recommendations for the MAHA Commission's strategy, most of which involve activities at the EPA.

We would like to request a meeting for a small group of these leaders and our most senior staff (approximately 7 total) to meet with the Administrator to discuss our recommendations. We understand the Administrator's availability is limited and as such we are available at any time on the day of the 16th or the morning of the 17th. If Administrator Zeldin is unable to meet with us, we would very much like to meet with newly confirmed Deputy Administrator Fotouhi.

We are intentionally asking to meet with the Administrator's office in this request, as our leaders seek to converse with the Administrator given his role leading the primary agency regulating our industry and his service on the MAHA Commission. CropLife America has regularly scheduled interactions with Dr. Beck and Dr. Dekleva in the Office of Chemical Safety and Pollution Prevention, which we appreciate. We have shared and will discuss our recommendations with Drs. Beck and Dekleva and welcome their participation in any scheduled meeting.

As I have yet to meet Mr. Amidon, I again note for introduction that I served at EPA in the first Trump Administration from 2018 through 2021, as EPA Region 1 Administrator (2018-2019), and as the unanimously confirmed Assistant Administrator of the Office of Chemical Safety and Pollution Prevention (2019-2021).

Thank you so much for considering our request.

With best regards,

Alex Dunn

Alexandra Dapolito Dunn, Esq.
President and CEO
CropLife America
4201 Wilson Boulevard, Suite 700
Arlington, VA 22203
Phone: 202-872-3850
Cell: 703-848-5687
Email: adunn@croplifeamerica.org



EPA ADMINISTRATOR MEETING INFORMATION FORM

This form assists in planning participation in meetings. Please be complete to minimize need for follow up. This is not a meeting confirmation.

Meeting Logistics

Requesting individual/organization:	*Alexandra Dunn, CropLife America* *Jeff Blackwood, CropLife America*
Contact information:	*Name, Email, Phone, Title* *Alexandra Dunn, President and CEO, (703) 848-5687* [HYPERLINK "mailto:adunn@croplifeamerica.org"] *cc:* [HYPERLINK "mailto:jblackwood@croplifeamerica.org"] *(202) 604-3771*
Title of the meeting:	*MAHA report comments and questions*
Describe the proposed meeting topic/ agenda, provide available briefing materials:	*MAHA, August 12 Strategy & CLA policy recommendations submitted June 30, 2025.*
Describe the action sought from the meeting and/or identify desired outcome(s):	*Encourge EPA to continue working with agricultural stakeholders to ensure the MAHA Commission uses science and evidence based approaches and claims in their work. Encourage EPA to raise the profile of several key pesticide programs for the strategy report: 1) reduced risk program; 2) endocrine disruption screening program; 3) alternatives to animal testing; and 4) 15 year reviews of pesticides, including chlorpyrifos, glyphosate, and atrazine*
Proposed meeting date and time (if date is flexible please indicate the range):	*July 16, 2025 at 11 am (confirmed with Emily Atkinson)*
Requested length of time:	*30 minutes*
Please explain any time sensitivity that impacts the date of the meeting, such as court-ordered or statutory deadline:	***N/A***
Proposed meeting location:	*EPA building*
If the Administrator is unable to meet, is a surrogate desired? If yes, who specifically?	*Deputy Administrator Fotouhi*

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EPA ADMINISTRATOR MEETING INFORMATION FORM

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Are you planning to issue a press-statement on this meeting?	*No.*
Will you be requesting photography from the meeting?	*We would like to take a group photo.*

Meeting Participants

Expected meeting participants:	*(-Name, organizational affiliation, email address. Please use the format in the table below)*

-Name, organizational affiliation	***Email with ";" at the end***
-Don Chew, PBI Gordon	*Dchew@pbigordon.com*
-Brian Naber, Bayer	*Brian.naber@bayer.com*
-Erik Lutt, Bayer	*Erick.lutt@bayer.com*
-Elizabeth Boylan, FMC	*Elizabeth.boylan@fmc.com*
-Cindy Smith, Gowan	*Csmith@gowanco.com*
-Alex Dunn, CropLife America	*Adunn@croplifeamerica.org*
-Jeff Blackwood, CropLife America	*JBlackwood@croplifeameirca.org*

Are any expected meeting participants federally registered lobbyists or lobbying organizations? (If yes, please identify.)	*N/A*
Are any expected meeting participants a partisan political candidate, a representative of a political party or a registered political action committee (PAC)? (If yes, please identify.)	*N/A*
Do any expected meeting participants seek or currently have any business interests with the Agency such as permits, contracts, litigation, grants, etc.? (If yes, please identify.)	*N/A*

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EPA ADMINISTRATOR MEETING INFORMATION FORM

This form assists in planning participation in meetings. Please be complete to minimize need for follow up. This is not a meeting confirmation.

Background for the Meeting

Will the meeting involve legislation, broad policy options, or other general matters that involve a large and diverse range of persons and interests? (If yes, please describe.)	*No legislation. No broad policy options. Pesticide programs do ultimately impact farmers and distributors.*
Will the meeting involve regulations, rules, or other matters that impact a specific industry, sector of the economy, or group of persons? (If yes, please describe.)	*Agriculture, Pesticides, Farmers.*
Will the meeting involve a litigation matter, a permit, a grant, a contract, or any other matter that involves specific parties? (If yes, please identify the matter and list the specific parties.)	*No.*
Any additional notes or information?	

Technology for Virtual Meetings

Preferred Virtual Meeting Platform?	*N/A*
Do you use Microsoft Teams?	*N/A*
Disclaimer for recording the meeting.	*N/A*

Please return this completed form to [HYPERLINK "mailto:zeldinscheduling@epa.gov"], *and copy* [HYPERLINK "mailto:brown.ashley@epa.gov"]

Message

From: Jeff Blackwood [jblackwood@croplifeamerica.org]
Sent: 7/15/2025 4:07:24 PM
To: Lauman, Lauren [Lauman.Lauren@epa.gov]
CC: Alexandra Dunn [adunn@croplifeamerica.org]; Bridgforth, Turner [Bridgforth.Turner@epa.gov]
Subject: CropLife meeting materials
Attachments: Final+CLA+Policy+Recommendations+ltr+MAHA+Commission.pdf; Key Pesticide Points MAHA Commission EPA 71525.pdf

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Hi Lauren,

In preparation for our meeting with Deputy Administrator Fotouhi, please find attached a letter from CropLife America to the MAHA Commission dated June 27.

Since sending this letter we have been engaged in discussions over several specific policy recommendations, which are attached as a separate document labeled 'Key Pesticide Points MAHA Commission EPA". This will be the basis of our discussion with the Deputy Administrator tomorrow.

Thanks and best regards,
-Jeff

Jeff Blackwood
Vice President, Government Relations
202-604-3771



CropLife ☆AMERICA☆

June 27, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary, U.S. Department of Health and Human Services
Chair, Make America Healthy Again Commission
200 Independence Avenue, S.W.
Washington, DC 20201

Submitted via e-mail to: Hannah Anderson, Deputy Chief of Staff for Policy

Dear Secretary Kennedy:

As the principal organization representing the United States (U.S.) innovators, producers, and distributors of pesticide products, CropLife America (CLA) is committed to working with you and members of the Make America Health Again (MAHA) Commission (Commission) to advance our shared goals of promoting children's health and ensuring that pesticide regulatory decisions are based on gold-standard science. We thank you for the opportunity for an open dialogue to achieve our shared goal of a healthier America.

In Section I of our letter, we are pleased to provide CLA's recommendations for policy topics the Commission should include regarding pesticides in the MAHA Strategy due August 12 (August Strategy), based on the topics raised in the MAHA Initial Assessment (Assessment) released May 22.[1] In Section II, CLA raises some concerns with the Assessment's reliance on flawed studies, incomplete references from the extensive body of scientific literature on pesticide safety, and unsupported claims that could undermine public confidence in the regulatory policies governing pesticide safety and consequently the domestic food supply.

CLA looks forward to further opportunities to engage with the Commission in advance of the August Strategy's release and are ready to provide more detailed information on any of the topics addressed in this letter. We may also supplement this letter with additional recommendations as we continue dialogue with the agricultural community, the Commission, and other stakeholders. We will follow up in approximately one week to find a time to meet with your team to further discuss our recommendations.

[1] The MAHA Report - The White House

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I. Ongoing Pesticide Activities and Innovations that Complement the Commission's Goals and Should be Referenced in the August Strategy

A. Pesticides are Vital to Children's Access to a Nutritious, Diverse, and Balanced Diet

CLA shares the Commission's goal of expanding access to and maintaining the affordability of fresh fruits, vegetables, and whole grains for American children. Pesticides are a part of all types of agricultural production systems, including conventional and organic, which are critical tools in a large toolbox that help American farmers to provide a safe, abundant, nutritious, and affordable food supply.

CLA recommends that in the August Strategy, the Commission specifically state that an agricultural production system that includes pesticides is vital to growing the fresh fruits, vegetables, whole grains, and animal protein that make up the nutritious diet that will support the health outcomes sought by the Commission. The Commission should consider observing in the August Strategy that without pesticide use in agricultural systems, there would be an estimated 78% loss of fruit production, 54% loss of vegetable production, and 32% loss of cereal (grains) production.[2] If the Commission's findings or recommendations were to have the effect of constraining American farmers' access to these important tools, food production would shift abroad and fruit and vegetable prices would increase substantially, putting healthy domestic options out of reach for millions of American families.

B. Pesticides Protect Children from Pest-Borne Disease

CLA recommends that in the August Strategy, the Commission state that responsibly regulated pesticides are critical to control ticks, mosquitoes, rodents, and other pests that spread diseases that can affect children.[3] Such diseases include Lyme disease, West Nile virus, Zika virus, and microbial infections. Household pests such as cockroaches can trigger or aggravate children's asthma and allergies – two of the chronic children's health conditions called out in the Assessment (page 9). The August Strategy provides the Commission with an opportunity to raise awareness and acknowledge that pesticides help to control these pests and are therefore protecting public health and, specifically, children's health.

C. EPA's Robust Risk and Science Based Pesticide Review System

CLA appreciates that the Assessment recognizes that EPA "has a robust risk-based approach that considers hazard and exposure for assessing the risks of … pesticides, to human health and the environment." (Assessment at 37). **CLA recommends that in the August**

[2] Agriculture Development, Pesticide Application and Its Impact on the Environment - PMC
[3] Pesticides, Disease Vectors and Public Health | US EPA

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Strategy, the Commission reiterate the robust, respected process used by EPA to review pesticides before and after regulation. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (later supplemented by the Federal Food, Drug, and Cosmetic Act [FFDCA]), no pesticide may be sold for use in the U.S. unless the U.S. Environmental Protection Agency (EPA or Agency) has approved it based on extensive scientific studies and data, which are independently evaluated by Agency experts across many scientific disciplines. EPA follows comprehensive and well-documented risk assessment processes developed over decades, which include internal cross-disciplinary peer review.

Pesticides registered for use as part of agricultural systems are thoroughly reviewed by governmental food, health, and environmental scientists to ensure they pose no unreasonable risk when used as directed and "a reasonable certainty that no harm will result from" exposure to pesticide residues on food. The test guidelines the EPA requires for these studies and models that are used to inform regulatory risk assessments are subject to extensive public scrutiny and independent scientific peer review before they are adopted.[4]

In addition to EPA's extensive internal scientific expertise, the Agency consults with external and independent experts to address novel or complex scientific questions. For example, EPA regularly convenes Scientific Advisory Panels (SAPs) under Section 25(c) of FIFRA, comprised of biologists, statisticians, toxicologists, and other specific experts to transparently provide independent scientific advice and to scrutinize proposed regulatory decisions on a range of health and safety issues.[5] EPA also obtains independent input from healthcare providers, academics, scientists, and other stakeholders on the Children's Health Protection Advisory Committee,[6] the Human Studies Review Board,[7] and the Pesticide Program Dialogue Committee.[8]

The net result of this legal and procedural framework is that our nation's science-based pesticide testing and risk assessment process is recognized as the gold standard globally.

D. Legally Mandated and Routine Pesticide Safety Review

CLA recommends that the Commission's August Strategy reference EPA's continual work to ensure pesticide safety. The Agency is required to re-evaluate each registered pesticide product and its registered uses every 15 years under FIFRA 3(g) to ensure that the pesticide satisfies current scientific standards.

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[4] OCSPP-TestGuidelines_MasterList-2019-09-24.docx
[5] FIFRA Scientific Advisory Panel | US EPA
[6] Children's Health Protection Advisory Committee (CHPAC) | US EPA
[7] Human Studies Review Board | US EPA
[8] Pesticide Program Dialogue Committee (PPDC) | US EPA

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Regarding the three pesticides specifically mentioned in the Assessment (*See* Assessment at pages 38, 45), **the Commission's August Strategy should state that EPA has scheduled registration review decisions for chlorpyrifos in 2025, and for atrazine and glyphosate in 2026.** These are among the over 200 pesticides for which EPA has scheduled registration review decisions, representing a major dedication and prioritization of EPA's finite scientific resources.[9]

E. EPA Procedures are Specifically Designed to Consider Children's Exposures

CLA recommends that the Commission's August Strategy explicitly state that EPA's pesticide review process comprehensively addresses the unique exposure pathways and developmental vulnerabilities of children discussed in the Assessment and includes the context provided below.[10]

For example, in evaluating dietary exposure levels of pesticide residues, EPA considers the food consumption patterns of infants and children, including disproportionately high consumption of certain foods. EPA also considers that children consume water at different rates than adults on a body weight basis.

In addition to assessing dietary exposures, EPA's rigorous scientific assessments include all other potential exposure pathways in all settings, giving special attention to children's body size and behaviors throughout development to adulthood. EPA's risk assessments consider where children spend time in indoor and outdoor settings where they may be crawling, walking, grasping, and engaging in hand-to-mouth behaviors. While approximately 50 percent of non-agricultural locations may not be treated with pesticides at all, EPA assumes there is exposure potential at all locations, resulting in highly protective safety factors for products.

Regarding toxicity, EPA reviews extensive data for each pesticide regarding any potential negative health outcomes, including (but not limited to) developmental issues, cancer, neurotoxicity, metabolic changes, acute symptoms, thyroid issues, and immune impacts. EPA must then consider information regarding the special susceptibility of infants and children to chemical residues "including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." 21 U.S.C. 346a(b)(2)(C). Under federal law, EPA may apply an additional ten times (10X) safety factor specifically to account for children's increased neurological and developmental sensitivity. This results in setting allowable pesticide residue levels that may be ten times lower than the calculated safe level. As EPA risk assessment decisions are driven by the highest risk group, many of EPA's pesticide approval decisions and use restrictions are decided in the end by EPA's analysis of the potential exposures and vulnerabilities of children.

[9] https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions
[10] *E.g.*, US EPA - EPA's Risk Assessment Process: Staff Paper #44

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The Assessment raises scientific uncertainty regarding the potential effects of aggregate and cumulative chemical exposures. (Assessment at 39). For pesticides, the Food Quality Protection Act of 1996 (FQPA) specifically addresses these topics.[11] Under the FQPA, EPA developed sophisticated and comprehensive risk assessment approaches for evaluating aggregate pesticide exposures from all sources[12] and cumulative exposure to pesticides identified as having common mechanisms of toxicity.[13] Under its detailed guidance on conducting cumulative and aggregate risk assessment, developed after public comment and multiple SAP reviews, EPA established a scientific approach for evaluating multichemical, multi-pathway risks to better protect public health and sensitive subpopulations – particularly children.[14]

F. Testing Pesticides for Possible Endocrine Effects

CLA recommends that in the August Strategy, the Commission discuss the significant progress EPA has made to implement the Endocrine Disruptor Screening Program (EDSP) for pesticides. The Commission's interest in this topic is timely, given the culmination of scientific advancement that has allowed EPA to establish a process and prioritization for completing this important work. CLA continues to support EPA's implementation of the EDSP.

The FQPA directs EPA to screen and test pesticides to identify potential endocrine disruptors, and substantial scientific resources have been dedicated to developing EPA's EDSP. After years of cutting-edge scientific work to develop valid scientific methods for screening and testing conventional pesticide chemicals for potential endocrine effects, EPA reached a significant milestone in 2023, publishing a plan to prioritize determinations regarding potential human estrogen, androgen, and thyroid effects for conventional pesticides.[15] On December 12, 2024, EPA entered a settlement agreement providing for the implementation of the EDSP, committing EPA to various action items.[16] On January 3, 2025, the Northern District of California entered a consent decree, committing EPA to court-enforceable deadlines for EPA's plan to implement the EDSP.

In 2025, EPA issued pesticide call in notices ("data call-ins"), establishing deadlines for companies to provide additional data regarding the pesticides identified as high priority for endocrine review.[17] More progress will be made throughout 2025 and into 2026.

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[11] Summary of the Food Quality Protection Act | US EPA
[12] General Principles for Performing Aggregate Exposure and Risk Assessments for Pesticides | US EPA
[13] Cumulative Assessment of Risk from Pesticides | US EPA
[14] US EPA: Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity
[15] Endocrine Disruptor Screening Program Timeline | US EPA; EPA Rebuilds Endocrine Disruptor Screening Program to Better Assess Human Endocrine Effects of Pesticides | US EPA
[16] EPA Finalizes Settlement and Announces New Tracking Website for Endocrine Disruptor Screening Program Data Call-In Notices | US EPA
[17] Status of Endocrine Disruptor Screening Program Data Call-In (DCI) Notices for Group 1 Chemicals | US EPA

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G. Innovations in Pesticide Application Technology

CLA recommends that in the August Strategy, the Commission discuss how private-sector innovation can focus and help to ensure the meticulous application of pesticides through precision agriculture. The agricultural sector is actively investing in new approaches and technologies to allow ever more targeted and precise pesticide applications, which increase crop productivity and reduce the total amount of pesticides needed to protect those crops.[18]

Senator Deb Fischer recently reintroduced three items of legislation intended to facilitate these precision application investments.[19] The agricultural sector is also working on improving pesticide labeling to facilitate the incorporation of these precision application methods, including targeted drone applications, computer-assisted targeted spray technology,[20] robotic monitoring, and related innovations.

H. New Approach Methods (NAMs) and Precision Toxicology

CLA supports the Commission's recommendation in the Assessment regarding developing testing methods for pesticides and other chemicals that do not use animals – known as New Approach Methods or (NAMs). (*See* Assessment at 72, Next Steps #9). Advancing NAMs is a topic of common interest to EPA, agricultural stakeholders, and non-governmental entities. **CLA recommends that in the August Strategy, the Commission discuss NAMs in more detail.**

The increased sophistication of NAMs is rapidly advancing through the work of scientists across academic institutions, governmental agencies, and the agricultural sector. Today, some hazards, like skin irritation, can be tested reliably through NAMs, while more complex effects are not yet reliably testable through NAMs. CLA agrees that more research is needed to support the development and validation of animal testing alternatives. Discussion of these points in the August Strategy would be appropriate.

CLA also supports the Commission including in the August Strategy a strong discussion of precision toxicology, as referenced in the Assessment. (*Id.* #10). Precision toxicology is the use of detailed "whole picture" biological information (*e.g.,* changes in gene expression profiles that are related to adversity). The rapid increase in large-scale biological data generation through genomic techniques has transformed biological research. The detailed information offered by these techniques can be especially useful in identifying the toxicological mechanism, which can play a significant role in determining whether a health effect observed in animal tests could be relevant to humans.

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[18] Precision Tech Ag Professional - CropLife

[19] https://www.fischer.senate.gov/public/index.cfm/2025/5/fischer-reintroduces-precision-ag-package

[20] See & Spray™ Customers See 59% Average Herbicide Savings in 2024 – CropLife Magazine (by Meister Media, unrelated to CLA)

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Substantial data processing is required to make this information useful, and even slight changes in this processing phase can significantly impact the results. Additionally, for precision toxicology approaches to be applied to human health, the disease or health effect being evaluated must be understood on a molecular level, which is often not the case. While work remains to standardize precision toxicology data generation, processing, and interpretation before it can be applied in regulatory decision making, CLA is committed to advancing this process with stakeholders.

I. Supporting USDA's Pesticide Data Program

CLA recommends that in the August Strategy, the Commission supports continuing USDA's Pesticide Data Program (PDP). The PDP is a national pesticide residue monitoring program that "produces the most comprehensive pesticide residue database in the U.S." and emphasizes the testing of "those commodities highly consumed by infants and children."[21] EPA relies on PDP data and USDA food consumption models to provide the children's diet information necessary for reliable pesticide risk assessments.[22] The Assessment cites PDP data that found that 99% of tested food samples were compliant with EPA residue limits. (Assessment at 45).

PDP's work helps EPA and other agencies make informed regulatory decisions, supports public confidence in the U.S. food supply, and facilitates the global marketing of U.S. agricultural products. In 2024 alone, the U.S. exported $176 billion in agricultural goods, significantly reducing the trade deficit, and reflecting the trust that global regulators and consumers place in American safety and quality systems.

J. Funding EPA's Office of Pesticide Programs and its Reduced Risk Pesticide Registration Program

CLA recommends that in the August Strategy, the Commission support Congressional funding of EPA's Office of Pesticide Programs (OPP) at the Pesticide Registration Improvement Act (PRIA) 5 statutory level of $166M. OPP employs the scientists and regulators who implement EPA's comprehensive pesticide risk assessment processes discussed in Sections C and E, the reevaluation program discussed in Section D, and the EDSP program discussed in Section F. Pesticide companies pay application and maintenance fees to EPA under PRIA,[23] however these fees account for about one-third of the costs of

[21] Pesticide Data Program | Agricultural Marketing Service
[22] US EPA - EPA's Risk Assessment Process: Staff Paper #44 at 6, 11.
[23] Application fees are due when the application is submitted, and the amount does not vary based on the outcome of EPA's review.

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operating EPA's pesticide regulatory program.[24] The remaining two-thirds are funded through annual appropriations by Congress which have regularly fallen short.

Adequate OPP funding at statutorily mandated levels is essential to allow EPA to timely complete its ongoing scientific safety review of existing pesticides, and to continue to implement initiatives like the EDSP. The scientific and regulatory innovations identified as desirable in the Assessment (*e.g.*, Page 39), require EPA engagement, review, and approval, placing further demands on OPP's already-limited resources.

CLA recommends that in the August Strategy, the Commission reference the importance of supporting OPP's Reduced Risk Program. This program provides an expedited review process for pesticides that are assessed as meeting reduced risk criteria, allowing them to be registered and available to users more quickly. Reviewing and approving reduced risk product applications puts additional strain on OPP staff, as they involve convening a Reduced Risk Committee, reviewing comparative risk data, and other supporting information to determine eligibility for such status. If reduced risk status is granted, OPP conducts the complete pesticide risk assessment and regulatory approval process on an expedited basis. In past years, OPP funding decreases have limited EPA's full implementation of the Reduced Risk Program.

Other innovations like those identified above (*e.g.*, precision agriculture, NAMs, precision toxicology) hold significant promise. But to be successful, these new methods require the dedication of OPP resources necessary for scientific review and approval prior to their application in order to inform regulatory decision making. **The August Strategy should include a strong call for support for the statutorily mandated OPP funding so that EPA's robust regulation of pesticides can continue and the Agency can also facilitate the innovations identified in the Assessment and sought by the Commission.**

K. Funding for State Pesticide Programs

CLA recommends that in the August Strategy, the Commission support funding for state pesticide programs. Federal funding is a critical element to ensure education across each state on the proper handling and use of pesticides, which helps to protect children. Reductions in federal assistance to state pesticide programs could have significant unintended consequences on children and public health.

States are both co-regulators and stakeholders in the regulation of pesticides. States play a critical role first in carrying out educational programs to help ensure proper use of pesticides. Second, they take necessary enforcement actions when pesticides are not used according to the label.

[24] US EPA - FY 2023 Pesticide Registration Improvement Act (PRIA) Annual Report.

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All EPA registered pesticides also must be registered in each state before they can be used in that state. As each state pesticide program has developed in its own manner, the states coordinate and exchange best practices and experiences with one another through a variety of professional forums. EPA and USDA are very engaged in supporting the capacity of state programs. **The Commission should recognize in the August Strategy the key role of states in advancing training on proper pesticide use and management, as well as the exchange of knowledge.**

II. Unfounded Scientific Claims and Unreliable References in the Assessment

A. Industry-Conducted Studies

The Commission's critique of industry-conducted studies (Assessment at 45-46) does not apply to pesticide studies for the reasons discussed here. First, core scientific data used to support EPA pesticide risk assessments and registration must conform to globally harmonized, peer-reviewed study guidelines, designed to ensure the quality, validity, and integrity of pesticide data. The conduct of such studies must also comply with rigorous Good Laboratory Practice (GLP) standards, established in EPA regulations at 40 C.F.R. Part 160.

Second, GLP standards impose detailed requirements for the personnel, facilities, equipment, and practices of pesticide testing facilities, including maintenance of an independent quality assurance unit, standards for equipment, requirements for handling test substances and samples, and extensive recordkeeping and reporting requirements. Facilities that conduct pesticide studies are subject to inspection by EPA and other officials, including laboratories outside the United States, and violations may be subject to civil and criminal penalties. Over several decades of EPA pesticide regulation, there have been only a few instances of significant data quality issues at commercial pesticide laboratories, and in those instances EPA reviewers and inspectors were able to promptly identify and remedy them.[25] These procedures and requirements ensure unbiased study designs and reliable, high-quality data.

Also unwarranted and unsupported is the Assessment's concern that "publication bias" could limit the publication of "unfavorable results" regarding pesticides. (Assessment at 46). Under Section 6(a)(2) of FIFRA, adverse effect information possessed by a pesticide registrant must be timely submitted to EPA, including unfavorable results from a scientific study, or incidents of alleged harmful effects from product use.[26] EPA's review is not limited to industry submissions, but also considers other scientifically relevant and reliable studies and information in scientific literature regarding a given pesticide. The data submitted to EPA concerning each pesticide product, and EPA's review process, are globally recognized as gold standard science.

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[25] *E.g.*, EPA Halts Acceptance of Data for Pesticide Registration from a Non-compliant Laboratory

[26] Incident Reporting by Pesticide Manufacturers/ Registrants | US EPA

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B. Unsupported Claims and Unreliable References in the Assessment

As the Commission moves forward towards the August Strategy, CLA recommends that it draws its conclusions exclusively from a weight-of-the-evidence evaluation of the entire body of high-quality science and data regarding agricultural systems and pesticide use. The Commission should avoid reliance on misleading, and outlier studies. Such studies will undermine public confidence and lead to misguided federal and state policies to restrict agricultural systems used to prevent pest-borne diseases and could limit farmers' tools to provide a safe, abundant, and affordable food supply.

A weight-of-the-evidence approach is consistent with EPA's established pesticide risk assessment process, and President Trump's recent Executive Order 14303 "Restoring Gold Standard Science." 90 Fed. Reg. 22601, 22603 (May 29, 2025).[27]

CLA is concerned that while acknowledging that the "American food system is safe" (Assessment at 16), the Assessment includes misleading and unfounded claims regarding exposure to chemicals including pesticides. The presence of one or more pesticides detected in food and feed residues does not translate to risk without evaluation of the amount and type of exposure and the toxicological characteristics of the substance. Epidemiology studies, for example, are typically observational, and it is notoriously difficult to derive reliable evidence regarding risk based on a statistical association from such studies. In general, a single study suggesting a correlation does not establish causation, and confounding variables are common.

Several of the Assessment's original references have been updated. **CLA recommends that the Commission remove reference to this study regarding "possible health effects" of glyphosate as it was rejected by a federal court as junk science.** ***In re Roundup Prods. Liab. Litig.*****, 737 F.Supp. 3d 898, 900 (N.D. Cal. 2024) (addressing Zhang et. al., cited in the Assessment on page 45, n. 305).**

[27] "When scientific or technological information is used to inform agency evaluations and subsequent decision-making, employees shall apply a 'weight of scientific evidence' approach."

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III. Conclusion

CLA shares the Commission's goal of improving the health of American children, including by increasing the availability of a nutritious, diverse, and balanced diet, which will help to advance overall children's health.

We are pleased to offer the preceding recommendations in response to the Commission's request for specific policy suggestions. We believe each suggestion is concrete, practical, relevant, consistent with law, and aligned with the Commission's vision.

CLA looks forward to discussing our letter with members of the Commission and other stakeholders as the August Strategy is developed, through the Commission's promised inclusive and transparent process and through meetings that we convene as CLA. As mentioned above, CLA may supplement this letter with additional recommendations as we continue our dialogue with the agricultural community, the Commission, and other stakeholders.

We are proud to be part of the agricultural system in the U.S. that helps our farmers offer the healthiest, most abundant, and most affordable food in the world. As noted on the first page, we will follow up in one week to find a time to meet with your team to further discuss our recommendations.

Sincerely,



Alexandra Dapolito Dunn, Esq.
President and CEO
CropLife America

cc: Vincent Haley, Assistant to the President for Domestic Policy – Executive Director
Brooke Rollins, Secretary of Agriculture
Scott Turner, Secretary of Housing and Urban Development
Linda McMahon, Secretary of Education
Douglas Collins, Secretary of Veterans Affairs
Lee Zeldin, Administrator of the Environmental Protection Agency

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Russell Vought, Director of the Office of Management and Budget
Stephen Miller, Assistant to the President and Deputy Chief of Staff for Policy
Dr. Kevin Hassett, Director of the National Economic Council
Dr. Stephen Miran, Chairman of the Council of Economic Advisers
Michael Kratsios, Director of the Office of Science and Technology Policy
Dr. Martin Makary, Commissioner of Food and Drugs
Dr. Jayanta Bhattacharya, Director of the National Institutes of Health

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ED_020825_00000011-00012

Prepared July 15, 2025

Talking Points for Meeting with EPA Deputy Administrator Fotouhi

Crop protection tools, which include pesticides, are vital to children's access to a nutritious, diverse, and balanced diet. An agricultural production system that includes pesticides is essential to growing the fresh fruits, vegetables, whole grains, and animal protein that make up a nutritious diet that will support the health outcomes sought by the Commission.

Pesticides are registered for use as part of responsibly regulated agricultural systems, and are thoroughly reviewed by U.S. Environmental Protection Agency (EPA) scientists to ensure they pose no unreasonable risk when used as directed and that "a reasonable certainty that no harm will result from" exposure to pesticide residues on food. Discussion of the laws and regulations used to oversee pesticides can help to build public confidence in the U.S. grown food they bring home to their families. EPA's pesticide review process addresses the unique exposure pathways and developmental vulnerabilities of children. In addition to assessing dietary exposures, EPA's assessments include all other potential exposure pathways in all settings, giving special attention to children's body size and behaviors throughout development to adulthood.

A. **Legally Mandated and Routine Pesticide Safety Review**

EPA is required to re-evaluate each registered pesticide product and its registered uses every 15 years (often sooner than 15 years as new information becomes available) under federal law ***to ensure that the pesticide satisfies current scientific standards****. The three pesticides mentioned in the Commission's May 2025 Initial Assessment are scheduled for review in* ***2025 and 2026****.*

B. **Testing Pesticides for Possible Endocrine Effects**

Federal law directs EPA to screen and ***test pesticides to identify potential endocrine disruptors, and substantial scientific resources have been dedicated to developing EPA's Endocrine Disruptor Screening Program (EDSP). In 2025****, EPA issued pesticide call in notices establishing deadlines for companies to provide more data regarding the pesticides identified as high priority for endocrine review. More progress will be made in* ***2025 and 2026****.*

C. **Innovations in Precision Pesticide Application Technology**

The agricultural sector is actively investing in new approaches and technologies to allow ever more ***targeted and precise pesticide applications****, which increase crop productivity and reduce the total amount of pesticides needed to be applied to protect those crops. Private-sector innovation is at the heart of the* ***precision agriculture movement****.*

D. **New Approach Methods (NAMs) and Precision Toxicology**

Testing methods for pesticides and other chemicals that do not use animals – New Approach Methods or (NAMs) – is a topic of common interest to EPA, agricultural stakeholders, and non-governmental entities. The increased sophistication of NAMs is rapidly advancing through the work of scientists across academic institutions, governmental

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agencies, and the agricultural sector. ***Further advancements in NAMs would be well received.***

Also of great interest is the ***refinement of precision toxicology*** *- the use of detailed "whole picture" biological information (e.g., changes in gene expression profiles that are related to adversity). The rapid increase in large-scale biological data generation through genomic techniques has transformed biological research. The private sector is an excellent partner here.*

E. Reinvigorating EPA's Reduced Risk Program & Elevating Biological Pesticides

EPA currently has a program in place at the Office of Pesticide Programs (OPP) called the Reduced Risk Program, which expedites pesticides applications when the products under the application meet reduced risk criteria. Due to OPP staffing and resource shortages, and outdated technology, ***the Reduced Risk Program has become backlogged at EPA. This backlog deserves attention*** *so that innovative products make it to the hands of American farmers more quickly.*

Related, EPA's OPP office that reviews biological-based pesticides (BPPD) is also facing a backlog due to limited resources and staffing and outdated technology. Investment in BPPD will allow integrated pest, disease, and weed management solutions to be brought forward for American farmers that incorporate biological solutions. While some pest and weed pressures will always require responsibly used conventional pesticides, the ***use of biologicals throughout growing seasons represents a growing and exciting sector that is enhancing the future of agriculture, and deserves attention and investment.***

F. U.S. Farmers' Waning Competitive Advantage Accessing New Crop Protection Products

Delays at EPA in registering pesticide products, both biological and conventional, are leading to U.S. farmers having less access to the most cutting-edge products – ***products that are reaching farmers in other nations****. The U.S. used to be among one of the first nations to register a new pesticide active ingredient (AI). In many instances now, the U.S is not among the top countries, and in specific cases currently before EPA, the U.S. will be the 14th and 21st country to register the new AI. This means* ***U.S. growers are at a significant competitive disadvantage fighting weeds, disease, and pests.*** *Investment in EPA's pesticide programs – conventional and biological – is critical to help restore equity for American farmers.*

Message

From: Bridgforth, Turner [Bridgforth.Turner@epa.gov]
Sent: 12/2/2025 2:20:24 PM
To: Erick Lutt [erick.lutt@bayer.com]
Subject: Re: Bayer welcomes Solicitor General support for U.S. Supreme Court review

Thank you sir!

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From: Erick Lutt <erick.lutt@bayer.com>
Sent: Tuesday, December 2, 2025 7:42:33 AM
To: Bridgforth, Turner <Bridgforth.Turner@epa.gov>
Subject: FW: Bayer welcomes Solicitor General support for U.S. Supreme Court review

Caution: This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Hey Turner, I hope you are doing well and had a nice Thanksgiving break.

You might have seen this last night, but last night, the Solicitor General submitted the government's amicus brief in support of U.S. Supreme Court review of the petition for a writ of certiorari in the Durnell case and agreement with the Bayer's arguments on preemption.

You can find the brief on the Supreme Court's docket here and Bayer's press release copied below.

Please let me know if you have any questions or need any additional information.

All the best,
Erick

Erick Lutt
Bayer U.S. – Crop Science

//////////////////////

Mobile: +1 202-701-8153
E-mail: erick.lutt@bayer.com

Bayer welcomes Solicitor General support for U.S. Supreme Court review

Company continues to advance multi-pronged strategy to significantly contain the litigation by the end of 2026

Leverkusen, December 2, 2025 – Bayer is pleased the Solicitor General supports U. S. Supreme Court review of the petition for a writ of certiorari in the Durnell case and agrees with the company's arguments on preemption. The company believes that the backing of the U.S. government will be important to the Court's consideration of its petition. The split among federal circuit courts in the Roundup™ personal injury litigation, on the cross-cutting question of whether federal law preempts state claims based on failure-to-warn theories, warrants review and resolution by the country's top court.

"The support of the U.S. Government is an important step and good news for U.S. farmers, who need regulatory clarity. The stakes could not be higher as the misapplication of federal law jeopardizes the availability of innovative tools for farmers and investments in the broader U.S. economy", said CEO Bill Anderson.

Similar preemption language to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is included in other federal statutes such as those regulating medical devices, poultry products, meat, and motor vehicles. It is time for the U.S. legal system to establish that companies cannot be punished under state laws for complying with federal label requirements.

As part of the company's multi-pronged strategy, a positive ruling on the central, cross-cutting preemption issue could help bring the company closer to closure of tens of thousands of Roundup™ cases, which are overwhelmingly based on claims grounded in failure-to-warn theories. The EPA and every other regulator worldwide that has independently assessed the safety of glyphosate, the active ingredient in most Roundup™ products, has concluded it can be used safely.

The company continues to advance its multi-pronged strategy designed to significantly contain the litigation by the end of 2026 as outlined in its Q3 communication.

About Bayer
Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is

committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Bayer AG is a holding company with operating subsidiaries worldwide. References to "Bayer" or "the company" herein may refer to one or more subsidiaries as context requires.

2025-0216e.pdf

URL : https://www.bayer.com/media/en-us/bayer-welcomes-solicitor-general-support-for-us-supreme-court-review/

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Message

From: Bridgforth, Turner [Bridgforth.Turner@epa.gov]
Sent: 12/5/2025 4:39:03 PM
To: Erick Lutt [erick.lutt@bayer.com]
Subject: Re: Statement Regarding Williams Study Retraction

Thank you sir

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From: Erick Lutt <erick.lutt@bayer.com>
Sent: Friday, December 5, 2025 8:31:01 AM
To: Bridgforth, Turner <Bridgforth.Turner@epa.gov>
Subject: Statement Regarding Williams Study Retraction

> **Caution:** This email originated from outside EPA, please exercise additional caution when deciding whether to open attachments or click on provided links.

Hey Turner, I saw EPA's quote on this issue in the Washington Post this morning. Copied below is Bayer's statement and bullets it's been providing on background.

Please let me know if you have any questions.

All the best,
Erick

Statement Regarding Williams Study Retraction
Final 12/4/25

"Glyphosate is the most extensively studied herbicide over the past 50 years. Thousands of studies have been conducted on the safety of glyphosate products, and the vast majority of published studies had no Monsanto involvement. The consensus among leading regulatory bodies worldwide is that glyphosate can be used safely as directed and is not carcinogenic. Because the Williams et al paper is 25 years old, the EU did not rely on this paper in its recent assessment and approval process. Furthermore, the Williams paper is a review article of properly-conducted studies which were separately provided to regulators for their review, and contains no original data.

"Monsanto's involvement with the Williams et al paper did not rise to the level of authorship and was appropriately disclosed in the acknowledgments. The listed authors had full control over and approved the study's manuscript. Two prior inquiries into the study previously found that the paper was appropriate, including the European Food Safety Authority (EFSA), and William's former employer."

On Background

- **Disclosure of Monsanto Involvement in Williams Paper**: The Williams et al paper discloses Monsanto's involvement appropriately in its acknowledgement section. It reads in part: "we thank the toxicologists and other scientists at Monsanto who made significant contributions to the development of exposure assessments and through many other discussions," and further identifies several key personnel at Monsanto who provided scientific support.

- **EFSA Prior Review of Williams**: In 2017, EFSA also addressed the allegations about the Williams et al paper. EFSA stated: "the Williams et al. paper acknowledges that Monsanto facilitated the authors' work by providing them with original, unpublished studies. This means that Member State and EFSA experts were under no illusion about the links between the study authors and the companies that funded or facilitated their work when the experts carried out the risk assessment... The review papers in question represented only two of approximately 700 scientific references in the area of mammalian toxicology considered by EFSA in the glyphosate assessment."
- **Investigation by Williams' Former Employer**: As reported in trade publication *Science* in 2017, "After a quick investigation, officials at a medical school in New York State say they have found 'no evidence' that a faculty member violated the school's prohibition against authoring a paper ghostwritten by others," and the school said, "the college does consider the matter in question to be closed."

Erick Lutt
Director
Federal Government Affairs

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