No. 14-72794

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PESTICIDE ACTION NETWORK NORTH AMERICA, and
NATURAL RESOURCES DEFENSE COUNCIL, INC.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

BRIEF OF *AMICI CURIAE* CROPLIFE AMERICA, AGRICULTURAL RETAILERS ASSOCIATION, ALMOND ALLIANCE OF CALIFORNIA, AMERICAN SOYBEAN ASSOCIATION, AMERICAN SUGARBEET GROWERS ASSOCIATION, BEET SUGAR DEVELOPMENT FOUNDATION, CALIFORNIA CITRUS MUTUAL, NATIONAL AGRICULTURAL AVIATION ASSOCIATION, NATIONAL CORN GROWERS ASSOCIATION, NATIONAL COTTON COUNCIL, NATIONAL POTATO COUNCIL, NATIONAL SORGHUM PRODUCERS, OREGONIANS FOR FOOD & SHELTER, SCHERTZ AERIAL SERVICE, INC., U.S. APPLE ASSOCIATION, WASHINGTON FRIENDS OF FARMS & FORESTS, AND WESTERN GROWERS ASSOCIATION IN SUPPORT OF NEITHER PARTY

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, *Amici Curiae* CropLife America, Agricultural Retailers Association, Almond Alliance of California, American Soybean Association, American Sugarbeet Growers Association, Beet Sugar Development Foundation, California Citrus Mutual, National Agricultural Aviation Association, National Corn Growers Association, National Cotton Council, National Potato Council, National Sorghum Producers, Oregonians for Food & Shelter, Schertz Aerial Service, Inc., U.S. Apple Association, Washington Friends of Farms & Forests, and Western Growers Association hereby disclose that they are not owned in whole or in part by a parent corporation and do not issue stock.

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INTERESTS OF *AMICI CURIAE*[1]

CropLife America ("CropLife")

CropLife is a national, non-profit trade association representing companies that develop and sell crop protection and biotechnology products for agriculture and pest management in the United States. The U.S. Environmental Protection Agency ("EPA") reviews the human health and environmental impacts of these products before and after they are approved for use in the United States pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.* and the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.* Once approved for use in the United States, EPA grants registrations (or licenses) for these products pursuant to FIFRA and FFDCA. CropLife's members have invested billions of dollars in research and testing to produce the scientific data necessary to obtain and maintain these registrations and have participated extensively in EPA's registration process.

[1] This brief was not authored in whole, or in part, by counsel for a party, and no party or party's counsel contributed money intended to fund the preparation or submission of the brief. Fed. R. App. P. 29(c)(5). Dow AgroSciences LLC, the primary registrant for chlorpyrifos and a member of *Amicus Curiae* CropLife, contributed money intended to fund the preparation and submission of this brief. *Id.*

Agricultural Retailers Association ("ARA")

ARA is a trade association representing agricultural retailers and distributors. ARA's members provide products to farmers and ranchers, including seed, nutrients, and crop protection products. ARA's members also provide consultative services such as crop scouting, soil testing, and custom application of pesticides. ARA's 300 members, operating in all fifty states, sell over seventy percent of all crop input materials purchased by U.S. farmers.

Almond Alliance of California ("AAC")

AAC is a trade association representing ninety percent of the California almond industry based on volume. Almonds are California's number one agricultural export and number two agricultural crop, valued at $5.9 billion in 2014. The California almond industry generates more than 100,000 jobs and more than $21 billion gross revenue across all industries in the state, adding approximately $11 billion dollars to the state's economy.

American Soybean Association ("ASA")

ASA is the national, non-profit trade association representing U.S. soybean farmers on domestic and international issues of importance to the soybean industry. ASA has approximately 22,000 farmers in thirty-one states and represents the interests of 301,000 American soybean farms. The farm-gate crop value of soybeans in 2015 exceeded $34 billion.

American Sugarbeet Growers Association ("ASGA")

ASGA is a trade association that promotes the common interest of sugarbeet growers and state and local beet grower associations. ASGA's member associations represent 10,000 family farmers in all eleven producing states.

California Citrus Mutual ("CCM")

CCM is a trade association dedicated to the sustainability of the California citrus industry. CCM's 2,500 citrus producers comprise seventy-five percent of California's 292,000 acre, $3.3 billion citrus industry. CCM advocates for citrus producers on critical economic, regulatory, and political issues.

Beet Sugar Development Foundation ("BSDF")

BSDF was established to advance sugarbeet production and beet sugar processing through science-based research and educational programs. BSDF members include beet sugar processing companies and sugarbeet seed and related companies.

National Agricultural Aviation Association ("NAAA")

NAAA provides networking, educational, government relations, public outreach, and other services on behalf of approximately 1,900 members in forty-six states. NAAA supports the interests of small business owners and pilots licensed as professional commercial aerial applicators who use aircraft to enhance food, fiber, and biofuel production, protect forestry, and control health-threatening pests.

National Corn Growers Association ("NCGA")

NCGA represents more than 40,000 corn farmers nationwide as well as the interests of more than 300,000 growers who contribute through corn check-off programs in their states. NCGA and its forty-eight affiliated state organizations work together to create and increase opportunities for corn growers.

National Cotton Council ("NCC")

NCC's mission is to ensure the ability of all U.S. cotton industry segments to compete effectively and profitably in the raw cotton, oilseed, and U.S.-manufactured product markets at home and abroad. NCC serves as the central forum for consensus-building among producers, ginners, and other industry participants.

National Potato Council ("NPC")

NPC was formed in 1948 for U.S. potato growers. NPC represents more than ninety percent of the approximately 6,000 potato farmers in the United States on regulatory and legislative issues that affect potato production nationwide.

National Sorghum Producers ("NSP")

NSP represents sorghum growers nationwide in education, legislative, and regulatory matters impacting the sorghum industry.

Oregonians for Food & Shelter ("OFS")

OFS is a member-funded grass roots coalition dedicated to public education and advocacy on issues impacting foresters and farmers. OFS's mission is to promote the efficient production of quality food and fiber while protecting human health, personal property, and the environment, through the integrated, responsible use of pest management products, soil nutrients, and biotechnology.

Schertz Aerial Service, Inc. ("Schertz Aerial")

Schertz Aerial provides aerial crop protection services to growers in central Illinois. It has been in continuous operation since it was founded in 1969.

U.S. Apple Association ("USApple")

USApple serves the interests of the American apple industry. Its members include forty state and regional associations representing the nation's 7,500 apple growers, as well as more than 1,000 individual firms involved in the apple business. Apples are the third most valuable fruit crop in the United States, with an annual farm-gate value of approximately $3.5–4 billion and a downstream value of $12–14 billion. Apples are the most valuable fruit export from the United States, with exports valued at over $1 billion in 2014.

Washington Friends of Farms & Forests ("WFFF")

WFFF is a trade organization representing 200 of Washington's agricultural and timber producers. WFFF supports producers of food and fiber by working to

ensure a science-based regulatory system. Washington leads the nation in the production of eleven crops, including apples, cherries, pears, mint, peas, juice grapes, and hops. All but one of the crops grown in Washington is a specialty crop, and there are limited pesticides registered for use on these crops. Insect pests cost Washington growers millions of dollars a year in crop damage.

Western Growers Association ("WG")

Founded in 1926, WG represents local and regional family farmers growing fresh produce in Arizona, California, and Colorado. WG members and their workers provide half the nation's fresh fruits, vegetables, and tree nuts, including half of America's fresh organic produce. For generations, WG members have provided variety and healthy choices to consumers. WG is a leading public policy advocate for the fresh produce industry and has a longstanding interest in environmental matters impacting the agriculture industry.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Court has directed EPA to act on a proposed rule to revoke all tolerances for the pesticide chlorpyrifos by December 30, 2016, unless "extraordinary circumstances" make compliance with that deadline "impracticable."[2] ECF No. 29.

[2] "Extraordinary circumstances" is a context-specific inquiry. This Court, however, has indicated that "extraordinary circumstances" is a "close correlate" of good cause. *Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 610 (9th Cir. 1992).

The revocation of tolerances for chlorpyrifos would effectively remove the product from the market, with significant agricultural, economic, and international trade repercussions. *Amici* agree with EPA's June 29 Status Report (the "Status Report") that "extraordinary circumstances" do indeed exist necessitating that the Court provide EPA with more time. But, under EPA's proposed timeline, the Agency would devote very limited time (only a couple of months) to additional scientific work on its assessment for chlorpyrifos, far short of the time needed by the Agency to complete a thorough, scientifically robust, and transparent review that fulfills the Agency's statutory obligations. *Amici* believe that EPA needs at least another year beyond the Court's current deadline to conduct its science work.

Until now, the Court has heard only from the petitioners who seek removal of chlorpyrifos from the market and EPA with respect to the deadline imposed for final agency action. The purpose of this *amicus* brief is twofold. First, this brief will provide the Court with information from wide-ranging agricultural stakeholders regarding the severe impacts that the removal of chlorpyrifos will have on growers and other participants in the agricultural industry. To date, no party's status reports or other submissions to the Court have adequately addressed this critical issue. Second, this brief will provide information to the Court on why EPA needs more time to complete its decision-making process regarding chlorpyrifos beyond the additional six months the Agency has requested in its Status Report.

Chlorpyrifos has served an important role in pest management efforts supporting a safe and abundant food supply for over forty years. Chlorpyrifos is currently one of the most widely used insecticide products in the world and protects over fifty valuable U.S. food crops from destruction due to insect pests.

EPA proposed to revoke all tolerances for chlorpyrifos on November 6, 2015. *See Chlorpyrifos; Tolerance Revocations*, 80 Fed. Reg. 69,080 (the "Proposed Rule"). As EPA concedes in its Status Report, the Proposed Rule was based on (i) the Agency's *incomplete* scientific analysis of epidemiology studies, in particular a taxpayer-funded study conducted by researchers at Columbia University (the "Columbia Study"), regarding the potential for neurodevelopmental effects that may arise from prenatal exposure to chlorpyrifos; and (ii) EPA's *incomplete* drinking water assessment based on a novel modeling analysis.

With respect to the epidemiology issue, in March 2016, EPA announced a new proposal to establish a precedent-setting regulatory standard for chlorpyrifos based essentially on the Columbia Study. EPA's proposal would effectively replace over four decades of established science based on a robust, animal-based toxicology database—a complete sea change in the pesticide risk assessment process.

In April 2016, EPA convened a Scientific Advisory Panel ("SAP") to seek guidance on its unprecedented proposal. The SAP is a Federal advisory committee

established under FIFRA to provide expert scientific advice and recommendations to the Agency. 7 U.S.C. § 136w(d)(1). In its oral comments during the proceeding, the SAP strongly rejected EPA's proposal, urging EPA to undertake further, more scientifically credible analyses, including a thorough review of the raw data underlying the Columbia Study. To date, despite repeated requests by EPA to the authors of the study, the raw data remain elusive and unavailable. The SAP's formal report is not due out until late July.

EPA's Status Report states that the SAP's formal report will inform EPA's final decision in selecting one of three regulatory standards: (i) EPA's traditional approach of using acetylcholinesterase inhibition, but relying on the Columbia Study to lower the exposure threshold for certain populations; (ii) EPA's new proposal based on the Columbia Study, or (iii) an unexplained hybrid of the two approaches. ECF No. 39-1 at 4–5, n.1. EPA estimates that it can complete any additional analyses the Agency believes are warranted and make a decision on which standard to use within two months of receiving the SAP's report, after which it will publish its decision for public comment. *Id.* at 5. But, as explained below, two months is not nearly enough time to complete the additional scientific analyses necessary to support any of these approaches.

With respect to drinking water, EPA's Status Report states that, since publishing its Proposed Rule, it has "completed the refined drinking water analysis

for all 21 major hydrologic regions of the country." *Id.* at 3. The Proposed Rule and Status Report do not fully describe EPA's methodology, but, as discussed herein, EPA appears to be using a modified version of a drinking water assessment methodology it began developing in 2011 that the SAP recently advised EPA may be years away from use in risk assessment.

In light of these developments, more time is needed, beyond the Court's current and EPA's proposed deadline, for EPA to complete a thorough analysis that has the requisite degree of scientific integrity. The serious flaws in the Agency's analytical process, the unprecedented techniques the Agency proposes to use, and the severe negative consequences of acting on the basis of a flawed analysis, were not before the Court when it set the current deadline. EPA should not be forced to rush to judgment on such a precedent-setting regulatory action, particularly one that would have far-reaching consequences for U.S. agriculture and consumers. As set forth below, *Amici's* position is supported by the U.S. Department of Agriculture and former EPA and other scientists who are very familiar with the time commitment necessary to complete a rational, science-based risk assessment in circumstances such as those presented here.

This mandamus action was initiated by the same petitioners (the "Petitioners") who had submitted to EPA the administrative petition to revoke tolerances for chlorpyrifos. In response to that petition, EPA initiated Registration

Review pursuant to FIFRA. *See* https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0850. EPA has a statutory mandate to ensure that Registration Review is based on sound, current science. *See* 7 U.S.C. §§ 136a(g); 136 (bb) (requiring periodic review of pesticide registrations to ensure that they align with evolving scientific standards); *see also* 40 C.F.R. § 155.53 (Agency will assess changes that may have occurred since last registration decision, including "any changes in statutes or regulations, policy, risk assessment procedures or methods, or data requirements."). Petitioners became impatient with EPA's Registration Review process and filed the instant action. But Petitioners' impatience should not replace Congress's purpose in enacting Registration Review and Congress's mandate that Registration Review be based on sound science.

Moreover, it appears that the Court's current deadline has been forcing EPA to favor expediency over thorough, scientifically sound analyses. In its Proposed Rule and during the recent SAP that preceded the Status Report, EPA repeatedly stated that it needs to act quickly in light of the Court's rapidly approaching deadline. *Amici* and other critical stakeholders have been left with the impression that the Agency has been driven by this deadline, not by science-based decision-making pursuant to Registration Review. However, the Court anticipated in its Order that circumstances could exist that necessitate an extension of the December

30, 2016 deadline, and *Amici* urge that such circumstances are indeed present in this matter.[3]

BACKGROUND

I. Regulatory Framework

EPA regulates pesticides under a comprehensive, science-based regime pursuant to its authority under FIFRA and FFDCA. Under Section 408 of the FFDCA, as amended by the Food Quality Protection Act ("FQPA"), before a pesticide may be used on any food crop, EPA specifies the maximum amount of pesticidal residue (called a "tolerance") that may legally remain in or on foods. *See* 21 U.S.C. § 346a. In setting tolerances, EPA must determine based on available scientific data that the tolerance is "safe," *i.e.*, that there is "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue." *Id.* § 346a(b)(2)(A)(ii). And Congress has made clear that this registration standard, when applied to a food-use pesticide such as chlorpyrifos, requires satisfaction of the FFDCA's safety standard for any residues of the pesticide that may be present in the food supply. *See* 7 U.S.C. §§ 136(bb). Thus, without the requisite food safety tolerances, EPA would be required to cancel the

[3] To be clear, while the merits of EPA's Proposed Rule are not at issue in this proceeding, *Amici* wholeheartedly disagree with the Proposed Rule. *Amici* further believe that additional time will allow the Agency the opportunity to determine, as it has in the past, that reliable science demonstrates that the current regulatory standard for chlorpyrifos meets the relevant statutory safety requirements.

underlying registrations.

Under FIFRA, all pesticide products must be registered by EPA before they can be marketed, sold, or distributed in the United States. *See* 7 U.S.C. §§ 136a(c)(5), 136j(a)(1). A FIFRA registration operates as a product-specific license. To become registered, an applicant must submit extensive scientific data to demonstrate to EPA that use of the product will not pose "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits" of the product. *Id.* § 136(bb). EPA can register a pesticide only if it affirmatively determines that the pesticide will not cause "unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(C), (D).

Once a pesticide is registered by EPA, FIFRA requires that EPA conduct periodic review of the pesticide registration every fifteen years, known as Registration Review.[4] *Id.* § 136a(g). This periodic review is required to ensure that, as scientific capabilities for assessing risk develop and as policies and pesticide use practices change over time, all registered products continue to meet the statutory standard of no "unreasonable adverse effects." *Id.* § 136(bb).

[4] Pesticides registered before 1984 were evaluated initially by EPA pursuant to Section 4 of FIFRA, a process known as "Reregistration." 7 U.S.C. § 136a–1. The results of EPA's reviews were summarized in Registration Eligibility Decisions ("REDs"). Pesticides that have undergone Reregistration are also subject to Registration Review.

II. The Vital Importance of Chlorpyrifos to Agriculture

Chlorpyrifos is a broad-spectrum organophosphate ("OP") pesticide. Chlorpyrifos was first registered in the United States in 1965 and received its first crop use approvals in 1974. Chlorpyrifos is currently registered in more than ninety-eight countries for use on numerous crops to protect against loss by a broad range of insect pests. *See, e.g., Use and Benefits of Chlorpyrifos in Agriculture*, submitted by Dow AgroSciences, LLC, Jan. 4, 2016, EPA-HQ-OPP-2015-0653-0227 ("Use and Benefits"); USDA Comments to April 2016 SAP, EPA-HQ-OPP-2015-0653-0369 ("USDA Comments").

In the United States, chlorpyrifos provides protection from insect pests for over fifty valuable crops, including soybeans, alfalfa, wheat, citrus, non-citrus fruit, tree nuts, vegetables, sugarbeets, and cotton, among others. Indeed, chlorpyrifos is the leading insecticide active ingredient to control a number of different insects in crops, including soybean aphids in soybeans, aphids and armyworm in alfalfa, European asparagus aphid and cutworm in asparagus, corn rootworm and lesser cornstalk borer in peanuts, and leafrollers and San Jose scale in apples, to name just a few. Use and Benefits at 33; 179. *See also* USDA Comments at 10–12 (listing crops, including alfalfa and asparagus, for which no or few alternative insecticides are available). Loss of chlorpyrifos could force growers to use more expensive alternatives or apply greater amounts of less

effective pesticides in order to control insect pests. Use and Benefits at 35. *See also* USDA Comments at 10.

American farmers rely on chlorpyrifos not only to protect their livelihoods from destruction by insect pests but also to minimize damage to beneficial insects that help control pests. Chlorpyrifos is significantly less disruptive to beneficial populations than some other insecticides. Use and Benefits at 36. *See also* April 30, 2015 USDA Comments on the Revised Human Health Risk Assessment, EPA-HQ-OPP-2008-0850 (attached to USDA Comments) ("Many of the alternatives to chlorpyrifos . . . are lethal to beneficial natural enemies, thereby requiring additional spray applications to control secondary pests."). In addition, the availability of chlorpyrifos allows growers to rotate between different insecticide modes of action, delaying insecticide resistance. *Id.* *See also* USDA Comments at 12.

Chlorpyrifos is often the first product growers use to attempt control of new or unknown insect pests due to its broad-spectrum control and effectiveness. Use and Benefits at 34. For example, when the deadly citrus greening disease was initially introduced into Florida by the Asian citrus psyllid, threatening to decimate Florida's citrus crops, chlorpyrifos was one of the first products utilized due to its broad-spectrum control and efficacy. USDA has stated that chlorpyrifos "is incredibly important to U.S. agriculture and related industries as it is often the key

defense against numerous unpredictable pests." Cover Letter to USDA Comments. *See also* Declaration of Allen Tucker ¶ 11 (chlorpyrifos is an "invaluable tool" for controlling sugarbeet root maggot infestations); Declaration of Kevin Hoyer ¶ 7 ("an integral part of my farming operation"); Declaration of Wesley Spurlock ¶ 5 ("one of the most broadly effective and economical pest control products available"); Declaration of Peter Cannon Michael ¶¶ 10–11 ("critical tool" for managing whitefly pest in cotton and "essential" for control of aphids).

III. The Administrative Petition and EPA's Subsequent Registration Review

In 2006, EPA completed a comprehensive review of chlorpyrifos, determined that chlorpyrifos continued to meet strict safety standards under FIFRA and the FFDCA, and reauthorized all existing agricultural uses for chlorpyrifos. *See* RED for Chlorpyrifos (2006).

In 2007, Petitioners filed a petition with EPA to revoke all tolerances and cancel all registrations for chlorpyrifos, challenging EPA's safety determinations with respect to chlorpyrifos on a number of grounds. *Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos*, EPA-HQ-OPP-2007-1005-0005 (Sept. 12, 2007) (the "Petition"). EPA determined that, to fully evaluate Petitioners' claims, further scientific study of chlorpyrifos was necessary. Decl. of Jack Housenger in Supp. of Opp'n to Pet. for a Writ of

Mandamus ("Housenger Decl.") ¶¶ 12–13, *In re Pesticide Action Network N. Am. v. U.S. EPA*, No. 12-71125 (9th Cir. 2012) ("*PANNA I*"), ECF No. 9-2.

In 2008, in response to the Petition, EPA initiated Registration Review for chlorpyrifos pursuant to FIFRA. 7 U.S.C. § 136a(g); Housenger Decl. ¶ 13. EPA commenced this process even though it had completed reregistration of all OPs, including chlorpyrifos, only two years earlier, and though it was not required by law to complete another review of these pesticides until 2022. Housenger Decl. ¶ 13.

EPA has taken several steps as part of its Registration Review for chlorpyrifos, including convening several SAP sessions regarding the Columbia Study and the potential for integrating epidemiology into risk assessment, and conducting multiple risk assessments for chlorpyrifos. *See* Housenger Decl. ¶¶ 14–18; Declaration of Dana Vogel ("Vogel Decl."), ECF No. 7-2, ¶¶ 6–7, 12–14. However, as set forth below, EPA's work on the Registration Review for chlorpyrifos is far from complete.

IV. The Mandamus Litigation and EPA's Proposed Revocation Rule

Despite EPA's ongoing Registration Review of chlorpyrifos, in 2012, Petitioners petitioned this Court for a writ of mandamus requiring EPA to respond to the Petition within a specified timeframe. *PANNA I*, ECF No. 1. The Court

denied the mandamus petition, finding no unreasonable delay by EPA. *PANNA I*, 532 F. App'x 649, 651 (9th Cir. 2013).

Petitioners renewed their mandamus challenge by filing this action in September 2014, expressing dissatisfaction that EPA "has yet to issue a final and reviewable decision on the request to ban chlorpyrifos." ECF No. 1-2 at 1–2.

In response, EPA explained the steps it had taken to resolve most of the claims raised in the Petition. *See* ECF Nos. 7, 8. EPA also detailed the remaining work to be done as part of its Registration Review, including refinements of its drinking water assessment to identify vulnerable watersheds where label mitigation may be appropriate. *See* ECF Nos. 14, 20.

On June 30, 2016, EPA advised the Court that residues of chlorpyrifos in certain watersheds "may" present an exposure concern. ECF No. 20 at 2. Drinking water was not an issue raised in the Petition, but was considered by the Agency as part of its Registration Review. And, consistent with Registration Review, EPA advised that it was working on a refined water assessment that would allow for the identification of at-risk watersheds and would develop appropriate risk mitigation for these watersheds, including possible label amendments. *Id.* EPA proposed a schedule by which it would issue a proposed rule to revoke tolerances "if needed" by April 15, 2016. *Id.* at 3.

Rather than allowing EPA to complete its Registration Review pursuant to FIFRA, on August 10, 2015, this Court granted the mandamus petition and directed EPA to "issue either a proposed or final revocation rule or a full and final response to the [A]dministrative [P]etition by October 31, 2015." ECF No. 23 at 12. As a result of the Court's Order, and in a complete regulatory turnabout, EPA issued the Proposed Rule to revoke all tolerances on November 6, 2015.

At the time of its Proposed Rule, EPA also advised the Court that it anticipated issuing a final revocation rule—an action it has taken only once in twenty years—by the end of 2016. ECF No. 25-1 at 3. However, EPA noted that the uncertainty surrounding the drinking water analysis along with other "extraordinary circumstances" could affect EPA's estimated timeline. *Id.* EPA advised the Court that it would "be in a better position to provide a more concrete timeline after all public comments have been submitted and the Agency has had an opportunity to assess what, if any, additional analysis needs to be completed to address those comments." *Id*.

On December 10, 2015, this Court rejected EPA's suggestion that its decision-making process would extend beyond the end of 2016 and directed EPA to take action on the proposed revocation rule and issue a final response to the Petition by December 30, 2016 unless "extraordinary circumstances . . . exist, that

make EPA's compliance with the final action deadline . . . impracticable to meet." ECF No. 29.

V. The April 2016 SAP Meeting and EPA's Request for Columbia Study Data

Since the Court's December 2015 Order, several significant developments have occurred with respect to EPA's review of chlorpyrifos.

First, on April 19–21, 2016, EPA convened an SAP meeting in order to seek guidance on EPA's reliance on biomonitoring data from umbilical cord blood collected as part of the Columbia Study to derive a new regulatory standard for chlorpyrifos—an abrupt and unprecedented departure from over four decades of established scientific and regulatory practice with respect to pesticides. *See* FIFRA Scientific Advisory Panel, Notice of Public Meeting ("SAP Notice"), 81 Fed. Reg. 12,099, 12,101 (Mar. 8, 2016); *see also* Declaration of Dr. Jennifer Seed ("Seed Decl.") ¶ 12.

As EPA concedes, the SAP strongly disagreed with EPA's proposal and outlined numerous recommendations for areas of further study. *See* Transcript of April 2016 SAP Meeting ("SAP Tr."), excerpts attached as Exhibit 1; Seed Decl. ¶¶ 13–17.

Second, on April 19, 2016, in response to public statements by Columbia that it would make the raw data available to the Agency,[5] EPA formally repeated its request for the raw data underlying the Columbia Study, observing that the Study was supported by federal grant funds and noting concerns with EPA's ability to "address our transparency goals as well as public feedback regarding access to the original ('raw') data."[6] *See* Apr. 19, 2016 Ltr. from J. Housenger, Exhibit 2. Indeed, the SAP repeatedly expressed incredulity regarding the absence of the raw data. *See, e.g.*, SAP Tr. at 494 ("[N]ot having [raw] data was just amazing, flabbergasting.").

Third, according to its Status Report, EPA conducted more work on its drinking water assessment since the Proposed Rule. However, as discussed below, the assessment is novel and complex and requires a great deal of additional work to pass scientific muster.

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[5] *See Industry, EPA at Odds Over Pesticide Science*, BNA Chemical Regulation Reporter (Apr. 14, 2016), http://www.bna.com/industry-epa-odds-n57982069835/.

[6] EPA has made previous unsuccessful requests to the Columbia investigators for the raw data. *See* Vogel Decl. ¶ 8 (EPA's efforts to further analyze the Columbia Study were "complicated and delayed by the Columbia researchers' refusal to release the raw data to EPA"); Jan. 25, 2013 Ltr. from S. Bradbury to PANNA and NRDC, ECF No. 1-2, Ex. 8 at 4 (Columbia study authors had "declined [EPA's] request to provide" the raw data).

ARGUMENT

I. The Action Contemplated in EPA's Proposed Rule Would Have Extremely Negative Consequences for Agriculture.

Revocation of chlorpyrifos tolerances would have severe negative consequences for growers. This has been underscored by USDA and growers representing a diverse array of U.S. agriculture. *See* USDA Comments at 10 (revoking tolerances for chlorpyrifos would have "a significantly negative impact on the production capabilities and economic stability of producers of many human and animal food crops, particularly where few or no efficacious alternatives are available"); Tucker Decl. ¶¶ 11, 13 ("[C]hlorpyrifos is our last line of defense against [sugarbeet root maggot] outbreaks."); Hoyer Decl. ¶ 8 (few economical alternatives exist for controlling both insects and mites); Michael Decl. ¶ 13 (use of chlorpyrifos to control aphid, whitefly, and other infestations "is essential to maintaining our overseas markets"); Declaration of Ryan Munn ¶ 9 (without chlorpyrifos, "there is a significant risk of damage to" and "possibility of complete destruction" of our onion crop); Declaration of Mark Dickman ¶¶ 8–9 ("[C]hlorpyrifos is the only product available that effectively controls onion maggots," without which "many of our crops are at risk of not being economically viable.").

Chlorpyrifos is the *only* insecticide registered to control the mealybug and reduces transmission of mealybug wilt disease in pineapple. Use and Benefits at

34. In addition, there are few other products available to control garden symphylans on strawberries. *Id.* *See also* USDA Comments at 10–11 (no or few alternative insecticides available for control of weevils and aphids on alfalfa, tree-boring insects on apple and peach trees, ants on citrus, and leaffooted bugs, stink bugs and navel orangeworm on almond).

In addition to harm to growers, the broader economic impact of revoking all tolerances for chlorpyrifos could be substantial. USDA has stated that, among the crops for which chlorpyrifos is used, cotton has a $5.1 billion value of production, alfalfa has a $10.8 billion value of production, non-citrus fruit has a $16.3 billion value of production, citrus fruit has a $3.4 billion value of production, tree nuts have a $10 billion value of production, and vegetables have a $13.1 billion value of production. USDA Comments at 10. It is vitally important to our economy for growers to be able to effectively protect these crops from destruction due to insect pests. *See* Cover Letter to USDA Comments ("This proposal [to revoke all tolerances for chlorpyrifos] will have serious impacts to U.S. agriculture[.]").

Revocation of tolerances would also disrupt trade with numerous international partners. USDA Comments at 12. Agricultural producers with significant exports to countries where Maximum Residue Limits ("MRLs") are not harmonized would suffer serious economic hardship if chlorpyrifos tolerances were revoked. *Id.* Many newer insecticides that are considered to be alternatives

to chlorpyrifos do not have established MRLs in target markets. *Id.* As a result, revocation of chlorpyrifos tolerances would impede trade and result in market losses for producers of crops utilizing these alternative materials. *Id.*

In short, EPA's proposed action would remove from the market one of the most widely used and critically important pest management tools available, with significant consequences for American growers, our economy, consumers, and our food supply. Accordingly, *Amici* respectfully urge this Court to provide EPA sufficient time to make a decision that is rational and science-based.[7]

II. EPA Needs Additional Time to Complete a Thorough, Science-Based Review.

EPA's risk assessment for chlorpyrifos raises novel scientific and regulatory issues, and EPA must comply with its statutory mandate under FIFRA to ensure that pesticide registrations satisfy *current* scientific standards. 7 U.S.C. §§

[7] EPA has repeatedly stated that it is under a court-ordered deadline, thus implying a rush to judgment that is not linked to science-based decision making. *See, e.g.*, Chlorpyrifos Issue Paper: Evaluation of Biomonitoring Data from Epidemiology Studies, EPA-HQ-OPP-2016-0062-0005, at 9 (Mar. 11, 2016) ("While EPA would have preferred to complete that [biomonitoring] analysis prior to commencing rulemaking, the timing for the proposal was directed by the U.S. Court of Appeals for the 9th Circuit, which ordered EPA to respond to an administrative petition to revoke all chlorpyrifos tolerances by October 31, 2015."); SAP Tr. at 15–16 (court deadline is "pretty much what is motivating us to finish all the work we have by the end of the year") (Dana Vogel, Director of the Health Effects Division in the Office of Pesticide Programs, EPA)); *Id.* at 87 ("Keep in mind as you [(the SAP)] deliberate, that we are under court order to complete this action. . . . December is eight months from now, so we're under a very short timeframe.") (Dr. Anna Lowit, Senior Scientist, EPA)).

136a(g), 136(bb). Moreover, Section 408 of the FFDCA mandates that, in order to revoke a tolerance, EPA must consider, among other relevant factors, "the validity, completeness, and reliability of the available data from studies of the pesticide chemical[.]" 21 U.S.C. § 346a(b)(2)(D)(i). An administrative petition, regardless of its merit, should not be relied upon to short-circuit FIFRA's Registration Review process or the tolerance revocation requirements of the FFDCA.

A. EPA Needs More Time to Address the SAP's Concerns and Recommendations.

EPA made it clear that it was offering its precedent-setting proposal based on the Columbia Study to, in large measure, address the upcoming Court deadline. *See* SAP Notice, 81 Fed. Reg. at 12,101. But SAP members uniformly disagreed with basing a new regulatory standard on a single, unreplicated epidemiology study.[8] *See, e.g.*, SAP Tr. at 534–38, 771–72 (reliance on one study goes "against standard practices of science" and sets "a bad precedent"); *see also* Seed Decl. ¶ 13. In addition, Panel members raised concerns about the representativeness of the Columbia Study sample, the use of a single measure of chlorpyrifos in cord blood, the exposures of other related pesticides, and the lack of analyses on the potential impact of postnatal exposures, among other issues. *See* Seed Decl. ¶ 14.

[8] The SAP's comments are fully consistent with those of the 2012 SAP. *See* Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held April 10–12, 2012 at 19 (July 11, 2012).

In light of these concerns and the ramifications of EPA's proposal, the SAP urged EPA to undertake further study, notwithstanding the Court-imposed timing concerns. *See* SAP Tr. at 763 ("[Y]ou're in a tight spot in terms of having to address the court order. . . . ***But I fully think that additional information is required.*** And I encourage you to try to design experiments . . . and I think . . . the panel will provide some additional experimental approaches that might be useful.") (emphasis added). The SAP recommended several additional investigative steps that EPA should take in order to properly conduct its risk assessment for chlorpyrifos and increase the rigor of the Agency's potential reliance on the Columbia Study to inform its decision-making, including exploring other routes of exposure, refining its modeling, verifying the Columbia Study's analytical methodology, conducting additional sensitivity analyses, and conducting and evaluating further epidemiology research.[9] Seed Decl. ¶¶ 15, 17, 22.

Each of the three regulatory standards EPA has outlined in its Status Report relies on the Columbia Study. *Id.* ¶ 23. EPA will need time to carefully consider and follow up on the SAP's recommendations, and rushing to do so in two months,

[9] Indeed, a recent study conducted by researchers in France found no link between prenatal exposure to OPs and cognitive outcomes in 6-year olds. *See* Cartier, *et al., Organophosphate Insecticide Metabolites in Prenatal and Childhood Urine Samples and Intelligence Scores at 6 Years of Age: Results from the Mother-Child PELAGIE Cohort (France)* (May 2016). EPA must have time to consider, as part of a thorough, weight-of-the-evidence approach, this and other significant epidemiology studies that challenge the validity of Agency's proposed action.

regardless of which standard EPA ultimately adopts, would be ill-advised and impracticable. *Id*.

In light of these issues, and given the immense ramifications for EPA's proposed action, an extension of the deadline for EPA action of at least one year is reasonable and appropriate. *Id.* ¶ 24.

B. EPA Needs More Time to Obtain and Consider the Raw Data Underlying the Columbia Study.

EPA's Status Report was conspicuously silent regarding the raw data underlying the Columbia Study. EPA needs time to analyze the raw data underlying the Columbia Study when they are made available to the Agency, as each of the three regulatory approaches the Agency has outlined relies on the Columbia Study. Declaration of Dr. Rita Schoeny ("Schoeny Decl.") ¶ 17.

The importance of the raw data in deriving a regulatory standard for chlorpyrifos based on epidemiology studies is critical. *Id.* ¶ 18. EPA and the SAP have repeatedly stressed that consideration of the raw data underlying epidemiology is inextricably linked to sound regulatory decision-making. *See* Ex. 2. Moreover, without the raw data, EPA will be unable to address key SAP recommendations, including a thorough consideration of the Columbia Study's analytical methodology. Schoeny Decl. ¶ 19. Regardless of the regulatory standard EPA ultimately adopts, the absence of a thorough analysis of the raw data presents a key vulnerability to the Agency's assessment. *Id.* ¶ 21. Indeed, the SAP

was troubled by the lack of raw data, particularly given the substantial implications of EPA's proposed action. *Id.* ¶ 20. Though EPA has recently formally requested (again) the raw data from Columbia investigators, *see* Ex. 2,[10] the result of that effort is unclear.

In addition, EPA stated in its request for the raw data that it intends to issue a notice "that will, among other things, ask for additional public comment on EPA's increased utilization of the [Columbia] research results." Ex. 2, at 2. For any such comment period to provide a meaningful and transparent opportunity for review, EPA will need to allow time to analyze and respond to comments *before* issuing a final rule.

C. EPA Needs More Time to Conduct its Drinking Water Assessment.

EPA implies in its Status Report that its drinking water assessment for chlorpyrifos is now complete. ECF No. 39-1 at 3. EPA offers little detail about the methodology for its drinking water assessment. However, EPA's methodology appears to be based on a methodology set forth in a drinking water model EPA began developing in 2011, known as the Spatial Assessment Model ("SAM"). *See* Declaration of Dr. Richard Reiss ¶ 14. Despite years of work by EPA, the SAP

[10] EPA's renewed request came at least three years after it first requested the raw data from the Columbia investigators. *See* Jan. 25, 2013 Ltr. from S. Bradbury to PANNA and NRDC, ECF No. 1-2, Ex. 8 (stating that the Columbia study authors had declined EPA's request for raw data).

determined in 2015 that SAM may be years away from the level of scientific validity necessary for use in risk assessment. *Id.* ¶¶ 14–16.

EPA should complete all of the steps it needs to take to ensure that its drinking water assessment is being conducted with the best, most scientifically robust methodology available. *Id.* ¶ 17. EPA's proposed drinking water assessment raises novel, complex scientific issues for pesticide risk assessment that EPA needs additional time to investigate and address. *Id.* Thus, even assuming that EPA continues to rely on its drinking water assessment as a basis for its proposed action, more time is needed to complete a robust and transparent scientific analysis.

III. EPA Needs More Time to Follow its Statutory Obligations, Policies, and Prior SAP Recommendations.

There are numerous additional reasons EPA needs time beyond December 30, 2016 to complete its decision-making for chlorpyrifos. EPA needs time to address the recommendations of prior SAPs, in particular the recommendation that EPA establish criteria for determining the quality and acceptability of epidemiology studies. *See* Minutes of the FIFRA Scientific Advisory Panel Meeting on the Draft Framework at 8, Housenger Decl. Attach. E. To *Amici's* knowledge, the Agency has never established these threshold criteria. This work is especially critical to chlorpyrifos given the concerns regarding reliability raised with respect to the Columbia Study. Moreover, EPA sought SAP guidance on a

draft framework for integrating epidemiology in the human health risk assessment process in 2010, which the Agency never issued for comment or finalized. *Id.* EPA's emerging reliance on epidemiology to inform its regulatory action must be rooted in sound, transparent scientific policy and should not be done on an *ad hoc* basis. Congress did not contemplate that the Registration Review process would be used to experiment with American agriculture or the Nation's food supply.

EPA also needs time to respond to registrant and other stakeholder comments on its risk assessment for chlorpyrifos and the Proposed Rule. EPA has a statutory obligation to consider and address all relevant substantive comments submitted in response to a human health risk assessment. *See* 40 C.F.R. §155.58(c) (Agency will issue Registration Review decision "*[a]fter considering any comments* on the proposed decision"; decision must include "Agency's response to significant comments"). Another reason that EPA must obtain and analyze the raw data underlying the Columbia Study is to fulfill its policies of data access and transparency in scientific decision-making. *See* President Obama's Mem. on Scientific Integrity (Mar. 9, 2009) ("[T]here should be transparency in the preparation, identification, and use of scientific . . . information in policymaking."); EPA Administrator Jackson Mem. to EPA Employees (May 9, 2009) ("Our regulatory decisions should include a full explanation of the science issues addressed," including "the data relevant to those issues").

A revocation of tolerances without reliable data and thorough, science-based review would violate FFDCA and raises serious due process concerns. *See* 21 U.S.C. § 346a(b)(2)(D)(i); *Indus. Safety Equip. Ass'n v. EPA*, 656 F. Supp. 852, 856 (D.D.C. 1987), *aff'd*, 837 F.2d 1115 (D.C. Cir. 1988) ("It is well settled that an agency license can create a protectible [sic] property interest, such that it cannot be revoked without due process of law."); *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 45 (D.D.C. 2011) ("A FIFRA registration is essentially a license to sell and distribute pesticide products in accordance with the terms of the registration and the statute."). In addition, EPA action in the absence of a comprehensive, transparent review may render the Agency's decision arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (Agency rule is arbitrary and capricious if it "entirely failed to consider an important aspect of the problem" or "offered an explanation for its decision that runs counter to the evidence").

CONCLUSION

The vital importance of chlorpyrifos to U.S. agriculture and the additional work that EPA must accomplish in order to complete a comprehensive, science-based evaluation of chlorpyrifos, represent "extraordinary circumstances" that make the Court's proposed timeframe "impracticable." Accordingly, *Amici* respectfully request that the Court provide EPA at least one additional year to

complete Registration Review for chlorpyrifos through the use of rational science-based analyses, and then make a final determination with respect to the Proposed Rule and the Petition.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and 32(a)(7)(B) because this brief contains 6,996 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), and this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Microsoft Word 2013, Times New Roman 14 point.

/s/ Donald C. McLean
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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on July 5, 2016.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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