No. 14-72794

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

STATUS REPORT

Respondent United States Environmental Protection Agency ("EPA" or "Agency") respectfully submits this Status Report pursuant to this Court's December 10, 2015 Order. *See* Dkt. No. 29.

On August 10, 2015, this Court ordered EPA to take action, by October 30, 2015, on Pesticide Action Network North America and Natural Resources Defense Council's (collectively, "PANNA") administrative petition to revoke the tolerances and cancel the registrations of the pesticide chlorpyrifos. *See* Dkt. No. 23. In compliance with the Court's Order, on October 28, 2015, EPA signed a proposed rule to revoke all chlorpyrifos tolerances, entitled "Chlorpyrifos; Tolerance

Revocations" ("Proposed Rule"). The Proposed Rule was published in the Federal Register on November 6, 2015, and public comments were accepted for 60 days. 80 Fed. Reg. 69,079 (Nov. 6, 2015).

After PANNA sought further relief, on December 10, 2015, the Court ordered EPA to take final action on the administrative petition concerning chlorpyrifos, whether by finalizing the Proposed Rule or denying the petition, no later than December 30, 2016. *See* Dkt. No. 29. The Court also ordered EPA to provide a status report by June 30, 2016, informing the Court on EPA's progress towards meeting the December 30, 2016 deadline and explaining whether any "extraordinary circumstances" would prevent the Agency from meeting the deadline. *Id*.

EPA has made significant progress towards—and fully intended to meet—the December 30, 2016 deadline to take final action on the administrative petition. For the reasons explained below and in the attached Declaration of Yu-Ting Guilaran, however, extraordinary circumstances exist that make it impracticable for the Agency to meet the Court's deadline. EPA presently estimates that it will be able to take final action on the administrative petition by June 30, 2017, and therefore requests a six-month extension of this Court's deadline.

In order to meet the Court's original October 30, 2015 deadline, EPA issued the Proposed Rule before completing two important scientific analyses that may

ultimately bear on EPA's conclusions regarding the safety of chlorpyrifos: (1) a refined drinking water assessment to determine any region-specific exposure considerations; and (2) an evaluation of available epidemiological data to determine whether EPA's toxicological point of departure in the Proposed Rule (based on acetylcholinesterase inhibition) accurately estimated the risks of chlorpyrifos for children. *See* 80 Fed. Reg. at 69,083, 69,095, 69,104-06. EPA explained in the Proposed Rule that the Agency would likely update the rulemaking to reflect these new analyses and seek additional public comment. *Id*. at 69,083.

Since publishing the Proposed Rule, EPA has been working diligently to complete these two analyses while simultaneously reviewing public comments received on the Proposed Rule. Guilaran Decl. ¶ 6. In the Spring of 2016, EPA completed the refined drinking water analysis for all 21 major hydrologic regions of the country. *Id*. This assessment may allow EPA to develop more tailored risk mitigation for some regions of the country, which could potentially eliminate the need to revoke all chlorpyrifos tolerances. *Id*.

EPA also completed its review of the biomonitoring data from the epidemiological study of people exposed to chlorpyrifos and concluded that the Agency had likely underestimated the neurodevelopmental risks of the pesticide in the Proposed Rule. *Id*. ¶ 7. As a result of these findings, EPA proposed a new,

more protective point of departure (than what was used in the Proposed Rule) derived from the epidemiological data. *Id*. This is the first time EPA has proposed to use epidemiological data instead of acetylcholinesterase inhibition as the point of departure in determining the safe level of an organophosphate pesticide. *Id*.

In light of the potential significance of this new point of departure, EPA submitted its results to a Scientific Advisory Panel in April 2016. *Id*. ¶ 8. At the April 2016 meeting, EPA asked the Panel to weigh in on the appropriateness of using the epidemiological data to establish a point of departure for chlorpyrifos. To EPA's surprise, the Panel advised against the new approach. *Id*. This was somewhat of a departure from the conclusions and recommendations of a 2012 Scientific Advisory Panel, on whose advice EPA conducted a series of dose reconstruction and modeling analyses to build a scientific foundation in order to utilize the epidemiological data. *Id*. At the same time, the April 2016 Panel also raised concerns about the approach EPA adopted in the Proposed Rule, namely that the continued use of acetylcholinesterase inhibition as the point of departure may not be sufficiently health protective. *Id*. ¶ 9. In short, the Panel seemed to recommend that EPA develop a hybrid approach but did not provide specific suggestions for doing so at the meeting. *Id*. The Panel's written report is due by the end of July 2016. *Id*. ¶ 10.

Although EPA is not required by law to follow the advice of a Scientific Advisory Panel, the Agency gives considerable weight to the Panel's expertise and recommendations. *Id*. Given the concerns the Panel raised about both approaches EPA has considered in this matter, i.e., the new use of epidemiological data or the traditional use of acetylcholinesterase inhibition as the point of departure, EPA believes it should wait until seeing the Panel's written report before making a final decision on the toxicological point of departure it uses for its final action.[1] *Id*.

EPA had prepared for publication and public comment a notice of data availability on its refined drinking water analysis and analysis of the epidemiological data, to be issued immediately after the Scientific Advisory Panel meeting in April. *Id*. ¶ 12. In light of the Panel's concerns, however, EPA decided to wait until after the Panel's report is released to issue further necessary public notice. *Id*. EPA plans to make a determination on what point of departure to use after reviewing the Panel's report and completing any additional analyses that the Agency believes are warranted. *Id*. EPA estimates that it could complete this process in approximately two months and then publish for public comment any re-

[1] The choice of a toxicological point of departure is significant. If EPA continues with the approach in the Proposed Rule, the refined drinking water analysis suggests that mitigation measures would allow some continued use of chlorpyrifos instead of revoking all tolerances as originally proposed. Guilaran Decl. ¶ 11. If EPA opts for the more conservative point of departure based on epidemiological data, all tolerances would likely have to be revoked. *Id*. And the outcome of any hybrid approach that the Panel might recommend is unclear at this time. *Id*.

proposal or notice of data availability by early Fall 2016. *Id*. That would give EPA approximately six months to consider public comments, adjust its analysis as needed, and take final action on the administrative petition by June 30, 2017. *Id*. ¶ 13.

If EPA is not afforded additional time, it would likely have to take final action on the administrative petition (i.e., a final rule or denial) without seeking public comment on any additional data considered or analyses conducted after the Proposed Rule was published for comment in November 2015. This would effectively preclude any opportunity for EPA to consider public comment on EPA's efforts to address the conclusions of the Panel and on the impact of EPA's refined drinking water assessment. In light of the circumstances and the importance of public comment to the rulemaking process, EPA believes it is appropriate to extend the current schedule. Six months represents a modest extension that ensures that EPA has the time necessary for addressing both the public process and extremely complex science associated with this action while holding EPA to an expeditious timeframe for completing an action that relates to the protection of public health.

In conclusion, EPA believes that it would be impracticable to take final action on PANNA's administrative petition by December 30, 2016, and requests an additional six months, until June 30, 2017.

Dated: June 29, 2016

Respectfully submitted,

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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 June 29, 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.

s/ *Erica M. Zilioli*

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DECLARATION OF YU-TING GUILARAN

I, Yu-Ting Guilaran, state the following:

I declare that the following statements are true and correct to the best of my knowledge and belief and are based upon my personal knowledge and/or my review of information contained in the records of the United States Environmental Protection Agency ("EPA" or the "Agency") or supplied by current employees.

1. I am the Director of the Pesticide Re-evaluation Division in EPA's Office of Pesticide Programs and have served in that role since February 7, 2016. I have held several positions within EPA during my 24 years with the Agency. I was the Director of the Office of Pesticide Programs' Biological and Economic Assessment Division from January 12, 2014 to February 6, 2016 and the acting director of that division from May 19, 2013 to January 11, 2014. Prior to joining the Office of Pesticide Programs, I have held various positions in EPA's Office of Water between 1999 and 2013.

2. The Pesticide Re-evaluation Division is the division assigned with the responsibility to develop EPA's regulatory position regarding the re-evaluation of conventional pesticides that are currently registered under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Part of the Pesticide Re-evaluation Division's responsibility includes developing and drafting proposed and final food

residue tolerance revocations under the Federal Food, Drug, and Cosmetic Act ("FFDCA") when EPA determines that the tolerances do not meet the FFDCA section 408(b)(2)(A)(ii) "reasonable certainty of no harm" safety standard. 21 U.S.C. § 346a(b)(2)(A)(ii).

3. As explained in EPA's status report of October 30, 2015, EPA complied with the Court's order to respond to Petitioners' administrative petition by issuing a proposed rule to revoke all chlorpyrifos food residue tolerances under section 408 of the FFDCA. That proposal was published in the Federal Register on November, 6 2015 (80 FR 69079) and provided for a 60-day public comment period.

4. On December 10, 2015, the Court ordered EPA to complete any final action on the petition by December 30, 2016, and it ordered EPA to file an interim status report not later than June 30, 2016 detailing the Agency's efforts to comply with the December 30, 2016 deadline. The Court's order also directed EPA to include in the status report a detailed explanation of any extraordinary circumstances that make EPA's compliance with the December 30, 2016 deadline impracticable to meet. This declaration will address both of these points.

5. As EPA noted in the proposed rule, in order to meet the Court's October 31, 2015 petition response deadline, the Agency issued the proposed tolerance revocations in advance of completing two important scientific analyses that may ultimately bear on EPA's final conclusions regarding the safety of chlorpyrifos: (1)

EPA's refined drinking water assessment; and (2) EPA's evaluation of available biomonitoring from epidemiological data. *See* 80 FR 69079 at 69083, 69095. The refined drinking water assessment is designed to allow EPA to consider region-specific exposure considerations (e.g., cropping patterns, watershed characteristics, water intake locations) that could ultimately allow for a more tailored approach to regulation than simply revoking all tolerances based upon a single national drinking water assessment that was used in the proposed rule. *Id*. at 69104-06. EPA's evaluation of biomonitoring from the epidemiological data is intended to assess whether the analysis supporting the proposed rule may have underestimated the potential for chlorpyrifos to cause adverse neurodevelopmental effects in children. *See Id*. at 69095. EPA also noted in the proposal that, given the potential for these assessments to bear on any final action, EPA would likely need to update the rulemaking action in some fashion to reflect EPA's revised analyses and to seek necessary additional public comment on any new analyses prior to finalizing its action. *Id*. at 69083.

6. Since publishing the proposed rule, EPA has been working to complete these additional analyses as well as evaluate comments received on the proposal. During the spring of 2016, EPA completed its refined drinking water assessment for all 21 major hydrologic regions of the country. As noted, this assessment allows EPA to take account of the differences in the amount of chlorpyrifos that people are

exposed to depending on the nature of the watersheds they live in and drinking water systems that serve them. Depending upon EPA's ultimate determination regarding the appropriate toxicological point of departure for regulation, this assessment may allow EPA to develop more tailored risk mitigation for some regions of the country that could potentially serve as an alternative to the revocation of some or all chlorpyrifos food tolerances.

7. In March 2016, EPA completed its review of the biomonitoring data from the epidemiological research (in this case, EPA's primary focus was umbilical cord blood data from participants in a study conducted by Columbia University researchers on the effects of pre-natal household exposures to chlorpyrifos) and concluded that the Agency likely did underestimate the risks of chlorpyrifos in the analysis supporting the proposed rule. *See* Chlorpyrifos Issue Paper: Evaluation of Biomonitoring Data from Epidemiology Studies EPA's Office of Pesticide Programs, March 11, 2016, available at https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2016-0062-0005. That Issue Paper included a proposal for a new, more protective point of departure to preclude the potential for neurodevelopmental effects that were observed in the epidemiological data.[1] This marked the first time that EPA had

[1] The household exposures evaluated for the study conducted by the Columbia University researchers ("Columbia Study") occurred prior to EPA's cancellation of

proposed to directly use the results of epidemiological data to establish a point of departure for an organophosphate insecticide such as chlorpyrifos. EPA has traditionally used a biomarker of adverse nervous system effects -- acetyl cholinesterase inhibition (AChEi) – as its point of departure in determining safe levels of organophosphates with the view that AChEi is sufficiently sensitive that it is protective for other possible adverse health outcomes. As EPA's analysis using the Columbia Study's biomonitoring data indicated, however, it did not appear that the AChEi point of departure used in the proposed rule was in fact protective for neurodevelopmental effects. EPA concluded that it was therefore appropriate for EPA to develop a new, more protective point of departure based on the epidemiological data. In light of the potential significance of its new assessment, in April 2016, EPA presented its results to the FIFRA Scientific Advisory Panel (SAP), the federal advisory committee established by Congress and used by EPA to provide advice and recommendations to EPA on the science underlying EPA's pesticide regulatory actions.

See https://www.epa.gov/sap/meeting-materials-april-19-21-2016-scientific-advisory-panel (web page for April 2016 SAP meeting).

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most residential uses of chlorpyrifos in 2000. The study remains relevant, however, in evaluating whether the existing approved uses of chlorpyrifos have the potential to cause similar adverse outcomes.

8. At the April 2016 SAP meeting, EPA charged the SAP with addressing several important questions regarding EPA's assessment of the epidemiological data, the most significant being whether it was appropriate for EPA to use the cord blood data from the Columbia Study to establish a point of departure for chlorpyrifos. In response to that question, the panel stated clearly that EPA should not be using the results of these data to establish a point of departure. *See* US Environmental Protection Agency (EPA) FIFRA Scientific Advisory Panel (SAP) Meeting On Chlorpyrifos: Analysis Of Biomonitoring Data at 623, transcript available at https://www.epa.gov/sites/production/files/2016-05/documents/fifra_sap_04_19_16_to_04_21_16_final_transcript.pdf.

While previous SAPs had also cautioned against the use of the biomonitoring data from the epidemiological data to establish a point of departure, in 2012 the SAP had also encouraged EPA to conduct additional analysis that might provide a sufficient basis for EPA to do just that. *See* SAP Minutes No. 2012-04. A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Chlorpyrifos Health Effects April 10 – 12, 2012, at 50. Available at https://www.epa.gov/sites/production/files/2015-06/documents/041012minutes.pdf

In keeping with the recommendations of the 2012 SAP, EPA developed a dose reconstruction analysis to assess the likely exposures of the pregnant women in the Columbia Study cohort to pesticide use in their homes, and EPA utilized

sophisticated physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling to evaluate the clearance of chlorpyrifos from the body over time in order to better understand the relationship between exposure and the measured cord blood levels. Going into the SAP meeting, EPA therefore had a measure of confidence that the Panel would generally endorse EPA's approach, despite its novel nature. EPA was therefore quite surprised when the Panel stated that EPA's direct use of blood measures from the Columbia Study to establish a point of departure for chlorpyrifos was inappropriate.

9. While the SAP recommended against the use of the Columbia Study to establish a point of departure, the SAP also appeared to raise concerns with respect to the sufficiency of EPA's continued use of AChEi as a point of departure – the point of departure used in developing the proposed revocation of chlorpyrifos tolerances published in November 2015.

See https://www.epa.gov/sites/production/files/2016-05/documents/fifra_sap_04_19_16_to_04_21_16_final_transcript.pdf. at 622, 629, 641. Several members of the Panel appeared to suggest that EPA should therefore consider developing a hybrid approach for regulating chlorpyrifos that somehow seeks to combine the results of the epidemiological data with the animal data EPA used to establish the point of departure in the proposed rule. *See id*. at 764-65,

767-69. However, these oral statements provided little in the way of explanation or guidance to EPA for how it might go about developing a hybrid approach.

10. While EPA is not required by law to follow the advice or recommendations of the SAP, given the expertise of the SAP and the statutory role it plays in advising EPA on the science underlying EPA regulatory actions, EPA affords considerable weight to the SAP's reports. Until EPA gets the SAP's written report, which is due in late July (under section 10(c) of the Federal Advisory Committee Act and the implementing regulations at 41 CFR 102-3.165, the minutes (reports) of advisory committees must be made available within 90 days), EPA's evaluation of the SAP's advice to date is limited to the transcribed oral statements of the panel members at the meeting. EPA therefore lacks a clear picture of the SAP's advice and recommendations as to how EPA should best complete its scientific assessment underlying the tolerance revocation rule. Depending on the nature of that advice and EPA's own evaluation, EPA's path forward could go in a number of different directions. EPA believes it should therefore wait for the submission of the SAP's written report before developing its final conclusion with respect to the point of departure it uses in any final action on the proposed revocation of chlorpyrifos tolerances.

11. To be clear, choosing between the possible options for establishing the appropriate toxicological point of departure is not an academic exercise. If EPA

adopts the regulatory point of departure it used in the November 2015 proposal, its recently completed revised water assessment suggests that, with appropriate mitigation (likely in the form of label changes limiting use in some fashion), it may be possible to retain some amount of chlorpyrifos use and therefore not revoke all tolerances, as EPA had proposed. This means that some level of exposure to chlorpyrifos would also continue. Conversely, if EPA finalizes the considerably more conservative approach it presented to the SAP in April 2016, it might have to revoke all or nearly all tolerances irrespective of any efforts to mitigate water exposures. It is unclear what the results of a possible "hybrid" approach recommended by some of the SAP panelists might render; at this point, EPA is awaiting the written SAP report before it determines the appropriateness of considering such alternative approaches.

12. As explained in Richard Keigwin's declaration of October 29, 2015 ("Keigwin Declaration"), attached to EPA's October 30, 2015 status report in this litigation, EPA had expected to publish a notice of data availability or a re-proposed rule in March or April of 2016 in order to seek public comment on EPA's refined drinking water assessment and on any additional analysis EPA completed regarding the potential for adverse neurodevelopmental effects to occur at levels below EPA's existing point of departure. As a result of the SAP's oral statements at the April 2016 meeting strongly rejecting EPA's proposed approach for

addressing neurodevelopmental effects, EPA decided not to issue a notice of data availability it had prepared for publication immediately following the SAP meeting. The Agency reasonably judged that it made little sense to seek public comment on an approach that had just been rejected by the SAP. The Agency decided that the better path forward would be to first take account of the SAP's recommendations, including the expected written report in late July 2016, and then determine whether to maintain or modify the November 2015 proposal, and at that point seek additional public comment on any revisions to EPA's assessment and any additional data and analysis underlying that assessment. EPA expects that it will be in a position to publish for public comment any re-proposal or notice of data availability by early fall, 2016. That will give EPA approximately two months to consider the SAP's written report and develop any additional analyses or modification of our risk assessment that EPA believes is warranted. To be clear, since EPA will not receive the written SAP report until late July, this represents a somewhat speculative estimate regarding how long it may take to appropriately take account of the SAP's written recommendations.

13. In light of these circumstances, EPA currently believes it reasonably will need an extension of six months to the present schedule to complete its final action. As noted in the Keigwin Declaration, EPA's estimated rulemaking schedule contemplated publishing a re-proposal or notice of data availability with its

additional analyses in March or April of 2016. EPA expects that any re-proposal or notice of data availability will most likely be ready for publication by October, or approximately six months later than anticipated at the time EPA issued the proposed rule. EPA would then likely provide for 60 days of public comment, in keeping with FFDCA section 408(e)(2). 21 U.S.C. § 346a(e)(2). Following receipt of those comments, EPA would expect to need the same amount of time it previously contemplated – six months -- for addressing comments on the re-proposal or notice of data availability and developing its final action. EPA therefore believes the deadline for EPA's final action should be extended to June 30, 2017.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 29 day of June, 2016.

Yu-Ting Guilaran