

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