IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

RED RIVER VALLEY SUGARBEET GROWERS ASSOCIATION, ET AL. Petitioners, v. MICHAEL S. REGAN, Administrator, U.S. Environmental Protection Agency, ET AL., Respondents.	No. 22-1422

Declaration of Timothy M. Kiely

I, Timothy M. Kiely, state as follows:

1. 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.

2. I am currently the Acting Deputy Director of the Pesticide Re-evaluation Division ("PRD") in EPA's Office of Pesticide Programs ("OPP"). I have worked for EPA for over 24 years. Since coming to the Agency, I have served in various positions within OPP, including as Chief of the Economic Analysis Branch ("EAB") Biological and Economic Analysis Division ("BEAD")

from January 2007 to November 2020 and Team Leader of EAB from August 2003 to January 2007. I have been the Acting Deputy Director of PRD since November 2020.

3. I am making this Declaration in support of EPA's opposition to Petitioners' Renewed Motion for a Partial Stay Pending Review filed in the above captioned case.

4. PRD 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, 7 U.S.C. §§ 136-136y ("FIFRA"). Part of PRD's responsibility includes overseeing the periodic "registration review" of conventional pesticides as required by section 3(g) of FIFRA, 7 U.S.C. § 136a(g). EPA's essential responsibility under registration review is to review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration.

5. FIFRA requires EPA approval of pesticides prior to their distribution or sale and establishes a registration regime for regulating the use of pesticides. 7 U.S.C. § 136a(a). EPA must approve an application for pesticide registration if, among other things, the pesticide will not cause unreasonable adverse effects on the environment. *Id.* The pesticide chlorpyrifos (0,0-diethyl-0-3,5,6-trichloro-2-

pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide that has been registered for use in the United States since 1965. The OPs are a group of closely related pesticides that affect functioning of the nervous system. Pesticide products containing chlorpyrifos are registered for use on many agricultural crops, including, but not limited to, corn, soybeans, alfalfa, oranges, wheat, and walnuts. Additionally, chlorpyrifos products are registered for use on nonfood sites such as ornamental plants in nurseries, golf course turf, and as wood treatment. There are also public health uses including aerial and ground-based mosquito adulticide fogger treatments, use as fire ant control in nursery stock grown in USDA-designated quarantine areas, and for some tick species that may transmit diseases such as Lyme disease. The majority of uses in residential settings were voluntarily canceled over two decades ago. *See*, *e.g.,* Chlorpyrifos; Cancellation Order, 65 Fed. Reg. 76,233 (Dec. 6, 2000); Chlorpyrifos; End-Use Products Cancellation Order, 66 Fed. Reg. 47,481 (Sept. 12, 2001). There are currently 25 chlorpyrifos registrants and 76 total chlorpyrifos registrations, and a total of 41 registered or conditionally registered supplemental distributor products.

6. On March 18, 2009, EPA opened a public docket to initiate registration review of chlorpyrifos. *See*, *e.g.*, Chlorpyrifos Summary Document Registration Review: Initial Docket, March 2009 (Mar. 18, 2009), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0002.

7. The registration review of chlorpyrifos has raised numerous novel and complex scientific issues. Reflecting that complexity, the Agency has engaged in extensive and ongoing analyses of the available science since initiating registration review in 2009, including multiple human health risk assessments and drinking water assessments, development of a new model for deriving points of departure to assess risks of chlorpyrifos, development of a framework for incorporating human epidemiology information into risk assessments as well as conducting an in-depth epidemiology and literature review, and in the process convening the FIFRA Science Advisory Panel at least six times.

8. In December 2020, EPA released the Proposed Interim Decision for the Registration Review of Chlorpyrifos ("2020 PID") for a 60-day public comment period. Pesticide Registration Review: Proposed Interim Decision for Chlorpyrifos (Dec. 7, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0964. The 2020 PID concluded that "[w]hen considering all currently registered agricultural and non-agricultural uses of chlorpyrifos, aggregate exposures are of concern." *Id*. at 19. However, the 2020 PID also noted that if one considered only the uses that result in estimated drinking water concentrations ("EDWCs") below the drinking water level of comparison ("DWLOC"), then aggregate exposures would not be of concern. *Id*. Accordingly, the 2020 PID proposed to limit applications of

chlorpyrifos in this country to only 11 uses in certain regions of the United States and with reduced application rates, which were the uses for which the EDWCs were below the DWLOC. This proposed path forward was intended to offer to stakeholders a way to mitigate the aggregate risk from chlorpyrifos.

9. In connection with the release of the 2020 PID, EPA also invited comments on the following assessments: Chlorpyrifos: Third Revised Human Health Risk Assessment for Registration Review (Sept. 15, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944 ("2020 HHRA"); Chlorpyrifos: Draft Ecological Risk Assessment for Registration Review (Sept. 15, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0940; Updated Chlorpyrifos Refined Drinking Water Assessment for Registration Review (Sept. 22, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941 ("2020 DWA"); Chlorpyrifos Usage and Benefits Assessment for Non-crop Uses (Nov. 9, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0966; and Revised Benefits of Agricultural Uses of Chlorpyrifos (PC# 059101) (Nov. 18, 2020), *available at* https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969. EPA subsequently extended the 60-day comment period by 30 days, which then closed on March 7, 2021. Comment Period Extension for Chlorpyrifos (Feb. 4, 2021),

available at https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-1014. The Agency received 144 public comments on the 2020 PID and supporting assessments, which the Agency has yet to fully consider. EPA intends to issue a final interim decision on or before the October 1, 2022 registration review deadline.

10. On April 29, 2021, following the release of the 2020 PID in which EPA indicated that it had found aggregate exposures of chlorpyrifos associated with registered uses to be unsafe but provided a possible path forward for mitigating risks from chlorpyrifos, the Ninth Circuit Court of Appeals issued a decision in a case concerning the longstanding challenge from a petition on the chlorpyrifos tolerances. *See League of United Latin Am. Citizens (LULAC)* v. *Regan,* 996 F.3d. 673 (9th Cir. 2021). In September 2007, Pesticide Action Network North America ("PANNA") and Natural Resources Defense Council ("NRDC") had submitted to EPA a petition (the "2007 Petition") seeking revocation of all chlorpyrifos tolerances under FFDCA section 408 and cancellation of all chlorpyrifos pesticide product registrations under FIFRA due to alleged safety concerns.

11. Ultimately, EPA denied the 2007 Petition in full on March 29, 2017, and then denied objections to the March 2017 denial order. *See* Chlorpyrifos; Order Denying PANNA and NRDC's Petition To Revoke Tolerances, 82 Fed. Reg.

16,581 (April 5, 2017) (the "2017 Order Denying Petition"); Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order, 84 Fed. Reg. 35,555 (July 24, 2019). Neither the 2017 Petition Denial nor the 2019 Order denying objections contained a determination concerning the safety of chlorpyrifos to support leaving the tolerances in place.

12. Finding that EPA could not leave tolerances in place without making the requisite safety finding under the FFDCA, the Court concluded that EPA's actions on chlorpyrifos violated the FFDCA and ordered EPA to: (1) grant the 2007 Petition; (2) issue a Final Rule within 60 days of the issuance of the mandate that either revokes all chlorpyrifos tolerances or modifies chlorpyrifos tolerances under FFDCA section 408(d)(4)(A)(i), provided that such modification is supported by a safety finding (the "Final Rule"); and (3) modify or cancel related FIFRA registrations for food use in a timely fashion. Since the mandate was issued on June 21, 2021, the deadline for issuing the Final Rule was August 20, 2021, less than four months from the date the Court issued its decision.

13. Despite the Court's conclusion that EPA's actions, based on the record before the court, were a "total abdication of EPA's statutory duty", the Court recognized that EPA might have additional information that would allow EPA to make a safety finding for modified tolerances. *See*, *e.g.*, the 2020 PID. Given the limited window for issuing the Final Rule and the Court's directive not

to engage in additional fact-finding or further delay, the Agency focused on whether the 2020 PID and completed 2020 HHRA and 2020 DWA were adequate to support a safety finding for the chlorpyrifos tolerances.

14. As stated above, EPA had concluded that aggregate exposures to chlorpyrifos from registered uses were unsafe. 2020 PID at 19. However, the Agency recognized that the 2020 PID proposed a subset of uses that might result in exposures below the Agency's level of concern if uses were eliminated and significant changes to the labels were made, including use cancellations and geographic limitations, among others. *Id*. EPA had conducted additional analyses of particular uses as reflected in the 2020 PID considered to have high benefits to chlorpyrifos users to determine whether those uses might be safe if certain restrictions were in place and other uses were cancelled. In particular, EPA examined whether the concentrations of chlorpyrifos and its oxon metabolite in drinking water would exceed safe levels if the only registered uses were the 11 considered and in the geographic areas evaluated. 2020 DWA. In order to retain these 11 uses, all other uses would need to be cancelled.

15. In order to determine if modification of tolerances was a viable option in accordance with the terms of the 2020 PID, EPA initiated discussions with Gharda Chemicals International, Inc. ("Gharda"), Corteva, Adama, and Drexel, each of which held technical registrations of chlorpyrifos, in a good-faith effort to

determine if the safety issues identified in EPA's record on chlorpyrifos by the Ninth Circuit could be sufficiently resolved in a timely manner to allow for the modification of tolerances by the Court's imposed timeline. EPA held several meetings with each of the technical registrants, including Gharda, to discuss their interests and concerns as EPA considered its response to the Court's directive to issue the Final Rule. The meetings with Gharda occurred on May 27, June 3, June 17, June 24, July 14, and August 16, 2021.

16. In addition to meeting with EPA, Gharda corresponded with EPA proposing terms for Gharda's voluntary cancellation of certain chlorpyrifos uses. Gharda's first letter, dated May 12, 2021 ("First Gharda Letter"), stated that Gharda is "willing to work with EPA to negotiate the voluntary cancellation of many currently approved uses of chlorpyrifos on mutually acceptable terms and in a manner that minimizes disruption on growers and other users." The First Gharda Letter further stated that Gharda was "willing to negotiate and execute an agreement with EPA containing at least" nine separate terms, including further discussion of the geographic restrictions proposed in the 2020 PID as to the 11 high-benefit crops identified therein, allowing use on several crops in addition to the 11 uses in the 2020 PID, phase-out schedules that would allow some uses to continue until 2026, additional existing stocks orders that would allow additional time for phase-out, and retention of all import tolerances for chlorpyrifos. EPA

could not accept Gharda's proposed terms for several reasons. Specifically, EPA could not accept the request to retain uses beyond the 11 identified in the PID since EPA specified it could only make a safety determination if all other uses were cancelled. Moreover, EPA had concerns about the extended phase-out and existing stocks requests and retention of all tolerances to cover residues in imported commodities, due to underlying safety concerns with the pesticide.

17. Following further discussions between EPA and Gharda, as discussed in Paragraph 15 of this Declaration, Gharda submitted a second letter, dated June 7, 2021 (the "Second Gharda Letter"). The Second Gharda Letter stated that Gharda "commits to voluntarily cancel all currently approved agricultural uses of chlorpyrifos other than uses for the 11 high-benefit agricultural crops in select regions that the Agency identified in the [2020 PID]…subject to [nine] conditions." These conditions included allowing use of chlorpyrifos on cotton in Texas in addition to the 11 uses identified in the 2020 PID, a proposal that EPA and Gharda "reach mutually agreeable provisions" allowing for the sale of all finished Gharda technical product in the United States and overseas to be processed and sold for all registered uses, retention of all import tolerances for chlorpyrifos, and agreement that all products lawfully treated with chlorpyrifos be permitted to clear the channels of trade, pursuant to 21 U.S.C. 346a(l)(5). EPA also could not accept the terms proposed in the Second Gharda Letter, given the

continued concern about lengthy existing stocks provisions, retention of import tolerances, and lack of a safety determination beyond what was proposed in the 2020 PID.

18. Following still further discussions between EPA and Gharda, Gharda emailed PRD on July 6, 2021 (the "July 2021 Gharda Email"). The July 2021 Gharda Email stated that Gharda was "willing to accept" certain voluntary cancellations, including the complete cancellation of certain of the 11 uses identified in the PID (*i.e.,* strawberry, asparagus, cherry (tart), and cotton) and cancellation of selected application methods for other crops (*e.g.,* cancellation of the air blast method of application for tree fruit crops). However, Gharda also stated that "in return for Gharda agreeing [to] certain voluntary cancellations," Gharda requested that EPA "allow for continued use on alfalfa, soybean, sugar beet, wheat (summer and winter), apple, citrus and peach in select states as outlined in the December 2020 PID," and that EPA allow the formulation and distribution of end use products for all then-current uses through the end of June 2022 instead of February 2022, and the use of existing stocks through June 2023 instead of August 2022, as EPA had suggested. As with the First Gharda Letter and Second Gharda Letter, EPA was unable to accept the terms proposed in the July 2021 Gharda Email, given its continued concern about Gharda's extended phase-out and existing stocks requests and lack of a safety determination beyond

what was proposed in the 2020 PID. Although discussions continued with Gharda throughout July 2021, ultimately, there was not agreement between EPA and Gharda on the terms Gharda was proposing.

19. Section 6(f) of FIFRA provides that "[a] registrant may, at any time, request that a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses." 7 U.S.C. 136(d)(1)(A). To implement a voluntary product cancellation or use termination, the registrant would submit a letter to EPA (specifically, to the product manager or chemical review manager) requesting voluntary cancellation of the product or use(s). To cancel one or more uses, while retaining other use(s), the registrant also needs to submit a revised label with the changes highlighted.

20. After receipt of the letter, EPA will publish a notice in the Federal Register with a comment period of at least 30 days. 7 U.S.C. 136(d)(1)(B). FIFRA provides for a 180-day comment period for certain actions. 7 U.S.C. 136(d)(1)(C)(ii). However, the registrant may request that the Agency waive the longer comment period in favor of a 30-day comment period, which speeds up the approval process. *Id.* At the conclusion of the comment period, unless there are substantive comments or the registrant rescinds the cancellation request, EPA typically will publish the final cancellation order and, for products with retained uses, approve the revised label. If EPA has received substantive comments, EPA

may modify or reconsider the cancellation as appropriate. The voluntary cancellation process is described in detail on EPA's website. *See* U.S. EPA, Voluntary Cancellation of a Pesticide Product or Use, *available at* https://www.epa.gov/pesticide-registration/voluntary-cancellation-pesticide-product-or-use. Chapter 21 of EPA's Pesticide Registration Manual, also publicly available on EPA's website, specifies the correct distribution code registrants should use when requesting a voluntary cancellation of a product or use(s). *See* U.S. EPA, Pesticide Registration Manual: Chapter 21 - Directions for Submitting Applications and Contacting EPA, *available at* https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications.

21. Typically, as part of registration review, when EPA identifies risks that need to be mitigated, PRD would receive label amendment applications and voluntary cancellation requests from pesticide registrants consistent with the terms of the Agency's regulatory determination. In general, most of these voluntary cancellation request submissions do not require discussions between the registrant and EPA. But in some instances, a registrant may want to negotiate different terms for label amendments or existing stocks for use or product cancellations. Submissions that include additional terms or conditions that have not been agreed to by the Agency cannot be accepted as voluntary cancellation requests by EPA.

Requests including such terms or conditions are instead considered by EPA to be proposals to be used to facilitate further discussion between the Agency and the requestor regarding the scope and terms of a voluntary cancellation. This is because, under section 6(a)(1) of FIFRA, EPA may allow the sale and use of existing stocks only to the extent consistent with FIFRA. 7 U.S.C. 136d(a)(1). If a voluntary cancellation request is conditioned upon continued sale and distribution of existing stocks that would be inconsistent with FIFRA, the Agency could not issue a cancellation order including those existing stocks terms.

22. Because the First Gharda Letter, Second Gharda Letter, and July 2021 Gharda Email included a number of terms and conditions beyond the scope of the 2020 PID (*see* Paragraphs 16 and 17 of this Declaration), EPA considered this correspondence to constitute proposals to be used for further negotiation between the Agency and Gharda, rather than voluntary cancellation requests.

23. Moreover, since the First Gharda Letter, Second Gharda Letter, and July 2021 Gharda Email are requests to delete certain uses, not requests for full product cancellations, Gharda was required to submit revised labels with the changes highlighted for EPA's review and approval. *See* Paragraph 18 of this Declaration. None of the First Gharda Letter, Second Gharda Letter, or July 2021 Gharda Email were accompanied by revised labels; as a result, EPA was unable to accept this correspondence as official requests for amendments to the terms and

conditions of Gharda's registration. As such, EPA considered the correspondence to be proposals for voluntary cancellation rather than actual voluntary cancellation requests.

24. Consequently, the First Gharda Letter, Second Gharda Letter, and July 2021 Gharda Email did not provide a sufficient basis for EPA to conclude that aggregate exposures to chlorpyrifos would be limited to the 11 geographically limited uses identified in the 2020 PID. Moreover, since no other registrant submitted a request for voluntary cancellation of the uses (and applications to amend labels for products) beyond the 11 geographically limited uses identified in the 2020 PID, there was no basis for EPA to conclude that aggregate exposures would be limited consistent with the proposal in the 2020 PID. After all, the proposed mitigation in the PID was just a proposal on which several entities submitted comments. For example, multiple groups submitted comments disagreeing with EPA's proposed subset of 11 uses in the 2020 PID. Some, including cranberry and banana growers, argued that their uses should be included among the 11 considered uses; others, including advocacy and environmental groups, argued that EPA's safety determination supporting even those limited 11 uses was not supported by the available science. *See, e.g.*, Comment submitted by Cranberry Institute et al. (Mar. 12, 2021), *available at* https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1075; the

Colombian Banana Association – Augura (Feb. 8, 2021), *available at* https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1021; and Comment submitted by Earthjustice et al. (Mar. 12, 2021), *available at* https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0850-1107.

25. Consequently, without acceptable voluntary cancellation requests providing a basis to conclude that modified tolerances would be safe (consistent with the 2020 PID proposal), EPA concluded that, based on the information before the Agency and taking into consideration the registered uses for chlorpyrifos at the time, it was unable to determine within the timeframe specified by the Ninth Circuit that the chlorpyrifos tolerances were safe, since aggregate exposures to chlorpyrifos exceeded safe levels. 86 FR 48315 (Aug. 30, 2021). Therefore, EPA issued the Final Rule revoking all tolerances for chlorpyrifos contained in 40 CFR 180.342. *Id*.

26. In response to that Final Rule, EPA received several objections and requests for hearing, as well as requests to stay the rule. On February 28, 2022, the Agency published its response to those objections and requests in the Federal Register. *See* Chlorpyrifos; Final Order Denying Objections, Requests for Hearing, and Requests for a Stay of the August 2021 Tolerance Final Rule, 87 FR 11222 (Feb. 28, 2022). Following the publication of the Agency's Order responding to objections and hearing and stay requests, EPA contacted registrants

and asked them to submit requests to voluntarily cancel food uses of their registered chlorpyrifos products by March 30, 2022. If such voluntary cancellation requests are not forthcoming, EPA intends to initiate cancellation proceedings under section 6(b) of FIFRA. 7 U.S.C. 136d(b). Any such cancellation proceedings – which may take up to two years – would address existing stocks consistent with FIFRA.

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

Executed this 10th day of March 2022.

Timothy M. Kiely