

**UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
BEFORE THE ADMINISTRATOR**

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| <b>In re FIFRA Section 6(b) Notice of Intent<br/>to Cancel Pesticide Registrations for<br/>Chlorpyrifos Products</b> | ) |                                      |
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| <b>Gharda Chemicals International, Inc. and<br/>Red River Valley Sugarbeet Growers<br/>Association, et al.,</b>      | ) | <b>Docket No. FIFRA-HQ-2023-0001</b> |
|  | ) |                                      |
| <b>Petitioners</b>   | ) |                                      |
|  | ) |                                      |

**RESPONDENT’S REBUTTAL PREHEARING EXCHANGE**

Respondent the U.S. Environmental Protection Agency (“EPA,” “Agency,” or “Respondent”), pursuant to 40 C.F.R. § 164.50(b) and the Presiding Officer’s June 5, 2023 Order Scheduling Hearing and Prehearing Procedures (the “Scheduling Order”), hereby submits this Rebuttal Prehearing Exchange (“Respondent’s RPHX”) to rebut Petitioners’ Initial Prehearing Exchange. Respondent may move to amend or supplement this Respondent’s RPHX as provided by 40 C.F.R. § 164.50(b).<sup>1</sup> As noted in Respondent’s previous filings in this matter, Petitioners seek to conflate the above-captioned challenge to EPA’s December 14, 2022 Notice of Intent to Cancel (“NOIC”) with the Agency’s prior action revoking chlorpyrifos tolerances, 86 Fed. Reg. 48,315 (Aug. 30, 2021), (“Final Rule”). *See, e.g.*, Respondent’s Response to Request for Stay, Dkt. #8. Petitioners are currently challenging the Final Rule in the U.S. Court of Appeals for the

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<sup>1</sup> Petitioner Gharda agreed, in an August 2, 2023 communication to Respondent, that it would not oppose on timing grounds a motion from Respondent to supplement the RPHX in response to Respondent’s eventual review of Petitioner Gharda’s unredacted prehearing exchange. That unredacted material has not yet been provided to Respondent. If the parties are unable to work out arrangements for all parties to access the unredacted materials, Respondent will seek an appropriate order from the Presiding Officer.

Eighth Circuit, which declined to stay EPA’s revocation of chlorpyrifos tolerances. Order Exercising Jurisdiction and Denying Motion for a Partial Stay Pending Review, *Red River Valley Sugarbeet Growers Ass’n v. Regan*, No. 22-1422 (8th Cir. Mar. 15, 2022), Entry ID 5136844 (RX 51). Both the Presiding Officer and the Environmental Appeals Board declined to stay Petitioners’ challenge of the NOIC in this proceeding while the challenge to the Final Rule remains pending before the Eighth Circuit. Order on Motion to Stay, Dkt. #10; Order Denying Petitioners’ Request for Certification to the Environmental Appeals Board, Dkt. #19; Order Denying Motion for Interlocutory Review (E.A.B. July 14, 2023). Accordingly, Respondent may move to exclude certain documents and witness statements provided as part of the prehearing exchange in this matter—including documents provided below as part of Respondent’s RPHX—to the extent that such records are not relevant to the NOIC or are offered for the purpose of inappropriately re-litigating the Final Rule in this matter.

The heading numbers below correspond to those set forth in the Scheduling Order.

**(A) List of Potential Witnesses**

Respondent may call the following additional witnesses at the evidentiary hearing in this matter.

1. Dr. Mary Elissa Reaves is the Director of the Pesticide Re-evaluation Division (“PRD”) in EPA’s Office of Pesticide Programs (“OPP”). PRD is the division responsible for overseeing the periodic “registration review” of conventional pesticides as required by section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136a(g). Dr. Reaves was the Director of PRD at the time the Agency issued the December 14, 2022 Notice of Intent to Cancel (“NOIC”) certain chlorpyrifos registrations that is the subject of this proceeding.

Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations, 87 Fed. Reg. 76,474 (Dec. 14, 2022). Dr. Reaves is expected to testify as to EPA’s engagement with Petitioner Gharda prior to issuance of the Final Rule and EPA’s assessment of impacts of the cancellation action. Dr. Reaves may testify as a fact witness on direct examination (*i.e.*, the verified written statement filed in tandem with Respondent’s RPHX) and on cross examination.

2. Steven A. Schaible is the PRIA coordinator in OPP. Mr. Schaible serves as the point of contact for internal and external inquiries regarding submissions under the Pesticide Registration and Improvement Act (“PRIA”). Mr. Schaible is expected to testify as to the PRIA categories, fees, and timing concerning submission of applications for registration. Mr. Schaible may testify as a fact witness on direct examination (*i.e.*, the verified written statement filed in tandem with Respondent’s RPHX) and on cross examination.

**(B) Verified Written Statements Attached**

Pursuant to the Scheduling Order, the witnesses listed above prepared verified written statements to serve as their direct testimony. Copies of these written statements are being filed in tandem with Respondent’s RPHX.

**(C) Documents and Other Exhibits**

An index is provided below that identifies additional Respondent’s Exhibits (“RX”) filed in tandem with this Respondent’s RPHX:

- RX 3 –Available Information on Assessing Exposure to Pesticides in Food: A User’s Guide (June 21, 2000).

- RX 4 – U.S. EPA (2010). Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment (Jan. 7, 2010).
- RX 5 – FIFRA Science Advisory Panel (2002). Transmittal of the Final Report of the FIFRA Scientific Advisory Panel Meeting Held February 5– 7, 2002 (Mar. 19, 2002).
- RX 6 – FIFRA Science Advisory Panel (2005). Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held August 23-26, 2005 on the Preliminary N-Methyl Carbamate Cumulative Risk Assessment (Oct. 13, 2005).
- RX 7 – U.S. EPA (2018). Science in Action: Physiologically-Based Pharmacokinetic (PBPK) Models (Feb. 2018).
- RX 8 – U.S. EPA (2014). Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation. (Sept. 2014).
- RX 9 – U.S. EPA (2002). Determination of the Appropriate FQPA Safety Factor(s) For Use in the Tolerance Assessment (Feb. 28, 2002).
- RX 10 – U.S. EPA (1996). Residue Chemistry Test Guidelines: OPPTS 860.1500 Crop Field Trials (Aug. 1996).
- RX 11 – U.S. EPA (2000). Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern (Mar. 16, 2000).
- RX 12 – U.S. EPA (2000). Chlorpyrifos Human Health Risk Assessment (June 8, 2000).
- RX 13 – FIFRA Science Advisory Panel (2020). Transmittal of Meeting Minutes and Final Report for the Federal Insecticide, Fungicide and Rodenticide Act, Scientific Advisory Panel (FIFRA SAP) Meeting held on November 19-21, 2019 (Feb. 18, 2020).

- RX 14 – U.S. EPA (2020). Framework for Conducting Pesticide Drinking Water Assessments for Surface Water (Sept. 2020).
- RX 15 – U.S. EPA (2016). Summary Reviews for Additional Epidemiological Literature Studies from Prospective Birth Cohort Studies (Mar. 25, 2016).
- RX 16 – U.S. EPA (2020). Appendix B. Case Study for Integrating a Distributional Approach to Using Percent Crop Area (PCA) and Percent Crop Treated (PCT) into Drinking Water Assessment.
- RX 17 – U.S. EPA (2012). Standard Operating Procedures for Residential Pesticide Exposure Assessment (Oct. 2012).
- RX 18 – U.S. EPA (2006). Organophosphorous Cumulative Risk Assessment, 2006 Update (July 31, 2006).
- RX 19 – U.S. EPA (2000). Office of Pesticide Programs Science Policy on: The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides (Aug. 18, 2000).
- RX 20 – U.S. EPA (2011). Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review (June 30, 2011).
- RX 21 – FIFRA Scientific Advisory Panel (2002). “Organophosphate Pesticides: Preliminary OP Cumulative Risk Assessment.”
- RX 22 – U.S. EPA (2016). Office of Pesticide Programs’ Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides (Dec. 28, 2016).
- RX 23 – U.S. EPA (2014). Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (Dec. 29, 2014).

- RX 24 – EPA Exposure Factors Handbook.
- RX 25 – FIFRA Scientific Advisory Panel (2012). Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held April 10-12, 2012 on “Chlorpyrifos Health Effects” (July 11, 2012).
- RX 26 – U.S. EPA (2016). Transmittal of Meeting Minutes of the April 19-21, 2016 FIFRA SAP Meeting Held to Consider and Review Scientific Issues Associated with “Chlorpyrifos: Analysis of Biomonitoring Data” (July 20, 2016).
- RX 27 – U.S. EPA (2014). Chlorpyrifos Acute and Steady Dietary (Food Only) Exposure Analysis to Support Registration Review (Nov. 18, 2014).
- RX 28 – U.S. EPA (2020). The Use of New Approach Methodologies (NAMs) to Derive Extrapolation Factors and Evaluate Developmental Neurotoxicity for Human Health Risk Assessment (Aug. 25, 2020).
- RX 29 – U.S. EPA (2020). U.S. Environmental Protection Agency Peer Review for: The Use of New Approach Methodologies (NAMs) to Derive Extrapolation Factors and Evaluate Developmental Neurotoxicity for Human Health Risk Assessment (2020).
- RX 30 – U.S. EPA (2006). Reregistration Eligibility Decision for Chlorpyrifos (July 31, 2006).
- RX 31 – U.S. EPA (2011). Revised Chlorpyrifos Preliminary Registration Review Drinking Water Assessment PC Code: 059101; DP Barcode: 368388, 389480 (June 30, 2011).
- RX 32 – U.S. EPA (2014). Chlorpyrifos Updated Drinking Water Assessment for Registration Review (Dec. 23, 2014).

- RX 33 – U.S. EPA (2016). Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (Nov. 3, 2016).
- RX 34 – U.S. EPA (2016). Chlorpyrifos Refined Drinking Water Assessment for Registration Review (Apr. 14, 2016).
- RX 35 – U.S. EPA (2011). Finalization of Guidance on Incorporation of Water Treatment Effects on Pesticide Removal and Transformations in Drinking Water Exposure Assessments (Dec. 5, 2011).
- RX 36 – FIFRA Scientific Advisory Panel (2008). Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held September 16-18, 2008 on the Agency's Evaluation of the Toxicity Profile of Chlorpyrifos (Dec. 17, 2008).
- RX 37 – FIFRA Scientific Advisory Panel (2010). Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting on the Draft Framework and Case Studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment (Apr. 22, 2010).
- RX 38 – World Trade Organization (2001). Implementation-Related Issues and Concerns (Nov. 14, 2001).
- RX 39 – U.S. EPA (2021). External Meetings Between EPA and Chlorpyrifos Stakeholders (assorted dates).
- RX 40 – U.S. EPA (2020). EPA Requests Comments on New Methodologies to Estimate Pesticide Concentrations in Surface Waters (Jan. 15, 2020).
- RX 41 – Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (1993). Guidance for Implementing E.O. 12866 (Oct. 12, 1993).

- RX 50 – U.S. EPA (2021). EPA Takes Action to Address Risk from Chlorpyrifos and Protect Children’s Health (Aug. 18, 2021).
- RX 43 – The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).
- RX 44 – Food and Agriculture Organization of the United Nations. Codex Alimentarius, Chlorpyrifos Maximum Residue Limits.
- RX 45 – U.S. EPA (2022). Frequent Questions about the Chlorpyrifos 2021 Final Rule.
- RX 46 – U.S. FDA (2022). Guidance for Industry: Questions and Answers Regarding Channels of Trade Policy for Human Food Commodities with Chlorpyrifos Residues (Feb. 2022).
- RX 47 – U.S. EPA (2021). Chlorpyrifos Revocation Small Business and Employment Analysis.
- RX 48 – Respondents’ Opposition to Petitioners’ Motion for Stay Pending Review, *Red River Valley Sugarbeet Growers Ass’n v. Regan*, No. 22-1294 (8th Cir. Feb. 18, 2022), Entry ID 5129078.
- RX 49 – Declaration of Neil Anderson, *Red River Valley Sugarbeet Growers Ass’n v. Regan*, No. 22-1422 (8th Cir. Mar. 11, 2022), Entry ID 5135786.
- RX 50 – Declaration of Timothy M. Kiely, *Red River Valley Sugarbeet Growers Ass’n v. Regan*, No. 22-1422 (8th Cir. Mar. 11, 2022), Entry ID 5135786.
- RX 51 – Order Exercising Jurisdiction and Denying Motion for a Partial Stay Pending Review, *Red River Valley Sugarbeet Growers Ass’n v. Regan*, No. 22-1422 (8th Cir. Mar. 15, 2022), Entry ID 5136844.



- RX 52 – Order Granting Joint Motion to Consolidate, *Red River Valley Sugarbeet Growers Ass’n v. Regan*, No. 22-1530 (8th Cir. Apr. 21, 2022), Entry ID 5149661.
- RX 53 – Chlorpyrifos Summary Document Registration Review: Initial Docket (March 2009).
- RX 54 – Chlorpyrifos Usage and Benefits for Non-Crop Uses (Nov. 9, 2020).
- RX 55 – Comment Period Extension for Chlorpyrifos (Feb. 4, 2021).
- RX 56 – Chlorpyrifos Order Denying Petition to Revoke Tolerances (2017).
- RX 57 – Chlorpyrifos Final Order Denying Objections.
- RX 58 – *LULAC et al., v EPA* (9<sup>th</sup> Cir. No. 19-71979) Mandate.
- RX 59 – EPA, Voluntary Cancellation of a Pesticide Product or Use (downloaded Aug. 1, 2023).
- RX 60 – Comment submitted by Cranberry Institute (Mar. 4, 2021).
- RX 61 – Comment submitted by Augura, Columbian Banana Association (Feb. 8, 2021).
- RX 62 – Farmworker and Conservation Comments on Chlorpyrifos Revised Human Health Risk Assessment (Mar. 4, 2021).
- RX 63 – Maine Public Radio, “Caribou broccoli farm will have to destroy crops after illegal pesticide is detected” (July 25, 2023).

**(D) Official Notice**

Respondent is not aware of any matters of which official notice should be taken but reserves the right to move for official notice of matters as appropriate.

**(E) Interpretation Services**

Respondent does not anticipate requiring the services of an interpreter.

(F) **Questions of Scientific Fact**

Respondent does not wish to refer one or more questions of scientific fact to a committee designated by the National Academy of Sciences pursuant to 7 U.S.C. § 136d(d) and 40 C.F.R. § 164.50(e).

Respectfully submitted,

Dated: August 4, 2023

/s/ Forrest Pittman  
Forrest Pittman  
Pesticides and Toxic Substances Law Office  
Office of General Counsel  
U.S. Environmental Protection Agency

Counsel for Respondent

**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing RESPONDENT’S REBUTTAL PREHEARING EXCHANGE, including the referenced witness statements and exhibits, dated August 4, 2023, was filed electronically with the U.S. Environmental Protection Agency, Office of Administrative Law Judges E-filing system, with a copy via electronic mail to the following:

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Dated: August 4, 2023

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