UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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

VERIFIED WRITTEN STATEMENT OF WITNESS STEPHEN A. SCHAIBLE IN SUPPORT OF RESPONDENT'S NOTICE OF INTENT TO CANCEL

I. Background

I, Stephen A. Schaible, declare under penalty of perjury that the following statements are true and correct to the best of my knowledge and belief and that they are based upon my personal knowledge, information contained in the records of Respondent, the United States Environmental Protection Agency ("EPA"), and/or information supplied to me by EPA employees under my supervision and in other EPA offices. *See* 28 U.S.C. § 1746.

I am currently the PRIA Coordinator in EPA's Office of Pesticide Programs ("OPP"), reporting to the OPP Office Director and Deputy Director of Programs. In this role, I serve as the internal and external point of contact regarding the Pesticide Registration Improvement Act ("PRIA") and its reauthorizations, including inquiries around which PRIA categories would apply to covered applications based on activities requested. I have served in this role since 2016, and before that was the PRIA Ombudsman for the Registration Division ("RD") for 6 years. I started at the EPA in January 1991 and have worked in OPP for over 32 years as a risk assessor

and risk manager. I have served in the ombudsman role for both RD and the Antimicrobials Division.

The Registration Division is responsible for, among other things, the registration and amendment of conventional pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y ("FIFRA") and the establishment of tolerances for conventional pesticides under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a. Chlorpyrifos is a conventional pesticide.

This verified statement is filed in support of EPA's December 14, 2022, Notice of Intent to Cancel ("NOIC") the registrations of three pesticide products containing the insecticide chlorpyrifos pursuant to section 6(b) of FIFRA, 7 U.S.C. § 136d(b), which identifies Petitioner Gharda Chemicals International, Inc. ("Gharda") as the registrant for the products subject to the NOIC. Chlorpyrifos; Notice of Intent to Cancel Pesticide Registrations, 87 Fed. Reg. 76,474 (Dec. 14, 2022). This verified statement constitutes my direct statement as a fact witness in the hearing prompted by a Request for Hearing and Statement of Objections and Request for Stay filed by Petitioner Gharda on January 13, 2023 ("Gharda's Objections") and a Request for Hearing and Statement of Objections filed by a collection of grower groups ("Grower Petitioners") on January 13, 2023 ("Grower Petitioners' Objections"), pursuant to the Presiding Officer's June 5, 2023 Order Scheduling Hearing and Prehearing Procedures ("Scheduling Order").

II. Pesticide Registration and Improvement Act

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

approves an application for pesticide registration if, among other things, the pesticide will not cause unreasonable adverse effects on the environment. *Id*. at § 136a(c)(5).

PRIA was enacted in 2004, Pub. L. No. 108-199 (Jan. 23, 2004), and established a new system for registering pesticides, including fees and timeframes for reviewing applications that vary depending on the request to the Agency. These provisions are located in FIFRA section 33, 7 U.S.C. § 136w-8. Because PRIA is a sunsetting statute, it is renewed every several years, with the last update to PRIA (PRIA 5) enacted in December 2022. Pub. L. No. 117-328 (Dec. 29, 2022).

For purposes of evaluating the fees and timeframe for registering conventional pesticides and uses, the relevant categories are found in the following statutory tables: Table 1. – Registration Division (RD) – New Active Ingredients; Table 2. – Registration Division (RD) – New Uses; Table 3. – Registration Division (RD) – Import and Other Tolerances; Table 4. – Registration Division (RD) – New Products; Table 5. – Registration Division (RD) – Amendments; and Table 6. – Registration Division (RD) – Other Actions. 7 U.S.C. § 136w-8(b)(3)(B).

Based on these tables, if chlorpyrifos was considered a "new active ingredient", the application to register these uses would be submitted under PRIA category R010, with a decision review time of 36 months and a fee of $1,079,356. This category is typically used for active ingredients that are not registered or have not been registered before because they typically involve an extensive amount of data review by the Agency. If, however, chlorpyrifos is not considered a new active ingredient because, for example, it remains registered, it could be more appropriate to consider the addition of a food use as a "new use". If all registered chlorpyrifos food uses are cancelled but other non-food uses remain registered and then tolerances for

residues of chlorpyrifos are reinstated by the 8th Circuit Court of Appeals, it might be more appropriate to submit an application under PRIA category R150 (for a "First food use"), with a decision review time of 23 months and a fee of $454,490. If not all registered food uses of chlorpyrifos are cancelled, it might be more appropriate to submit an application under PRIA category R190 (for an "Additional food use, 6 or more uses"), with a decision review time of 17 months and a fee of $682,357. Still other PRIA categories with shorter timeframes and lower fees for "new products" may apply depending on whether the food use is identical or substantially similar to a registered use, whether the source product used to manufacture the pesticide is registered, what data review EPA would need to conduct, and how the registrant satisfied the data requirements.

Ultimately, determining the correct PRIA category for submission of a product application depends on the situation at the time the application is submitted and includes consideration of the type of application being made to the Agency, e.g., whether the product is considered a new active ingredient, a new use, or a product or use that is identical or substantially similar to any other registered product; whether data need to be developed by the registrant or reviewed by EPA to support a registration determination. Furthermore, while PRIA specifies timeframes for review, the time to review the application and make a determination on a product or use may vary depending on, e.g., the amount of review the Agency needs to do, the quality of the application and the data submitted, if any, and whether any additional data is needed to support the registration. There may be other factors outside of the PRIA framework that influence the length of time it takes for the Agency to issue a final decision on a given application, e.g., whether consultation under the Endangered Species Act is required or whether a cumulative risk assessment is needed. Concerning the PRIA fees collected with an application,

the Agency has discretionary authority to provide refunds in certain circumstances. *See* 7 U.S.C. § 136w-8(b)(8)(C). Because of the many factors that are considered in figuring out the appropriate PRIA category, EPA often engages in conversations with registrants prior to their submission to assist them in determining the appropriate PRIA category. As it does with other registrants, EPA would be willing to work with Gharda to determine the appropriate PRIA category for submission of any application.

VII. Conclusion

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Respectfully submitted,

Dated: August 4, 2023

/s/Stephen A. Schaible
Stephen A. Schaible
PRIA Coordinator
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency