

EXPERT REPORT OF CARLTON R. LAYNE

I. PROFESSIONAL BACKGROUND AND QUALIFICATIONS

I began my professional career in the United States Department of Agriculture in 1968 before the formation of the United States Environmental Protection Agency (EPA or Agency). I joined the Agency shortly after its formation and the consolidation of all federal pesticide regulatory functions within its domain. I served in various capacities while employed by EPA, Region 4, Pesticides & Toxic Substances Branch, including, but not limited to Enforcement Officer, Project Officer, Chief Investigator and Chief of the Pesticides Section. In those capacities I conducted investigations, evaluated evidence and made determinations regarding the prosecution of Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) violations – including allegations of the misuse and misbranding of EPA registered pesticides and the failure to report information to the EPA pursuant to FIFRA section 6(a)(2). 6(a)(2) cases were typically initiated by the 6(a)(2) desk in the Office of Pesticides Programs (OPP) to validate or investigate incident reports or to respond to media reports of pesticide incidents prior to the receipt of submissions from registrants. The 6(a)(2) cases were then turned over to enforcement for investigation and determination as to whether 6(a)(2) violations had occurred. Some investigations were started on the initiative of enforcement personnel as warranted.

I was also partly responsible for the development of the original federal regulations for and the state implementation of the Certification and Training of Pesticide Applicators (C&T) as well as directly training pesticide applicators pursuant to state and national standards. I addressed applicators at so-called “grower meetings” usually sponsored by registrants or pesticide distributors. My C&T activities in the early days of the 1972 amendments to FIFRA included working with states in the drafting and submission of their State Plans for the Certification and Training of Pesticide Applicators. This involved working with State Lead Agency officials including Commissioners of Agriculture, state Attorneys General, and other state officials to ensure appropriate state legislation content.

While the bulk of my responsibilities focused on enforcement-related activities (investigations, inspections, audits, case development, and prosecutions) in varying degrees, my work reflected the range of most of the activities described in FIFRA (C&T, state and local liaison and support, etc.). Ultimately, I became very active as a regional and national Training Officer serving in various roles.

In the late 1980s, before my transfer to the Atlanta Regional Office, Chevron Chemical Company ceased being the primary registrant and responsible party for paraquat. Those activities were assumed by the Imperial Chemical Industries (ICI), the paraquat registrant of record at the time. As indicated above, part of my duties as the resident EPA Enforcement Officer in Florida was to participate in training opportunities targeting pesticide users. I was invited by ICI field representatives to participate in a series of grower meetings they were holding to familiarize their customers with ICI and provide growers with information regarding the use of paraquat. I would give “The Label is the Law” presentations at these meetings emphasizing the requirement that paraquat be used in a manner consistent with labeling. At the

time, I considered ICI's approach to be good stewardship of their product and a great opportunity for EPA to encourage FIFRA compliance through education.

During my career with EPA, I have been involved with several cases involving paraquat – mostly pesticide drift cases, but also a human incident case and an import case. I served as either the primary or follow-up investigator in all these cases.

My curriculum vitae, which includes a more detailed summary of my education and experience is attached as Appendix A to this Report.

I was asked to review background documents and render an opinion as to, among other things, whether Syngenta and Chevron, as registrants of Paraquat in the United States violated the requirements of FIFRA section 6(a)(2) by failing to timely submit factual information regarding unreasonable adverse effects of Paraquat as required by federal law and federal regulations.

II. COMPENSATION AND MATERIALS CONSIDERED

My work on this case is billed at my standard hourly rate of \$300. My compensation does not depend in any way upon the outcome of this case or the content of this report.

A list of the materials I considered in connection with my report is provided in Appendix B.

III. OPINIONS

I hold the following opinions to a reasonable degree of certainty based on my education, training, knowledge, and experience.

A. United States Environmental Protection Agency and FIFRA

The United States government regulates the manufacture, sale, distribution, and use of pesticide products primarily through the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as Amended (FIFRA). FIFRA was passed by Congress in 1947 and initially vested oversight and registration power with the United States Department of Agriculture (USDA). The early versions of FIFRA, in comparison to today's standards, established rudimentary labeling provisions and focused on ensuring that chemicals were not adulterated.¹ To register a pesticide, manufacturers (registrants) had to file a statement with the Secretary of the Department of Agriculture containing a draft copy of the label to accompany the pesticide, including directions for use and a statement of all claims made for the product.² The focus of FIFRA, up until the creation of the EPA in 1970 and the passing of the Federal Environmental

¹ <https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities#:~:text=In%201972%2C%20the%20Federal%20Environmental,protecting%20health%20and%20the%20environment>

² Lange, M., "The Federal Environmental Pesticide Control Act of 1972: A Compromise Approach" 3-2 Ecology L.Q. 277 (1973).

Pesticide Control Act (FEPCA) in 1972, was not on the environment and public health effects of pesticide use.

Since around 1910, USDA had been focusing on adulteration and efficacy. The 1947 Act (FIFRA) required the registration of pesticides moving in interstate commerce and the acceleration of data submission requirements to support the claims. Data requirements were most certainly evolving in the years prior to the creation of the EPA for a variety of reasons better discussed in a different forum.

The 1972 Amendments to FIFRA transferred the authority for pesticide regulation to the EPA and provided much broader regulatory coverage of pesticides.³ The amendments also required, for the first time and among other things, that a pesticide registered to be sold in the United States “will perform its intended function without unreasonable adverse effects on the environment.” FIFRA sec. 3(c)(5). FIFRA defines the term, “unreasonable adverse effects on the environment” to mean: “. . . any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.” FIFRA sec. 2(bb)(1). Under the statute, the EPA is tasked with balancing the benefits of using a pesticide against risks to human health and the environment that may be associated with its use.

A company seeking authorization to sell or distribute a pesticide in the United States must submit an application to EPA to obtain a registration. Under FIFRA, when EPA registers a product, it registers the specific pesticide formulation, i.e., the chemical composition, of each product. EPA also reviews and accepts⁴ the specific “label.” All other “labeling” for the product must be consistent with the accepted labeling. Labeling consists of the graphic and printed material that appears on or accompanies the pesticide product.

Through the 1972 amendments, Congress mandated that EPA assess the status of all of the pesticide products that had been previously registered by the federal and state governments in terms of the new registration standards. Additional amendments to FIFRA in 1978 sanctioned a chemical-by-chemical rather than a product-by-product approach to registration (and reregistration) allowing the EPA to first assess the active ingredients instead of each product. This streamlined approach allowed the EPA to focus its resources on 600 active ingredients instead of over 50,000 formulated products. At this time, EPA was facing substantial difficulties in meeting its Congressional mandate to timely reregister all of the pesticide products on the market prior to the formation of the EPA including paraquat. EPA’s inability to meet its mandate

³ U.S. GENERAL ACCOUNTING OFFICE, PESTICIDES: EPA'S FORMIDABLE TASK TO ASSESS AND REGULATE THEIR RISKS 10 (RCED-86-125, 1986)

⁴ It is more appropriate to say that EPA accepts labeling proposed by a registrant, instead of “approves.” Federal regulations and EPA manuals provide examples of false or misleading statements or representations that constitute misbranding. 40 CFR 156.10(a)(5) and the Label Review Manual. Statements directly or indirectly implying endorsement by the EPA is considered misbranding. This would include phrases such as “approved” or “EPA-approved” used in connection with a reference to the EPA.

was due to several factors including a lack of registration data and the availability of well-conducted safety studies.⁵

As part of the registration of a pesticide product, EPA may classify each product for “general use,” or “restricted use.” A pesticide will be classified as “restricted use” when a greater regulatory restriction is needed to protect against unreasonable adverse effects to public health or the environment. In making this determination the EPA will compare information about the potential adverse effects of specified uses of the pesticide with the risk criteria listed in FIFRA. The regulatory restriction for a “restricted use” pesticide will require that an applicator be certified by a State or the Federal government as being competent to buy and use these pesticides safely, responsibly, and in accordance with label directions – or must work under the direct supervision of a Certified Applicator.

Under FIFRA, EPA also registers formulations of pesticide products, meaning not just the active ingredient (i.e. paraquat) but all ingredients in the container sold to consumers. FIFRA defines a “pesticide product” as “a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed and sold.”⁶ EPA’s review of formulations is based on EPA’s prior review and registration of the pesticide’s active ingredient. Registrants must submit a Confidential Statement of Formula, which enumerates each component/ingredient in the product, the percentage amount of that ingredient contained in the formula, and even the source of the listed ingredients. Chronic toxicity testing of a formulated product is not conducted by the EPA.

The EPA does not generally consider the risks and benefits of the adjuvants used in pesticide mixes, including any synergistic effects of the pesticide and adjuvants. The EPA considers “adjuvants” as chemicals added to the pesticide by users prior to application, including surfactants and drift control agents. EPA will not assess the toxicity of a pesticide product together with adjuvants in the registration or reregistration process, unless it is aware of data that specific combinations enhance the toxicity of the active ingredient.⁷ EPA primarily relies on data provided by registrants to alert them to concerns relating to combinations in order to determine whether additional measures are necessary, including the requirement for more testing or modifications to the labeling.⁸ To a lesser extent, EPA can learn of concerns regarding combinations of chemicals from open literature reports or reports from the public.

The applicant’s proposed product labeling is the starting point of EPA’s review of the risks and benefits of a pesticide. FIFRA and EPA’s regulations contain specific requirements regarding the content of pesticide product labeling. EPA has supplemented these rules with guidance documents meant to provide clarification and expand on the requirements. EPA interprets FIFRA secs. 12(a)(1)(E) and 2(q), together, to impose a continuing duty on registrants, like Chevron and Syngenta, to ensure that the labeling of their products will adhere to the federal

⁵ Pamela A Finegan, “FIFRA Lite: A Regulatory Solution or Part of the Pesticide Problem?” (1989) 6 Pace Environmental Law Review 615

⁶ 40 CFR 152.3

⁷ EPA Response to the 2017 Citizen Petition from the Center for Food Safety and Others Relating to the Whole Formulations Testing and Mixtures for Conventional Pesticides (September 28, 2023).

⁸ Id.

standards and requirements and thus mitigate potential risks. FIFRA sec. 12(a)(1)(E) also prohibits the sale and distribution of a product that is misbranded, i.e., if, among other things, the product's labeling is "false or misleading in any particular."

The label also specifies actions that should be taken to minimize or prevent harmful exposure to humans and the environment. For example, labels often require specific personal protective equipment (PPE) that must be worn during the mixing, loading and application operations to minimize exposure. Labels must also contain information about the hazards of a pesticide along with warnings and instructions about how to avoid undue risks when transporting, storing, mixing, loading, handling, applying, and disposing of the product. EPA's policy approach is that the labeling of a pesticide must include all the information – use directions, restrictions and requirement, and warnings – necessary for the product to be used in a manner that will not cause unreasonable adverse effects. When data or information show that a hazard "may exist to humans or domestic animals" the label must bear precautionary statements describing the hazard, the route(s) of exposure and the precautions to be taken to avoid injury or to mitigate the effect.⁹

In 2007, amendments to FIFRA added a process called "registration review," and directed EPA to periodically review existing pesticide registrations every fifteen years.¹⁰ This registration review program "is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects."¹¹

EPA's reevaluation of previously registered pesticides starts with a determination of whether new toxicity, exposure, and/or efficacy data are needed to characterize the risks and/or benefits of the pesticide. In this regard, information reported under FIFRA sec. 6(a)(2) may signal potential concerns that were not recognized at the time the pesticides were registered.

1. Continuing Obligation of Registrants – FIFRA Section 6(a)(2)

The registrant of a registered pesticide has an ongoing legal obligation to ensure that the product's labeling is adequate to protect health and the environment. The registrant has a duty to report to EPA information bearing on whether the product continues to meet this standard, including an affirmative duty to submit information regarding unreasonable adverse effects. According to FIFRA:

⁹ 40 CFR 156.70

¹⁰ <https://www.epa.gov/pesticides/pesticide-registration-review-deadline-status-update-and-plans-remaining-work#:~:text=In%202007%2C%20an%20amendment%20to,human%20health%20or%20the%20environment.>

¹¹ <https://www.epa.gov/pesticide-reevaluation/why-we-review-pesticides#:~:text=The%20registration%20review%20program%20is,of%20no%20unreasonable%20adverse%20effects.>

If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

7 U.S.C. § 136d(a)(2)(hereinafter 6(a)(2)). EPA interprets this reporting requirement expansively; registrants do not have discretion to withhold reportable information based on their belief that the information would not materially affect EPA's regulatory decision.

The purpose of enacting section 6(a)(2) in 1972 was to ensure that EPA promptly receives any data that may lead to a conclusion that the use of a pesticide may pose unreasonable health or environmental risks.¹² EPA has stated that "receiving such information early is important because doing so permits the agency to take prompt regulatory action to minimize human exposure to potentially dangerous pesticides." *Id.* In a way it's a fact check for EPA on the registration process. It often answers lingering questions like "Did we miss something?" or "Did we misinterpret the data?" 6(a)(2) submissions also can identify environmental or human health issues that were not anticipated at the time of registration – such as the likelihood of groundwater contamination. It also can catch unknown unanticipated adverse effects that are revealed by evolving improvements to the technology of medicine, chemistry and environmental monitoring.

In September 1997, EPA published a final rule in the Federal Register codifying EPA's interpretation and enforcement policy regarding the reporting of information concerning unreasonable adverse effects under 6(a)(2). The final rule is codified in 40 CFR part 159 and clarifies the different types of data and information that registrants must report under FIFRA 6(a)(2). The regulations require a registrant to submit information to the EPA "if the registrant possesses or receives the information, and the information is relevant to the assessment of the risks or benefits of one or more specific pesticide regulations currently or formerly held by the registrant." 40 CFR § 159.158(a). This includes the reporting of conclusions or opinions of individuals: (1) employed or retained the registrant; (2) from whom the registrant requested the opinions or conclusions; or (3) individuals who are qualified experts.¹³

There are limited exceptions to the rule. A registrant is not required to submit information to the EPA if the information is clearly erroneous, has already been submitted to the EPA, concerns inert ingredients, contaminants or impurities no longer in the product, or the information appears in specified publications or government reports of the United States.¹⁴

¹² "EPA Lacks Assurance That All Adverse Effects Data Have Been Reviewed" Statement of Peter F. Guerrero, Associate Director Environmental Protection Issues Resources, United States General Accounting Office, October 30, 1991.

¹³ A qualified expert is defined as "one who, by virtue of his or her knowledge, skill, experience, training or education could be qualified by a court as an expert to testify on issues related to the subject matter on which he or she renders a conclusion or opinion." 40 C.F.R. 159.153. In other words, "EPA wants registrants to report information when a person has relevant expert credentials." *Id.*

¹⁴ The exception for "Publications" would not require the reporting of information if it appears in:

(i) Any scientific article or publication which has been abstracted in a recognized database of scientific and medical literature, such as Medline, ENBASE, Toxline or Index Medicus, if the

There are also requirements for the registrant to report adverse effect information from toxicological studies, ecological studies, epidemiological studies, exposure studies, incomplete studies demonstrating serious adverse effects, and discontinued studies. 40 CFR §§ 159.165; 159.167; 159.170.

A registrant must also submit incident reports relating to any toxic or adverse effect suffered by a human or non-target organism following exposure to the registered pesticide. In addition to incident reports, 40 CFR § 159.170 also requires registrants to submit information regarding higher-than-expected exposures. Specifically, it states:

Information must also be submitted which concerns exposure monitoring studies that indicate higher levels of risk or exposure than would be expected based on previously available reports, data, or exposure estimates. Such information must be submitted regardless of whether the registrant considers any observed correlation or association to be significant.

Even if the information does not fall within one of the enumerated categories included in the EPA regulations, the registrant must submit the information to EPA if it “knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product.” 40 CFR 159.195. Examples of the types of information that would need to be reported include (1) information showing that “use of a pesticide may pose any greater risk than previously believed or reported to the Agency; and (2) “any information which might tend to invalidate a study submitted to the Agency to support a pesticide regulation.

Finally, the registrant must provide the EPA with information not falling within a specified category if the EPA informs the registrant that such additional information has the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

Additionally, the registrant may file an amended registration to update the label to ensure compliance with FIFRA. 40 C.F.R. § 152.50. The registrant must provide the EPA with “draft labeling incorporating the proposed labeling changes.” 40 C.F.R. § 152.50 (e). The registrant shall also “furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be

abstract in question clearly identified the active ingredient or the registered pesticide(s) to which the information pertains.¹⁴

- (ii) Reports or publications which have been made available to the public by any of the following Federal agencies: Centers for Disease Control and Prevention, Consumer Products Safety Commission, Department of Agriculture, Department of the Interior, Food and Drug Administration or any other agency or institute affiliated with the Department of Health and Human Services.

If otherwise reportable information appears in publications, reports, or scientific articles that do not meet these specified exceptions, the registrant has a duty to report the information to the EPA.

required to be reported under FIFRA sec. 6(a)(2) if the product were registered.” 40 C.F.R. § 152.50(f)(3).

a. EPA’s Guidance on the Submission of Adverse Effect Information Under 6(a)(2)

On April 3, 1998, EPA provided registrants with comprehensive guidance on implementing 6(a)(2) regulations. The Guidance was published as Pesticide Registration Notice 98-3 and provided clarification on what information the EPA expected registrants to submit.

The EPA requires conclusions or opinions of experts to be submitted if (1) the information is otherwise reportable under one of the substantive provisions of the rule; or 2) the registrant knows, or should reasonably know, that the information, alone or in conjunction with other information, might raise concerns about the continued registration of a pesticide or about the appropriate terms and conditions of registration of a pesticide. PRN 98-3 at 8. EPA made it known that they frequently rely on the “weight of the evidence” in their regulatory decisions and therefore expert opinions play an important role in their decision-making. EPA provided specific examples of when expert opinions should be reported, including (1) opinions that exposure to a pesticide may have caused a particular adverse effect; (2) scientific opinions that test data demonstrate that a pesticide causes a particular adverse effect; and (3) expert opinions that the aggregate risks posed by a pesticide may be higher than previously believed.

In PRN 98-3, EPA also addressed questions that arose regarding the need to report studies or incidents that occurred outside the United States. EPA informed registrants that “information derived from studies or incidents occurring outside the United States is reportable if the information is relevant to a pesticide registration held by the registrant possessing the information and if the information is otherwise reportable under section 6(a)(2).” EPA recognized that the reportability of a study or incident may be affected by differences in the United States formulation and the formulations used in the country where the reportable information was generated. Nonetheless, the EPA confirmed that, absent an expert opinion that the formulation differences make the “information irrelevant to the product registered in the United States” it should be reported: PRN 98-3 at 13.

EPA advises that if the registrant has questions or is unsure about whether the expert opinion is reportable, the registrant should “either submit the opinion or contact the 6(a)(2) Officer in the Office of Pesticide Programs.”

b. A registrant’s duty to report factual information regarding unreasonable adverse effects has been in effect since 1972

Since 1972, registrants have always been required under 6(a)(2) to report factual information in their possession relating to unreasonable adverse effects. Neither the 1997 final rule nor EPA’s guidance set forth in PRN 98-3 fundamentally altered the nature or spirit of 6(a)(2). Granted, the process of the submission of the reports required the drafting of the supporting regulations.

EPA's first regulation under section 6(a)(2) required registrants to report any information about adverse effects. 40 Fed. Reg. 28242, 28277 (July 3, 1975). These initial EPA regulations implementing 6(a)(2) were immediately challenged by the chemical industry resulting in a 1978 interpretative memorandum broadly defining the reach of 6(a)(2). EPA published the 1978 interpretative rule and a 1979 enforcement policy in 1985 setting forth its position that 6(a)(2) required registrants to submit any information in its possession that, if true, would be relevant to an evaluation of the risks and benefits of the pesticide product. 50 Fed.Reg. 38115, 38116 (Sept. 20, 1985).¹⁵

The duty and obligation of a registrant to submit information to the EPA pursuant to 6(a)(2) has been required under the 1972 amendments to FIFRA since its passage and implementation. Over the years, EPA has made clear that it interprets this reporting requirement expansively.

B. EPA's Registration of Paraquat

Paraquat (1, 1'-dimethyl, 4,4'-bipyridyl) is a broad spectrum, non-selective contact herbicide. Imperial Chemical Industries (ICI), a predecessor of Syngenta, discovered the herbicide potential of Paraquat in 1954.¹⁶ The first formulated paraquat herbicide product was introduced to the market in 1962 under the brand name "Gramoxone." Paraquat was first registered as a pesticide in the United States in 1964.

Chevron Chemical Company licensed the right to sell paraquat in the United States and was the initial registrant of Paraquat. ICI and Chevron shared the cost of completing studies required by the EPA. Chevron was the exclusive distributor of Paraquat in the United States until 1982, and during this time, they purchased Paraquat directly from ICI. In 1982, ICI began selling Paraquat in the United States and Chevron ultimately withdrew from selling Paraquat in the United States in 1986.

In 1978, EPA initiated a Rebuttal Resumption Against Registration (RPAR) action due to concerns over acute toxicity, chronic toxicity and lack of an emergency treatment for poisoning victims.¹⁷ The RPAR was concluded in 1982 with the result being several changes to the labeling of Paraquat and new requirements for additives to Paraquat formulations.

The final Reregistration Eligibility Document (RED) for paraquat was issued in August 1997 (EPA, Reregistration Eligibility Document (RED) Paraquat Dichloride, EPA 738-F-96-018). The "Dear Registrant" letter was signed by Lois Rossi, Director of the Special Review and Reregistration Division. It contains this passage:

¹⁵ EPA resorted to formal notice and comment rulemaking with codifying its rules in 40 C.F.R. Part 159. The effective date of the final rule was August 1998.

¹⁶ SYNG-PQ-32525420

¹⁷ Due to a lack of staff and resources, EPA retained a third-party contractor, Clement & Associates, to conduct an assessment of Paraquat under the RPAR. Clement & Associates assigned Maurice Green, a former ICI employee, to complete the review on behalf of the EPA. Deposition Transcript of Philip Botham (September 17, 2024) at 117-130. There is no evidence that EPA was aware of the connection between Maurice Green and ICI during the review process. Id.

“Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 1, 1996...This RED takes into account, to the extent currently possible, the new safety standard set by the FQPA for establishing and reassessing tolerances...In making these early case-by-case decisions [re the impact of the FQPA], EPA does not intend to set broad precedents for application of the FQPA.”

C. Syngenta Failed to Report Critical Information to the EPA Under Section 6(a)(2)

Syngenta established policies and procedures for the handling of 6(a)(2) submissions to the EPA, including the creation of several committees responsible for considering whether information would need to be reported to the EPA under 6(a)(2).

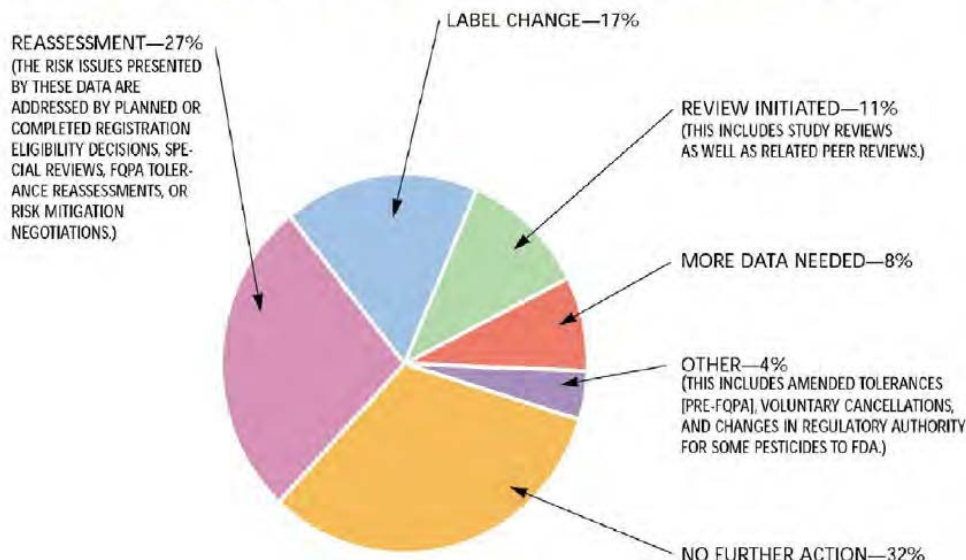
Syngenta recognized the importance of the 6(a)(2) data to the EPA. As its own Guidance Documents provides:

EPA believes that Section 6(a)(2) serves a special purpose by providing continuing assurance that the Agency's decision to register a pesticide remains correct and that the pesticide can be used without posing unreasonable adverse effects to human health or to the environment. Registrants, EPA states, may become aware of important information that might otherwise be unavailable to the Agency without the reporting requirements of Section 6(a)(2).

SYNG-PQ-05055006; Syngenta Crop Protection, Inc. Potentially Referable Findings Policy for Reporting Under TSCA Section 8(e) and FIFRA Section 6(a)(2). Syngenta further recognized in its own policy documents that “EPA’s policy in the rule is to require registrants to report information broadly without regard to its validity.” Id. Therefore, Syngenta recognized that the EPA relied on registrants to report important information relating to its products that would not otherwise be available to the Agency and, for that that reason, it should not take a restrictive approach to 6(a)(2) reporting.

Syngenta also knew that EPA would use the information submitted pursuant to 6(a)(2) for reassessment, labeling change reviews, or to request additional data to clarify the meaning of the submitted information. A slide in its 6(a)(2) training provided:

How EPA Uses Adverse Effects Information



SYNG-PQT-ATR-1135506 at 1135513.

Despite the recognition of the importance of 6(a)(2) data for the protection of human health, Syngenta failed to timely report critical factual information regarding Paraquat's unreasonable adverse effects to the EPA as required under FIFRA. The failure to submit the information detailed below prevents the EPA from conducting a thorough reassessment evaluation of Paraquat to assure that Paraquat can carry out its intended function without causing unreasonable adverse effects to human health.

1. Syngenta's Approach to 6(a)(2) Reporting was not in Accordance with EPA's Regulations or Guidance

Syngenta used the term "Potentially Referable Finding" (PRF) to encompass information that may be referable to the EPA under 6(a)(2) and other federal regulations. Syngenta defined PRF as "any information/finding that is new, real and adverse, arising from a study/publication or practical in-use experience, which may:

- Impact the conditions of registration or
- Affect the registerability of a new product or
- Be deemed by a regulatory authority to fall within the scope of their adverse data reporting requirements."¹⁸

¹⁸ SYNG-PQ-32449505

Syngenta created a two-tier approach to considering potentially referable findings. First, when there was information that was flagged internally as potentially requiring reporting to EPA or other regulatory agencies, Syngenta would refer the matter to a “Potentially Referrable Findings Committee” or PRF Committee.¹⁹ This was a global committee within Syngenta who would review the information and decide whether the information warranted a possible submission to regulatory agencies. The issue would then be sent, with the recommendation from the global PRF committee to a separate team in the United States responsible for deciding whether the information would need to be submitted to the EPA under the requirements of section 6(a)(2).²⁰

The committee in the United States was referred to as the “U.S. PRF Committee” or the “6(a)(2) Committee”. For the purposes of this report, I will refer to the committee in the United States as the “6(a)(2) Committee”. The 6(a)(2) Committee would then review the information to determine whether it would be submitted to the EPA. The individuals on the 6(a)(2) Committee would then vote on whether to submit the information to the EPA.²¹

Syngenta provided training to the members of the PRF committee regarding what information would need to be reported to the EPA.²² The training materials provide insight into Syngenta’s approach to 6(a)(2) reporting. The training PowerPoint notes that “If we have information that may change the risk assessment or require label changes, we have to provide it to regulatory authorities, so they can make a judgment, regardless of our own assessment.” Id. In practice, the focus of the PRF committees at Syngenta was determining whether the finding or information was “real, new and based on ‘sound science’”.²³

Syngenta, therefore, conditioned the reporting of information under 6(a)(2) in some measure to whether the company determined that the results were indicative of an adverse effect that could affect a risk assessment determination. Syngenta’s corporate representative, Dr. Philip Botham, confirmed this to be the case when he testified that a study finding paraquat in the brain of squirrel monkeys was not submitted to the EPA because the finding was not “new” and did not necessarily represent an adverse effect.²⁴ Dr. Botham, however, confirmed that a finding that Paraquat could get into the brains of nonhuman primates was indeed “a new finding” and was one that was not previously reported to the EPA.²⁵ Dr. Botham stated that Syngenta would not report a finding if the company determined that the effects were not “adverse”.²⁶ In the view of Syngenta, if the finding from a study, according to the company, would not permit the EPA to

¹⁹ Deposition of Monty Dixon (Dixon Dep.) at 186:1-187:3.

²⁰ Id.

²¹ Id. at 269-270.

²² SYNG-PQ-13129254

²³ SYNG-PQ-05411940

²⁴ Deposition Transcript of Philip Botham (June 17, 2020) at 827:5-19 and Deposition Transcript of Philip Botham (June 18, 2020) at 890:24-891:9.

²⁵ Deposition of Philip Botham (June 18, 2020) at 901:6-21

²⁶ Id. at 953:17-955:8.

make a different judgment about the safety of Paraquat it would not be reportable.²⁷ At the time, Syngenta knew that the EPA was considering the issue of Paraquat and neurotoxicity. The determination of whether Paraquat in the brains of non-human primates was “adverse” or “relevant” is a determination that should be made by the EPA, not Syngenta.

According to Syngenta, they are the determiners of what information is “relevant to the assessment of the risks or benefits” under 40 CFR 159.158. But EPA does not view 6(a)(2), its regulations, and/or guidance, as empowering the registrant absolute authority to determine what is relevant to EPA’s risk assessment. Doing so would render 6(a)(2) useless as the registrant would have unfettered discretion to ascertain what information was accurate and reliable for the purpose of EPA’s decision-making. This determination lies with the EPA.

The overly restrictive nature of Syngenta’s approach to 6(a)(2) reporting is evident when compared to other registrants. One example relates to a 6(a)(2) submission by the company BASF relating to Dicamba. On June 4, 2019, BASF submitted information to the EPA pursuant to 6(a)(2) notifying the Agency of the results of a Comet Assay on Dicamba.²⁸ Meanwhile, Syngenta’s PRF Committee considered the same exact study and determined that “the outcomes cannot be concluded to be positive and so are not referable.”²⁹ Accordingly, Syngenta did not submit the information to the EPA “based on the technical merits of the findings.” This example is highlighted to show the fundamental problem with Syngenta’s approach to 6(a)(2) reporting. Under its approach, Syngenta is the sole arbiter of whether the results were “real”, “positive”, “relevant” or “adverse.” In practice, this allowed Syngenta to cherry-pick what was reported to the EPA. It certainly was not consistent with the “broad” application envisioned by the EPA.

Syngenta apparently also implemented a blanket-rule that the company was not required to report any information concerning Paraquat formulations not registered in the United States. In other words, if they conducted a study on a Paraquat formulation registered in Europe, Asia, or Africa that differed even in the slightest degree from what was registered in the United States, the information from that study would not need to be reported regardless of the results. Such a position directly contradicts EPA’s guidance on the issue. EPA would require the results to be submitted (if they met one of the reporting criteria) unless an expert determined that the formulation differences make the “information **irrelevant** to the product registered in the United States.” PRN 98-3 at 13 (emphasis added). I’ve seen no evidence that such an expert opinion was ever obtained. Members of the PRF committee confirmed their understanding that any information from a non-US formulation does not need to be reported to the EPA.³⁰

By way of example, Monty Dixon, an employee in the regulatory department with no toxicology experience and by his own admission was not an expert in formulations, would cast a vote on whether to report information relating to non-US formulations.³¹ Mr. Dixon confirmed

²⁷ Id. at 979:6-21; Similarly, there are instances where new data obtained from third parties were not submitted to the EPA because Syngenta had concerns about the quality of the study. SYNG-PQ-05411940

²⁸ SYNG-PQ-31575241

²⁹ Id.

³⁰ Dixon Dep., Deposition of Timothy Pastoor at 281-310.

³¹ Dixon Dep. at 286:1-290:11.

that he would have made his vote without conducting a systemic evaluation of the differences between the US formulation and the formulation used in a study.³²

Another example of a fundamental flaw in Syngenta's approach to 6(a)(2) reporting was that Syngenta would not report information if it was in "the public sphere" regardless of where it could be found. Mr. Dixon testified that "if the information is known in the public sphere, whether it's literature, professional society meetings or other reputable sources, then it's not considered a new finding; therefore, it's not reportable."³³ EPA, however, is very specific on the types of publications and reports that would fall within the exception to reportability. As will be discussed below, the fact that information known to a registrant exists publicly somewhere in the world does not justify withholding the information from the EPA.

There is no indication that Syngenta ever reached out to the 6(a)(2) Officer at the EPA regarding questions about whether information should be submitted.³⁴ Instead, Syngenta relied on its own, restrictive, flawed interpretation of its obligations under 6(a)(2).

2. Factual Information that Syngenta Was Required to Report to the EPA

a. Exponent, Sensitivity Analyses of the Tanner et. al. Case-Control Study of Parkinson's Disease in the Agricultural Health Study; September 10, 2013³⁵

In 2011, a nested case-control study within the Agricultural Health Study (AHS) found a statistically significant positive association between Paraquat and Parkinson's Disease.³⁶ This study was known as the Farming and Movement Evaluation (FAME) study. Syngenta retained a consultant, Jack Mandel with Exponent, to publish a critique of the FAME study. The critique, funded by Syngenta, was published online in October 2011 in Regulatory Toxicology and Pharmacology.³⁷ The primary criticism of the FAME study outlined in the published article paid for by Syngenta was its failure to distinguish between incident and prevalent cases in evaluating etiology.

On December 11, 2011, the EPA opened the re-registration review docket for Paraquat.³⁸ The EPA notified registrants that it was considering the Tanner (2011) study stating "Concerning Parkinson's disease, authors reported elevated odds of PD among those who used paraquat in comparison to those who did not (OR 2.5 (95% CI 1.4, 4.7)). This result is supportive of the toxicological findings...concerning Parkinson's Disease, recent evaluations support observations in experimental toxicology."³⁹ Syngenta provided its 60-day comments to the EPA with

³² Id. at 290:19-292:11.

³³ Id. at 417:9-13

³⁴ Id. at 204:2-7; 270:10-271:10.

³⁵ SYNG-PQ-36932783

³⁶ Tanner, et. al, "Rotenone, paraquat, and Parkinson's disease" Environ Health Perspect. 2011 Jun; 119(6) 866-72

³⁷ Mandel, et. al, "Paraquat and Parkinson's Disease: an overview of the epidemiology and a review of two recent studies" Regul Toxicol Pharmacol. 2012 Mar; 62(2) 385-92

³⁸ EPA-HQ-OPP-2011-0855

³⁹ SYNG-PQ-22670768

statements critical of the Tanner (2011) study stating “Mandel et al. (2011) concluded that the FAME study by Tanner et al. is difficult to interpret due to important methodological issues, the most significant of which were: distinguishing between prevalence and incidence cases...”⁴⁰ On December 12, 2012, Syngenta directly emailed the Mandel (2011) critique of the FAME study to Hope Johnson, the EPA Product Manager for Paraquat.⁴¹ On February 21, 2013, Syngenta scientists met EPA scientists in person to present Syngenta’s views on epidemiology.⁴²

Exponent, on behalf of Syngenta, submitted a FOIA request to obtain study data related to FAME. An agreement was reached with the National Cancer Institute and Exponent received a de-identified dataset for the FAME study in April 2012.⁴³ Exponent performed a number of statistical analyses to assess the reliability and validity of the FAME study results, including separate analyses for incident and prevalent Parkinson’s Disease cases. After conducting the further analyses, Exponent concluded that despite some Parkinson’s Disease cases being misclassified as incident or prevalent, the estimated association between Paraquat and Parkinson’s disease “exhibited a degree of robustness” and their analyses restricted to incident PD cases did not reveal dramatic differences in the estimated association with Paraquat. This analysis was never published nor otherwise made publicly available. This analysis of the FAME study was never submitted to the EPA.

The EPA specifically referenced the prevalent versus incident criticism in its 2019 Epidemiology Report for its reregistration review⁴⁴:

“The results of AHS and FAME provide some evidence of a positive association between self-reported paraquat use and PD; however, the investigators reported somewhat conflicting findings for incident and prevalent PD cases. Specifically, the AHS Kamel et al. (2007) study reported a non-significant positive association with prevalent cases, but no association with incident cases. This is relevant to the evaluation of evidence because the prevalent cases are more likely to be subject to recall bias if self-reported pesticide use is not independent from their previous diagnosis of PD. For example, PD cases may be subject to recall bias if they recall past exposure more accurately or incorrectly self-report the use of paraquat relative to controls. The Tanner et al (2011) FAME study, nested within AHS, does not help clarify this issue because the investigators did not examine incident and prevalent PD cases separately in their statistical analysis. Moreover, FAME may also have introduced additional recall bias because a separate exposure assessment was conducted after cases and controls were enrolled in the study.”

The Report also states, “the FAME study combined incident and prevalent PD cases in its statistical analysis and thus does not provide additional clarification of the findings reported in Kamel et al (2007).”⁴⁵

⁴⁰ Syngenta, Paraquat Dichloride Registration Review 60 Day Comments, 2/21/2012

⁴¹ SYNG-PQ-00855357

⁴² SYNG-PQ-MDL-000003628

⁴³ SYNG-PQ-36932783

⁴⁴ EPA Paraquat Dichloride: Tier II Epidemiology Report (June 26, 2019).

⁴⁵ Id. at 35-36.

In December 2019, Syngenta retained its former employee Charles Breckenridge to draft an evaluation of EPA's Registration Review of Paraquat for the purpose of submitting the document to the EPA.⁴⁶ Dr. Breckenridge was responsible for retaining Dr. Mandel and was fully aware of the results of Exponent's Sensitivity Analysis report. Nonetheless, Dr. Breckenridge again criticized the FAME study for its failure to "examine incident and prevalent PD cases separately in their statistical analysis."⁴⁷ This failure, according to Dr. Breckenridge was "a major limitation that does not warrant the high-quality ranking given to the Tanner study by EPA."

Syngenta also submitted comments to EPA's draft risk assessment criticizing FAME on the basis that the study did not differentiate between incident and prevalent cases.⁴⁸ Syngenta argued that the FAME study did not deserve to be considered high quality because "an important limitation of the study is that the investigators did not differentiate between incident and prevalent cases in their statistical analysis" and "the pooling of incident and prevalent cases...is a major limitation that considerably negates the other aspects of its design."⁴⁹ These arguments were made despite having a report that, in some measure, contradicted these arguments.

Syngenta was required to submit the September 10, 2013 Exponent Report to the EPA under 6(a)(2) on multiple grounds to allow the EPA to determine the significance of the findings to its assessment of the risks and benefits of Paraquat:

1. The report includes information, conclusions and opinions relevant to the assessment of the risks or benefits of Paraquat from: (1) a consultant employed by the registrant; (2) asked to provide those opinions and conclusions by Syngenta; and (3) who would be considered a qualified expert. 40 C.F.R. 159.158.
2. The report includes information concerning a study that Syngenta's own consultant concludes could show that a correlation may exist between exposure to Paraquat and Parkinson's Disease. 40 C.F.R. 159.170.
3. The September 10, 2013 Exponent Report directly contradicts arguments Syngenta made to the EPA regarding the FAME study. This is the sort of information that is required to be reported to the EPA pursuant to 40 C.F.R. 159.195. Syngenta knew that EPA was undertaking a review of the scientific literature concerning Paraquat and Parkinson's Disease and the EPA considered the failure to distinguish incident and prevalent cases as a substantial, if not the most significant, flaw of the FAME study. Syngenta reasonably should have known that the EPA might have regarded the re-analysis of the FAME data, together with the other literature, as raising concerns about the appropriate terms and

⁴⁶ Deposition Transcript of Charles Breckenridge (Breckenridge Dep.) at 373-382

⁴⁷ SYNG-PQ-37233007

⁴⁸ Syngenta's 60-Day Comments in Response to the Publication of EPA's Draft Human Health and Ecological Risk Assessments for the Registration Review of Paraquat Dichloride; EPA-HQ-OPP-2011-0855; Case Number 0262 (December 16, 2019).

⁴⁹ Id. at 27, 29.

conditions of Paraquat's registration. Certainly, the information would invalidate, to some degree, the arguments previously made by Syngenta to the EPA.

Not only did Syngenta fail to report the results of the 2013 Exponent Report, but the company also continued to criticize the FAME study to the EPA knowing full well that the arguments were no longer valid. This is an obvious dereliction of Syngenta's obligations under 6(a)(2).

b. Studies Relating to the Penetration of Paraquat Formulations Through Protective Clothing Materials

Section 6(a)(2) required the submission of factual information from the following studies:

1. ICI Report CTL/P/1467: Ward, Scott, "Paraquat: Penetration Through Protective Clothing Materials From a Malaysian 'Gramoxone' Formulation (March 14, 1986)⁵⁰; and
2. ICI Report CTL/L/1680: Corrigan, Scott "Paraquat: Absorption Through Wellington and Trooper Boot from Gramoxone (November 30, 1987)⁵¹

In 1986 and 1987, Syngenta's predecessor ICI conducted two studies to provide information regarding the efficiency of various protective clothing materials against paraquat penetration. One study tested the penetration rate and breakthrough time of various types of Tyvek, Kimguard, Corovin and unfinished cotton. The other study tested the penetration of Paraquat through two types of boots. A Gramoxone formulation from Malaysia was used in each of the studies.

The Syngenta employees, experts in their respective fields, concluded the following from the results of the study on the penetration of the Gramoxone formulation through protective clothing:

These data would indicate that both polyethylene-coated and Saran-coated TYVEK will offer spray operators protection against both concentrate GRAMOXONE and the spray strength dilution.

From the results obtained, TYVEK, COROVIN and unfinished cotton cannot be recommended for protective clothing for use during the application of GRAMOXONE.

The study on the two boots resulted in the following conclusion:

⁵⁰ SYNG-PQ-30817606

⁵¹ SYNG-PQ-02776558

No paraquat was detected to have penetrated through the wellington boot material during 7 hours continuous contact.

However, paraquat penetrated the Trooper boot material within 0.25 hour. The subsequent steady state absorption rates were not proportional to the applied concentration. It is possible that the neat formulation altered the structure of the TROOPER boot material enhancing the rate of paraquat penetration.

The results of these studies suggest that the Paraquat labeling in the United States specifying the personal protective equipment to be worn by applicators may not be sufficient to adequately protect against unreasonable adverse effects. The results of these studies fall directly within the reporting requirements of 40 C.F.R. 159.195. If the results of these studies proved correct, the EPA would likely regard the information as raising concerns about the appropriate PPE labeling as use of Paraquat, in accordance with the label, may pose a greater risk than previously believed or reported to the EPA. 40 C.F.R. 159.195(a)(3).

Syngenta's corporate representative testified that the basis for not submitting these studies to the EPA was that they were done with a non-US formulation and "it's EPA and traditional practices within industry that if a formulation is not registered in the – at the EPA, we would not typically send information for them to consider."⁵² This is not correct. EPA's practices regarding other formulations is set forth in PRN 98-3 and states that the information is reportable unless an expert concludes that differences between the formulation of product involved in the foreign information and product registered in the United States make the information irrelevant to the product registered in the United States.

It is my understanding that there is no evidence that any expert ever concluded that the Malaysian Gramoxone formulation made the findings irrelevant to the formulations in the United States.⁵³ It would be difficult to imagine how Syngenta could make a finding of irrelevance considering the company has relied on biomonitoring studies conducted in Malaysia, with Malaysian Gramoxone formulations, in submissions to the EPA. If the foreign formulations are relevant to studies used to support registration, they cannot then be considered irrelevant when it suits Syngenta.

For example, during an August 30, 1994 meeting between Syngenta and the EPA, Syngenta presented data from biomonitoring studies in Malaysia and Sri Lanka to advocate for a reduction in the PPE requirements for Paraquat applicator by removing requirements for a

⁵² Dixon Dep. at 386:22-387:10.

⁵³ I requested information relating to meeting minutes, correspondence or other documents relating to the submission of these studies to the EPA. I have been informed that no such evidence exists. It is also my understanding that Syngenta cannot currently provide details of the Malaysian formulation that was used in these two studies.

“second layer of clothing and respirator for applicators from the WPS paraquat label.”⁵⁴ Syngenta did not present data from its study on Gramoxone penetration through clothing and boots. Based on [these](#) data, the EPA agreed that the label need only advise users to wear “long-sleeved shirt, long pants, waterproof gloves and shoes plus socks” when spraying.⁵⁵

c. Factual Information Relating to the Increased Absorption of Paraquat with Surfactants

The labeling for all Paraquat formulations registered in the United States has always required applicators to mix Paraquat with a non-ionic surfactant. A review of internal documents demonstrates that Syngenta and Chevron have known since at least the early 1970s that Paraquat with the addition of a surfactant increases absorption and toxicity versus Paraquat alone. In fact, Syngenta and Chevron conducted studies with Paraquat and a surfactant for the purpose of registering a formulation in the United States with a built-in surfactant (wetter). These efforts were abandoned upon learning that the surfactant increased absorption and toxicity.⁵⁶

The fact that nonionic surfactants increase the absorption and toxicity of Paraquat is not disputed within Syngenta. Multiple toxicologists and product safety specialists within Syngenta have affirmed this to be the case.⁵⁷ Yet, based on my review of the available documents, it does not appear that Syngenta has ever informed the EPA of this fact.⁵⁸ The factual information from the studies combining Paraquat with a surfactant is relevant to the EPA’s assessment of Paraquat and human health.

In my opinion, Syngenta should have submitted information from the following studies to the EPA under 6(a)(2)⁵⁹.

- Report No. CTL/R/373 – The Effect of Surfactants on the Toxicity and Intestinal Absorption of Paraquat (January 1976)⁶⁰
- Report No. CTL/L/1428 – Preeglox-L: Pharmacokinetic Study in the Rat (September 30, 1986)⁶¹
- Paraquat Oral Studies in Dogs Summary Report (February 25, 1988)⁶²

⁵⁴ SYNG-PQT-ATR-05665695

⁵⁵ SYNG-PQ-01823567

⁵⁶ CUSA-00174168

⁵⁷ Deposition of Philip Botham (Sept. 17, 2024) at 141-143; Deposition of Lewis Smith at 71:8-15.

⁵⁸ Dixon Dep. 281:6-13

⁵⁹ These three studies represent information that should, at the very least, have been submitted to the EPA to inform them of the increased toxicity with surfactants. The reporting, however, could have come in many forms considering the recognition and acceptance by the scientists in Chevron and Syngenta that surfactants increased the toxicity and absorption. See SYNG-PQT-ATR-15058108; SYNG-PQ-02452243; SYNG-PQ-0247001; SYNG-PQ-13113911.

⁶⁰ CUSA000193960

⁶¹ SYNG_P-01969605

⁶² SYNG-PQ-03713245

In 2017, a Citizen Petition was filed requesting EPA to amend its regulations to require testing for whole pesticide formulations and tank mixes to assess any differences in toxicological effects of inert ingredients or combinations of ingredients.⁶³ The EPA denied the Petition in 2023 but the findings highlight the importance of 6(a)(2) reporting, something the EPA reiterated to registrants in its response to the Citizen Petition itself. It also highlights why 6(a)(2) reporting of **the** increased toxicity of paraquat and surfactants was necessary.

The EPA highlighted that it currently requires toxicity data on formulated, end-use products, including acute toxicity data known as the “six-pack.” The EPA can then compare the toxicity results from the end-use products to those of the active ingredient and determine whether additional tests are necessary. EPA refers to its requirement for additional tests concerning glyphosate and the surfactant POEA after reports suggested that the surfactant increased toxicity. It also pointed to examples where it requested specific toxicity testing of tank mixes upon concern of additive toxic effects. EPA therefore acknowledges that there remains uncertainty but there are mechanisms in place to alert the Agency of adverse effects that may occur, i.e. 6(a)(2) reporting.⁶⁴

Unlike the requirement to have some toxicity testing of formulated, end-use products, there is no requirement for the toxicity testing of tank mixes. Therefore, by not including the surfactant in the formulation, and requiring applicators to mix the surfactants with Paraquat in the tank, Syngenta and Chevron were able to avoid conducting toxicity testing for the purpose of registration. But this does not permit Syngenta and Chevron to shield these data from the EPA under 6(a)(2) knowing full well that applicators will be exposed to the Paraquat/surfactant mixture.

Syngenta and Chevron not only failed to notify the EPA of increased toxicity with the surfactant but then used the fact that their formulation in the United States did not contain a surfactant to justify not submitting results and information from studies using formulations containing surfactants on the basis that it was not a US formulation. In my opinion, this tactic is in violation of the rules and guidance underlying 6(a)(2).

There are representative examples of Syngenta’s manipulation of formulations to avoid the submission of data relating to increased toxicity of Paraquat with surfactants.

- Syngenta submitted a 6(a)(2) report concerning an acute oral study in dogs for registering a Paraquat formulation, Gramoxone Inteon, in the United States. In that study, one of four dogs died after administration at dose level. Syngenta, however, conducted the same exact study with a different formulation (Korean formulation containing surfactant) for the purpose of introducing new formulations in the United States. In that study, three of the four dogs died at an equivalent dose level. This study was not reported to the EPA on the basis that it was not a formulation registered in the United States. Syngenta stated in correspondence discussing the reportability of the findings that the only difference was a trace of surfactant in the Korean formulation; the formulation that was not reported.

⁶³ <https://aglaw.psu.edu/wp-content/uploads/2023/10/3-EPA-Petition-Denial-CFS-9.28.23.pdf>

⁶⁴ Id.

- Syngenta conducted an inhalation study aimed at exposing rats to spray strength paraquat under conditions simulating potential operator exposure. A non-ionic surfactant was mixed with the Paraquat as “this may be included in tank mixes.”⁶⁵ One animal died at a concentration lower than the Medial Lethal Concentration (MLC) which was deemed unexpected. The PRF Committee deemed the death at a very low concentration as treatment related, and thus it was a new finding to be reported. The information was not reported to the EPA, however, under 6(a)(2). The purported basis was that it was not reportable under 40 CFR 159.165(a)(2). This rationale ignores the importance of the surfactant to the treatment-related death, as determined by the Syngenta scientists responsible for the study. The importance of the finding was the increased toxicity with a surfactant, not the MLC. Syngenta did later repeat the study without a surfactant and no deaths were reported in the lowest concentration.⁶⁶ This study was submitted to the EPA for the purpose of establishing an MLC of Paraquat.⁶⁷ No reference was made to the earlier study with the surfactant.

There is no way for EPA to know that the tank mix of Paraquat with a nonionic surfactant is potentially more toxic to humans and the environment than Paraquat alone. EPA relies on the registrant to submit these crucial data when it is available. Syngenta has failed to meet its obligations relating to the submission of factual information concerning surfactants mixed with its’ registered product.

d. DEFRA: An Examination and Analysis of the Role of Paraquat and Maneb in Induced Neurodegeneration of the Substantia Nigra at Representative Human Exposure Doses (November 2012)

In May 2010, Syngenta met with the EPA to provide an update on their current study program for Paraquat and EPA’s human health risk assessment.⁶⁸ At the meeting, Syngenta referenced a UK DEFRA study in support of applicators having very low exposure to Paraquat, including the fact that human brain exposures were 6 to 9 orders of magnitude lower than mouse brain exposures.⁶⁹ Following the meeting, EPA requested a copy of the poster from the DEFRA presentation.⁷⁰

In November 2012, Syngenta received a copy of the final DEFRA report. The study was the first to test effects in mice at 16 months of age and there was a decrease in TH+ neurons in the substantia nigra in mid and high dose males. Additionally, there were findings relating to intranasal transport of Paraquat to the brain. The study found that intranasal dosing of Paraquat resulted in fast and extensive circulation of paraquat in the brain tissue and the amount of paraquat detected in the brain after intranasal exposure “was ten-fold higher than the model predicted based on systemic flow.” The authors concluded that the observations from the study

⁶⁵ SYNG-PQ-03691234

⁶⁶ SYNG-PQ-01423242

⁶⁷ Id.

⁶⁸ SYNG-PQT-ATR-04955158

⁶⁹ Id.

⁷⁰ Dixon Dep. at 410:6-9

“has implications for exposure of humans to any neuroactive or neurotoxic substances that deposit in the nasal cavity during inhalation, including but not limited to pesticides.” The intranasal findings were not included in the 2008 DEFRA poster presented to the EPA during the 2010 meeting.

I understand that this was the first intranasal study finding that Paraquat could be delivered directly to the brain from the nasal cavity. Syngenta did not report these findings from the final DEFRA study to the EPA. Syngenta’s corporate representative testified that the reason it was not submitted to the EPA was that “it was a non-Syngenta study” and it was publicly available.⁷¹ But it was not actually publicly available according to another of Syngenta’s representatives – Philip Botham – who testified:

this is the interesting thing here because the DEFRA study, you might argue, was never really made fully available. It was never properly externally published, so I got hold of a report because of the links that I was just described. There were two presentations made, posters. That's all that ever appeared from that project.⁷²

The report was never published in a “scientific article or publication which has been abstracted in a recognized database of scientific and medical literature, such as Medline, ENBASE, Toxline or Index Medicus, if the abstract in question clearly identified the active ingredient or the registered pesticide(s) to which the information pertains.” 40 CFR 159.158(c)(3). The fact that it may appear on a website or through some other online labyrinthine does not put it under the “Publications” exception for 6(a)(2) reporting.

The fact that it was a “non-Syngenta study” is also irrelevant to reporting under 6(a)(2). Syngenta received the information, and it is the registrant who has the duty to report, not DEFRA or the authors of the study.

There is evidence that the EPA was concerned about intranasal exposure to Paraquat for decades. In 2000, EPA issued a Memorandum that stated:

Both the Wesseling et al. (1997) and the NIOSH (1996) reports suggest that large droplets that could get into the nasal mucosa may pose a serious hazard. These droplets may be swallowed or absorbed across the nasal membrane. This latter scenario is especially likely if there are nosebleeds which are known to occur through prolonged exposure to spray droplets of paraquat (Howard 1979, Castro-Gutierrez et al 1997). Nasal exposure to non-respirable droplets of paraquat could cause serious and perhaps fatal poisoning by paraquat.⁷³

EPA’s concerns with intranasal exposure combined with EPA’s review of paraquat’s neurotoxicity and its stated interest in DEFRA, should have made it clear to Syngenta that it was required to submit the findings of the DEFRA study under 6(a)(2).

⁷¹ Dixon Dep. 416:15-22.

⁷² Deposition Transcript of Philip Botham (Sept. 17, 2024) at 256:8-14.

⁷³ Blondell, “Memorandum: Review of Paraquat Incident Reports Involving Inhalation, U.S. Environmental Protection Agency (August 10, 2000)(SYNG-PQ-31436268)

e. Reports from the Brazilian Regulatory Agency

Syngenta met with the EPA in February 2017 to provide an update on its research program and discuss the ongoing reregistration review by the EPA.⁷⁴ Syngenta notified EPA that Australia and Brazil were also considering the registration of Paraquat. Syngenta informed EPA that Australia had completed their review and provided a link and instructions on how EPA could locate Australia's three review documents including their detailed neurotoxicity review.⁷⁵ As for Brazil, Syngenta noted only that the Brazilian equivalent to a Ministry of Health (ANVISA) was conducting a review with an expected completion date of 2017.⁷⁶ At the time of the meeting, however, ANVISA had already issued three separate reports on Paraquat, including detailed neurotoxicity findings:

1. ANVISA Technical Reassessment Opinion No. 01 of 2015/GGTOX/ANVISA⁷⁷
2. ANVISA Technical Reassessment Opinion No. 08/GGTOX/ANVISA(June 13, 2016)⁷⁸
3. ANVISA Technical Opinion No. 13/CREAV/GEPOS/GGTOX/ANVISA(Jan. 5, 2017)⁷⁹

Monty Dixon confirmed that no other information relating to ANVISA's evaluation was presented to EPA during this meeting,⁸⁰ and Syngenta confirmed that the ANVISA reports were never submitted to the EPA.⁸¹

Syngenta claims that the reports did not need to be reported because they would have been published and in the public domain⁸² and, more generally, they were not reportable as they were a technical assessment from Brazil.⁸³

Again, Syngenta is mistaken in their assertion that any document in the public domain does not need to be submitted under 6(a)(2). The only public information that does not need to be reported is specifically set forth in 40 CFR 159.158(b)(3). The ANVISA reports do not fall within this exception.

In my opinion, the scientific findings detailed in the ANVISA reports constitute conclusions and opinions from qualified experts requiring their submission under 40 CFR 159.158. It is true that the review was undertaken on behalf of a regulatory agency, but the scientific review and ultimate findings were the result of a thorough literature review by qualified experts in their field. It is possible that EPA may have been independently aware of ANVISA's findings, but a registrant cannot and should not assume this to be the case. For

⁷⁴ Powerpoint Syngenta's Paraquat Research Program Update: US EPA Meeting Feb. 6, 2017

⁷⁵ Id.

⁷⁶ Id.

⁷⁷ SYNG-PQ-01214493

⁷⁸ SYNG-PQ-06641238

⁷⁹ SYNG-PQ-22721559

⁸⁰ Dixon Dep. at 301-306.

⁸¹ Exhibit 37 to Dixon Dep.; Dixon Dep. at 394:3-395:1; 447:15-17.

⁸² Dixon Dep. at 394:397:20

⁸³ Exhibit 37 to Deposition of Monty Dixon

example, it seems clear that EPA was not aware of the ANVISA reports at the February 2017 meeting with Syngenta.

f. Biomonitoring Studies Showing Applicators with Exposures Greatly Exceeding Acceptable Levels

In 2006-2007, Syngenta conducted a series of habitual biological monitoring studies in France and Martinique. The studies were conducted with a Paraquat formulation known as R-BIX (19409AL). In an internal December 2009 review of operator exposure studies, Syngenta referred to the French and Martinique studies as “the most modern, guidance-compliant studies available and are the ones of choice for assessment of absorbed dose for risk assessment purposes under the specific conditions of habitual use.”⁸⁴ In both studies, applicators had measured exposures (in urine) to Paraquat that greatly exceeded the Acceptable Operator Exposure Level (AOEL).⁸⁵ The AOEL is defined as the maximum amount of active substance to which the operator may be exposed without any adverse health effect.

Syngenta’s PRF Committee decided that the results should be referred to regulatory agencies due to the exceedance of the EU regulatory operator exposure level (AOEL).⁸⁶ This was the proper decision considering 40 CFR 159.170 provides that:

Information must also be submitted which concerns exposure monitoring studies that indicate higher levels of risk or exposure than would be expected based on previously available reports, data, or exposure estimates. Such information must be submitted regardless of whether the registrant considers any observed correlation or association to be significant.

The significance of the two studies was the fact that applicators had higher levels of exposure than would have been expected. Syngenta specifically noted in the PRF Form, as it related to FIFRA 6(a)(2), that “the referral is based not on any observed adverse health effect, but the exceedance of an EU regulatory operator exposure level.”⁸⁷ But Syngenta’s reporting under 6(a)(2) does not provide the EPA with meaningful results from the biomonitoring studies. Rather, Syngenta submitted the information in a way that the EPA could not possibly ascertain any significance from the studies.

Syngenta elected to submit the results of the biomonitoring studies as “adverse effect incident reports” under 40 CFR 159.184. More specifically, Syngenta submitted the findings as aggregate reports where the registrant has been informed that the applicators in those studies “may suffer a delayed or chronic adverse effect in the future.” 40 CFR 159.184(a)(2); 40 CFR 159.184(c)(5)(E).⁸⁸ In such a reporting, the EPA is not provided with any specifics, including the fact that the incidents were from biomonitoring studies or that individuals within these studies

⁸⁴ SYNG-PQ-01698767

⁸⁵ SYNG-PQ-06721544; SYNG-PQ-21846928; Exhibit 17 to Deposition of Monty Dixon SYNG-PQ-01408983

⁸⁶ SYNG-PQ--04274074

⁸⁷ SYNG-PQ-01408984

⁸⁸ SYNG-PQ-02415576_R2 and SYNG-PQ-02415384_R2.

had higher levels of exposure than would be expected and previously reported to the EPA. In both cases, the entirety of the information received by the EPA consisted of the following:

EPA Reg. No.	Active Ingredient	Trade Name	Total Incidents	H-D	H-E	D-A	D-B	D-C, D, E	W-B	ON T	S-B	S-C	G-B	G-C	P-A	P-B	PD-B	PD-C
	Paraquat Dichloride	Paraquat (non-specific)	1		1													

The reporting of the results from the biomonitoring studies as an H-E aggregate report does not satisfy Syngenta's obligation to submit "factual information regarding unreasonable adverse effects." Syngenta was required to provide the EPA with information relating to the nature of the study and the fact that certain applicators exceeded the expected exposure level.

Syngenta's was initially going to properly report the findings from these studies to the EPA but elected to proceed as an H-E aggregate report for purely strategic reasons. The internal discussion within the 6(a)(2) Committee included the following:

"I think we should re-evaluate our decision to communicate directly with the 6(a)(2) desk regarding the paraquat study we discussed today. As we are all aware of the sensitivities surrounding paraquat, we need to be particularly careful regarding actions we take with respect to this AI."⁸⁹

As detailed further below, a registrant's submissions to the EPA should be dictated by EPA's specific rules and regulations, the "sensitivities **surrounding a product**" and a desire to protect the product from regulatory restrictions should not factor into the decision-making process.

3. Syngenta Should Have Submitted Factual Information to EPA Upon Their Specific Request for Information in 2021 and 2023

In May 2021, EPA notified Syngenta that a law firm had contacted the Agency and referenced some documents the EPA has never seen relevant to Parkinson's disease.⁹⁰ In that correspondence, the product manager with the EPA specifically said "I just wanted to check in with you to see if there's anything we don't already have and you think we should take a look at...we want to make sure we're not missing anything as we get ready to complete the Paraquat ID"⁹¹ Syngenta responded that it had already submitted all relevant Paraquat studies, reports and/or information to the EPA.⁹²

In August 2023, Earthjustice and the Michael J. Fox Foundation send correspondence to the EPA suggesting that there may be information regarding the risks of Paraquat that the registrants had not previously submitted to the EPA.⁹³ Syngenta responded to Earthjustice's

⁸⁹ SYNG-PQ-01411287

⁹⁰ Dixon Dep. 355:20-366:14; Exhibit 35 to Dixon Dep.

⁹¹ Id.

⁹² Dixon Dep. 358:5-20.

⁹³ Exhibits 15 and 18 to the Deposition Transcript of John Abbott

letter on December 1, 2023 and told the EPA that it has submitted to EPA any and all information required under 6(a)(2) and that “EPA has already evaluated all relevant information related to paraquat.”⁹⁴

On December 8, 2023, EPA sent a letter to all Paraquat Registrants reminding them of their obligations under 6(a)(2), directing them to PRN 98-3 and requesting certification in writing that each registrant has fully complied with their obligations.⁹⁵ On December 19, 2023, Syngenta again confirmed that it was in “full compliance with its obligations to report pertinent information to the Agency under FIFRA section 6(a)(2) with respect to paraquat.”⁹⁶

The factual information identified in Section III(C)(3) above should have been submitted to the EPA upon receipt, however, when EPA specifically reached out for the purpose of requesting whether any additional information existed, Syngenta had a duty to either submit the information at that time or inquire of the EPA whether they believed the information was relevant for their assessment of Paraquat. Syngenta did neither.

4. Syngenta’s Approach to 6(a)(2) Reporting

In my opinion, Syngenta made strategic decisions regarding whether to submit information to the EPA pursuant to 6(a)(2) to prevent further product restrictions on Paraquat rather than on a consistent application of EPA’s rules and regulations. This opinion is based on the totality of my review, including my opinions set forth in this report, but there are other specific incidents that should be highlighted.

First, Syngenta developed a research strategy geared towards avoiding the creation of 6(a)(2) reports. This strategy is included in Syngenta’s own policy documents which state that “The potential for generating adverse effects should be considered when studies are being designed...Studies should be designed where possible using a strain, sex, dose, level, etc. for which there are data, so that PRFs are not generated needlessly.”⁹⁷ Syngenta explicitly took steps to avoid the risk of PRF reporting.⁹⁸ This policy/research strategy puts into context precisely why Syngenta’s restrictive interpretation of 6(a)(2) would render EPA’s regulations and guidance meaningless. Syngenta would simply design studies in a manner, or with a formulation, that (in its view) would not result in a 6(a)(2) submission. If the results were positive for Syngenta and paraquat, the results would be submitted to the EPA voluntarily. If the results were negative, Syngenta would not need to submit the information under its application of 6(a)(2) and the EPA would never know about the negative findings. This runs counter to the entire purpose of 6(a)(2).

Second, Syngenta’s handling of the submission of litigation reports involving Paraquat and Parkinson’s Disease also supports a conclusion that its submissions to EPA are not

⁹⁴ Exhibit 19 to the Deposition Transcript of John Abbott

⁹⁵ Exhibit 20 to the Deposition Transcript of John Abbott

⁹⁶ SYNG-PQ-PA-00032379; Exhibit 21 to the Deposition Transcript of John Abbott

⁹⁷ SYNG-PQ-02446865.

⁹⁸ Exhibit 74 and 75 to Deposition Transcript of Philip Botham (Sept. 18, 2024); SYNG-PQ-11382182; SYNG-PQ-01982312; SYNG-PQ-01971065

consistent and are subject to strategic decision-making. In November 2022 and November 2023, Syngenta submitted certain expert opinions/reports to EPA under 6(a)(2).⁹⁹ For experts that opined that Paraquat was associated with Parkinson's Disease, Syngenta submitted almost fully redacted expert reports or deposition transcripts.¹⁰⁰ In one instance, Syngenta submitted more than 500 completely redacted pages while leaving 1 ½ pages identifying the opinion/conclusion of the expert witness.¹⁰¹ Syngenta did not identify the name or credentials of the experts providing the opinions. There was one exception. Syngenta also submitted the deposition transcript of one of Chevron's expert witnesses who supported Syngenta's position that there was no association between Paraquat and Parkinson's Disease. For Chevron's expert, Syngenta submitted the entire deposition transcript, without redactions, identifying the expert, the expert's credentials, the opinions, and the full factual basis for the opinions.¹⁰² There would be no reason to handle the reports of plaintiffs and Chevron's experts differently other than to try to improperly influence the EPA in its assessment of Paraquat.

IV. SUMMARY OF OPINIONS

The 6(a)(2) provision in FIFRA essentially completes the registration circle of pesticide regulation. The process is a partnership between industry and government and relies on mutual communications, continuous dialogue and trust that both entities participate in the process in good faith throughout. A draft label is submitted with the initial package of data and the label evolves as the data are reviewed and assessed. When risks are identified, the label must be modified to mitigate the risks as much as possible. When a pesticide registration is accepted the Agency presumes that if all accepted directions for use are followed, there is a reasonable certainty that there will be no unreasonable adverse effects on human health or the environment.¹⁰³

Congress mandated in FIFRA that, should an unanticipated adverse effect occur, the registrant must report it to the EPA. As described above, over time the reporting mandate was extended to all manner of reports, studies, and publications of which the registrant becomes aware in addition to actual incidents. The reporting provides an opportunity for the Agency to validate its own processes and conclusions for accuracy. Labels may be modified as warranted to reflect the new information. The government is as transparent as possible given confidentiality obligations and, in turn, the registrants provide the data and the mandated reports in good faith. To work as intended, the process requires the manifestation of old-fashioned values such as adherence to the truth, high ethical standards, and honor.

Syngenta knew the 6(a)(2) requirements as illustrated in the PowerPoint training referenced above – POTENTIALLY REFERABLE FINDINGS. Having established the intent of 6(a)(2) requirements and informing staff how to comply, they set about systematically dismantling what they created until they had a scheme firmly in place to intentionally deceive and obfuscate the truth and obstruct the legitimate registration process unless a report or submission benefited the

⁹⁹ SYNG-PQ-PA-00029175; Exhibit 32 to Abbott Dep.

¹⁰⁰ Exhibits 33-41 of Abbott Dep.

¹⁰¹ SYNG-PQ-PA-00029176; Exhibit 33 of Abbott Dep.

¹⁰² SYNG-PQ-PA-00030563; Exhibit 44 to Abbott Dep.

¹⁰³ This is a very simplified description of the registration process.

continued distribution and sale of Paraquat and minimized label requirements or concerns about its safety regardless of the potential increased risk of harm to the health of applicators.

Chevron and Syngenta should have submitted to the EPA under the provisions of 6(a)(2) factual information known to the companies that the addition of surfactants increased the absorption and toxicity of paraquat. Additionally, other examples where failed to submit information to the EPA under 6(a)(2) include:

- a. Exponent, Sensitivity Analyses of the Tanner et. al. Case-Control Study of Parkinson's Disease in the Agricultural Health Study; September 10, 2013
- b. Studies Relating to the Penetration of Paraquat Formulations Through Protective Clothing Materials
- c. DEFRA: An Examination and Analysis of the Role of Paraquat and Maneb in Induced Neurodegeneration of the Substantia Nigra at Representative Human Exposure Doses (November 2012)
- d. Reports from the Brazilian Regulatory Agency
- e. Biomonitoring Studies Showing Applicators with Exposures Greatly Exceeding Acceptable Levels

These studies and reports that were not submitted to the EPA contain significant factual information relating to paraquat. The registrants failure to submit this information, as required under 6(a)(2), was not the result of an oversight or error of judgement. The decisions were debated and reasoned entirely for the benefit of the registrants and not to comply with either the spirit or the letter of the requirements of 6(a)(2).

As described in III(C)(3), when Syngenta was given an opportunity to correct the record during EPA's reassessment of paraquat. Unfortunately, when they had the chance to have EPA clarify whether the aforementioned studies should have been submitted, Syngenta falsely claimed that all relevant paraquat studies, reports and/or information had already been reported.

Lastly, as if to put an exclamation mark on their attitude toward 6(a)(2) requirements, III(C)(4) above describes how in the 6(a)(2) submission of documents from litigation involving Paraquat and Parkinson's Disease, it appears that Syngenta systematically and severely redacted portions of documents which could be perceived to be negative to Syngenta's position, while a positive document was submitted in its entirety without a single redaction. In my opinion, this demonstrates that Syngenta's decisions relating to 6(a)(2) reporting were not based on a consistent application of the rules and regulations but rather on what would best benefit the company.

As a result of the registrants' failure to submit critical factual information to the EPA, the EPA cannot accurately evaluate paraquat, conduct a proper risk/benefit analyses or assure pesticide users that their health is adequately protected. Such an evaluation aimed at protecting

the American people from unreasonable adverse effects requires that all the players in the pesticide registration process are playing by the rules. In my opinion, based on my review of the documents, the EPA is working with incomplete data at best. What makes these actions particularly grievous is that Paraquat is a restricted use pesticide and its potential for adverse effects on human health has long been a concern of the Agency. Due to the registrants' failure to properly submit information under 6(a)(2), the EPA has not had an opportunity to consider the factual information contained in the unreported studies and reports in their health and safety deliberations and label development.

A handwritten signature in black ink that reads "Carlton R. Layne". The signature is written in a cursive, flowing style.

Carlton R. Layne

Dated: October 4, 2024

APPENDIX A

Expert Report of Carlton Layne

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Carlton R. Layne

Education

1968, Clarion State University, Clarion, Pennsylvania
BA, Biology

1982, Rollins College, Winter Park, Florida
MS, Criminal Justice

Professional experience

Since July 2004, **Executive Director of the Aquatic Ecosystem Restoration Foundation**, www.aquatics.org

Responsible for conducting and coordinating the activities of the Foundation

- Coordination and monitoring of Foundation-sponsored research
- Conducting symposia, seminars, etc. regarding the science of aquatic plant management and pesticide use and regulation
- Liaising with regulatory agencies and universities
- Conducting education & outreach and making speeches & presentations at association, society, and public meetings

Since January 2003, **Private consultant**

- Expert witness in the regulation of pesticides & toxic substances
- Speaker
- Training Specialist
- Compliance audits and investigations
- Case review, analysis and resolution with state and federal enforcement entities
- Enforcement program reviews and the development and presentation of individualized training

1999-2003, U.S. Environmental Protection Agency, Atlanta, Georgia

National Pesticides Expert/Life Scientist

- Resource and advisor to EPA Region 4 and Headquarters management on issues regarding pesticides.
- Responsible for conducting Federal, State and Tribal Inspector training on a national level.
- Coordinated complex pesticides investigations and served as Chief Investigator for the Region 4 Pesticides program.
- Provided expert witness testimony for EPA and other federal agencies in litigation involving the manufacture, regulation and use of pesticides.

1990-1999, U.S. Environmental Protection Agency, Atlanta, Georgia **Chief,
Pesticides Section, Pesticides & Toxic Substances Branch**

- Responsible for Implementing the provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) including the Certification and Training of Pesticide Applicators, Worker Protection, Endangered Species Protection, Groundwater Protection, Enforcement, Education, Outreach, Compliance Assistance and Pesticide Stewardship.
- Coordinated pesticide-related activities between the EPA and the eight southeastern states.
- Conducted law enforcement investigations as warranted;
- Managed a staff of twenty-four investigators, scientists, professionals and staff assistants.

1975-1990, U.S. Environmental Protection Agency, Lakeland, Florida
Consumer Safety Officer

- Conducted administrative, inspections and civil/criminal investigations related to the enforcement and implementation of FIFRA and the Toxic Substances Control Act.
- Served as the Regional Inspector Training Officer, Project Officer for Florida, Mississippi, North Carolina and Tennessee, and assisted states in case development and prosecutions.
- Served on numerous national work groups and task forces related to pesticide regulation.

1973-1975, U.S. Environmental Protection Agency, Atlanta, Georgia
Pesticides Program State Liaison Officer

- Worked with state lead agencies responsible for pesticide registration and regulation in the development and implementation of legislation and regulations.
- Provided assistance to the states in Region 4 the development of State Plans for the Certification of Applicators, the training and certification of pesticide applicators and the establishment of national standards

1968-1973, U.S. Department of Agriculture, Agricultural Marketing Service, Processed Products Division, Winter Haven, Florida, Camilla, Georgia, and other temporary assignments in numerous locations
Agricultural Commodity Inspector

- Conducted plant inspections and operated laboratories responsible for certifying processed agricultural commodities and assigning U.S. Food Grades.
- Operated USDA aflatoxin analytical laboratories.

**Specialized Training
and Responsibilities**

Past President, Vice President, Treasurer and Director of the Florida Aquatic Plant Management Society

Past Director, Vice President, and President of the Aquatic Plant Management Society

When employed by the EPA, was credentialed to conduct Pesticide Registration Data Audits and Good Laboratory Practice Inspections and investigations which included over 400 hours of specialized training regarding pesticide toxicology, human health and ecological effects, environmental fate and pesticide chemistry.

FBI Criminal Investigation Course for EPA Investigators

Basic Criminal Investigations Course for Environmental Crimes, Federal Law Enforcement Training Center

White Collar Crimes, Investigations and Audits, Federal Law Enforcement Training Center

Co-authored the EPA Pesticides Inspector's Manual and the EPA Project Officer's Manual

Served as guest faculty at the Federal Law Enforcement Training Center, Glynco, GA

Served on the faculty of the National Enforcement Training Institute, Washington, D.C. and Denver, CO

Serves on the faculty of the annual Dodd Short Course, Florida Mosquito Control Association and the University of Florida Aquatic Short Course.

Past member of the faculties of the Pesticide Regulatory and Enforcement Program for state regulatory officials and the Pesticide Inspector Regulatory Training Program for state inspectors.

Awards

Numerous Special Act and Sustained Superior Performance Awards and Eight EPA Bronze Medals for Commendable Service and Special Acts

EPA Silver Medal for Superior Service for assisting the Florida State Attorney in a complex investigation in Miami, FL

EPA Gold Medal for Outstanding Service in the Methyl Parathion Investigations in Mississippi and Tennessee

Meritorious Service Award, Florida Mosquito Control Association, 2004

President's Award, MidSouth Aquatic Plant Managent Society, 2010

President's Award, Northeast Aquatic Plant Management Society, 2012

Honorary Lifetime Membership, Florida Aquatic Plant Management Society, 2012

Honorary Lifetime Membership, MidSouth Aquatic Plant Management Society, 2018

Florida Lake Management Society Scott Drive Award, 2018

Florida Aquatic Plant Management Society President's Award 2021

Midwest Aquatic Plant Management Society Distinguished Service Award, 2022

Special Skills

Extensive public speaking experience, especially in regard to pesticides and pesticide regulation and enforcement. Receives frequent invitations to serve as keynote speaker. Regularly makes presentations at universities, professional societies, and association meetings and conventions, and industry and trade association meetings. Details and references can be provided on request. Experience also includes some motivational presentations and entertaining after-dinner speeches in fora related to pesticides and environmental chemical management.

Has participated in various capacities in meetings, work groups and committees of the American Association of Pesticide Control Officials, the State FIFRA Issues Research and Evaluation Group, and the Association of Structural Pest Control Regulatory Officials. As a result of participation in the activities of these organizations and the nationwide presentation of training programs is recognized by states, tribes and EPA Regions throughout the country as an expert in pesticide regulation, enforcement, labeling, etc.

Extensive experience preparing and presenting training in a variety of topics, but primarily enforcement and compliance with environmental regulations – especially in regard to federal pesticide legal requirements. The material includes the legal foundations and requirements for conducting administrative, civil and criminal environmental investigations. The training includes evidence gathering from crime scenes, pesticide and toxic substances sampling, environmental sampling, sample preservation and chain of custody requirements. Other training topics include interviewing, identifying deceptive behavior, pesticide and inspector safety and multiple other topics related to pesticide regulation, compliance, use, misuse, etc. Customers have included all EPA Regions, representatives from nearly all pesticide State Lead Agencies, local environmental agencies, many tribal entities, industry and trade associations, University Extension Services, the Ministry of Health in Trinidad-Tobago, IBAMA (Ministry of the Environment) and ANVISA (Ministry of Health) in Brazil, and Alberta, Canada.

Particularly skilled in the investigation of pesticide incidents to determine compliance with federal, state and/or tribal requirements under applicable statutes and ordinances. These investigations typically recreate incidents involving pesticides which may be associated with alleged injury or harm to human health or the environment. Evidence collected meets the requirements for admissibility under federal, state, and tribal Rules of Practice for administrative, civil and criminal prosecutions.

Has had extensive training and personal experience involving the rules and procedures involving the registration and reregistration of pesticides and establishments under the requirements of the U.S. Environmental Protection Agency and state regulatory agencies. In particular, has expertise in both label interpretation and development in terms of applicability in the field by users, legal requirements, and enforcement. Has often conducted in-depth qualitative reviews and audits of technical and administrative environmental programs at the federal, state and local levels and prepared written analyses and recommendations.

**Testimony and
Case Experience**

Criminal prosecution of Holley Electric Co., Jacksonville, FL (PCBs), 1982

Criminal prosecution of American Electric Corp., Jacksonville, FL (PCBs), 1983

Civil trial of Holloway Waste Oil v. Dept. of Defense, Jacksonville, FL (PCBs), 1983

Criminal prosecution of George Trepal for murder, State prosecution, Bartow, FL (Pesticides) 1991

Criminal prosecution of Paul Walls, Hattiesburg, MS (Pesticides), 1997

Criminal prosecution of Dock Eatmon, Biloxi, MS (Pesticides), 1997

Criminal prosecution of Robert Kelley, Jr. and Robert Kelley, III, Memphis, TN (Pesticides), 1998

Criminal prosecution of Donald Keel, Memphis, TN (Pesticides and Migratory Bird Treaty Act), 2003

Hawkins, et.al. v. Otis Termite and Pest Control Service, Inc. (Deposition), Tennessee

Administrative Hearing in North Carolina in AgMart case (Pesticides), Florida v. AgMart, and New Jersey v. AgMart, 2006-2008

Sidran v. DuPont, Deposition, 2011, Florida

Deposition and Civil trial – Gary Scott v. Southern States, May 2013, Kentucky

Bradley v. Simpson Co-op, deposition, 2015, Tennessee

Daily Farms, v. TruGreen Chemlawn, deposition, 2015, Indiana

Everhart v. Reckitt Benckiser, deposition, 2018, Florida

Davenport v. Rentokill, 2020-21, Wyoming

Ahrens v. Hartford Florist Supply, Inc., Ongoing

Testified before federal Grand Juries

Testified in numerous federal, state and local administrative hearings and civil trials prosecuting corporations and individuals for alleged violations of state and federal pesticide laws.

Confidential - Paraquat Litigation

Testified in numerous private litigation cases and depositions both under subpoena and when in the interest of the government or the client. Additional information can be provided with the permission of the attorneys managing those cases.

The following cases/companies have retained my services for a variety of reasons from case resolution, pesticide registration issues, litigation, pesticide expertise, etc.

Millipore, pesticide consultation, 2008-Current, U.S., Ireland, France and Germany

Pinnacle, pesticide compliance, 2009, Arizona

Ecomist, Pesticide registration, 2009, New Zealand

Cecon Project# 4387, Pesticide registration, 2009, Illinois

Lipitech, pesticide case consultation, 2010-2012, India

Lexmark, pesticide requirements, 2011, Georgia

Tornado Personal Defense Systems, Inc., state registrations, 2011-2012, Canada and US

EPA v. Brewer, SP, 2011-2012, Florida

California v. Natural Chemistry, 2012, California

EPA v. Plant Food Systems, 2012, Florida

Kansas v. Estate Management Services, 2013, Kansas.

Cecon Project # 5798, Internet advertising and Sales 2013, Georgia

Gary Scott v. Southern States, case review, deposition, and trial, 2012 and 2013

EPA v. WellShield, 2014-2015, Florida

CSX, NPDES, 2014-2015, Florida

Veolia, Inc., Pesticide requirements, 2014-2015, Illinois

Florida v. Plant Food Systems, 2014-2015, Florida

Kamman's Farms, Investigation, 2014-2015, Indiana

Life-Threads, Analysis, 2015, New York

Progressive Southeastern Insurance v. Schuyler, Inc. of Syracuse, 2015, Indiana

Morning Songbird Food Class Action Litigation, 2015 - Present

First Priority, Inc., Label analyses, 2015

Dr. Raj Patel, Pest Control Products Depot, Website Review and compliance consultations, 2016 – current

Borrmann v. Citrus County Mosquito Control District, consultation, 2015 & 2016

Bradley v. Simpson Co-op, Consultation, case review, and deposition, 2016

Frank Everhart v. Reckitt Benckiser, opinion and deposition, 2017

Garden Masters of SW Florida & Earthcare Landscapes/ Millbrook Village, et al, case review and recommendations, 2017

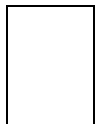
U.S. Continental Consultants, consultation, 2020

Davenport v. Rentokill, case review and expert opinion, 2020 & 2021

Ahrens v. Hartford Florists Supply, Inc. 2018 - Present

Bergeson & Campbell, ongoing consultation services

Additional information regarding current cases can be supplied on request with the permission of the clients and the attorneys managing those cases. Attorney contact information can be provided on request.



APPENDIX B

Expert Report of Carlton Layne

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Expert Report of Carlton Layne

MATERIALS CONSIDERED LIST

Federal Fungicide, Insecticide and Rodenticide Act of 1972 (FIFRA)

7 U.S.C. § 136d

40 CFR 152

40 CFR 156

40 CFR 158

40 CFR 159

40 Fed. Reg. 28242 (July 3, 1975)

50 Fed.Reg. 38115 (Sept. 20, 1985)

81 Fed. Reg. 12489 (March 9, 2016)

ANVISA Technical Reassessment Opinion No. 01 of 2015/GGTOX/ANVISA SYNG-PQ-01214493

ANVISA Technical Reassessment Opinion No. 08/GGTOX/ANVISA(June 13, 2016) SYNG-PQ-06641238

ANVISA Technical Opinion No. 13/CREAV/GEPOS/GGTOX/ANVISA(Jan. 5, 2017) SYNG-PQ-22721559

Blondell, “Memorandum: Review of Paraquat Incident Reports Involving Inhalation, U.S. Environmental Protection Agency (August 10, 2000)(SYNG-PQ-31436268)

EPA: Amendment to Paraquat Dichloride Human Health Mitigation Decision, February 6, 2018

EPA: Paraquat Dichloride: Systematic review of the literature to evaluate the relationship between paraquat dichloride exposure and Parkinson’s disease, June 26, 2019

Environmental Protection Agency: Paraquat Dichloride: Draft Human Health Risk Assessment in Support of Registration Review, June 26, 2019

EPA Paraquat Dichloride: Tier II Epidemiology Report (June 26, 2019)

EPA “Summary of the IBT Review Program” Office of Pesticide Programs (July 1983)

EPA Response to the 2017 Citizen Petition from the Center for Food Safety and Others Relating to the Whole Formulations Testing and Mixtures for Conventional Pesticides (September 28,

2023). <https://aglaw.psu.edu/wp-content/uploads/2023/10/3-EPA-Petition-Denial-CFS-9.28.23.pdf>

EPA, Paraquat: Response to Comments on the Draft Human Health Risk Assessment (September 24, 2020)

EPA, Pesticide Registration Notice 98-3 Notice to Manufacturers, Formulators, Producers, Distributors and Registrants of Pesticide Products (April 3, 1998)

EPA Paraquat Decision Document, Office of Pesticide Programs (July 1982); SYNG-PQ-01796364

EPA Reregistration Eligibility Decision (RED): Paraquat Dichloride (August 1997)

“EPA Lacks Assurance That All Adverse Effects Data Have Been Reviewed” Statement of Peter F. Guerrero, Associate Director Environmental Protection Issues Resources, United States General Accounting Office, October 30, 1991.

Exponent, Inc. An Examination and Analysis of the Role of Paraquat and Maneb in Induced Neurodegeneration of the Substantia Nigra at Representative Human Exposure Doses, DEFRA Project Code: PS2608

Finegan, Pamela A., “FIFRA Lite: A Regulatory Solution or Part of the Pesticide Problem?” 6 Pace Environmental Law Review 615 (1989)

Gramoxone SL 2.0 Current Product Label: https://www.syngenta-us.com/current-label/gramoxone_sl_2.0

ICI Report CTL/P/1467: Ward, Scott, “Paraquat: Penetration Through Protective Clothing Materials From a Malaysian ‘Gramoxone’ Formulation (March 14, 1986) SYNG-PQ-30817606

ICI Report CTL/L/1680: Corrigan, Scott “Paraquat: Absorption Through Wellington and Trooper Boot from Gramoxone (November 30, 1987) SYNG-PQ-02776558

Lange, M., “The Federal Environmental Pesticide Control Act of 1972: A Compromise Approach” 3-2 Ecology L.Q. 277 (1973).

Mandel, et. al, “Paraquat and Parkinson’s Disease: an overview of the epidemiology and a review of two recent studies” Regul Toxicol Pharmacol. 2012 Mar; 62(2) 385-92

Paraquat Oral Studies in Dogs Summary Report (February 25, 1988) CUSA-00174168

Report No. CTL/R/373 – The Effect of Surfactants on the Toxicity and Intestinal Absorption of Paraquat (January 1976) SYNG-PQT-ATR-05665695

Report No. CTL/L/1428 – Preeglox-L: Pharmacokinetic Study in the Rat (September 30, 1986) SYNG-PQ-01823567

Syngenta’s Paraquat Research Program Update: Powerpoint Slides: US EPA Meeting Feb. 6, 2017

Syngenta, Paraquat Dichloride Registration Review 60 Day Comments, (February 21, 2012)

Syngenta's 60-Day Comments in Response to the Publication of EPA's Draft Human Health and Ecological Risk Assessments for the Registration Review of Paraquat Dichloride; EPA-HQ-OPP-2011-0855; Case Number 0262 (December 16, 2019)

Tanner, et. al, "Rotenone, paraquat, and Parkinson's disease" Environ Health Perspect. 2011 Jun; 119(6)

U.S. General Accounting Office "Pesticides: EPA's Formidable Task to Assess and Regulate their Risks 10 (RCED 86-125, 1986).

EPA Websites

<https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities#:~:text=In%201972%2C%20the%20Federal%20Environmental,protecting%20health%20and%20the%20environment>

<https://www.epa.gov/pesticides/pesticide-registration-review-deadline-status-update-and-plans-remaining-work#:~:text=In%202007%2C%20an%20amendment%20to,human%20health%20or%20the%20environment>.

<https://www.epa.gov/pesticide-reevaluation/why-we-review-pesticides#:~:text=The%20registration%20review%20program%20is,of%20no%20unreasonable%20adverse%20effects>

Deposition Transcripts

Deposition of Timothy Pastoor (March 21, 2024) with Exhibits

Deposition of Monty Dixon (July 11, 2024) with Exhibits

Deposition of John Abbott (July 24, 2024) with Exhibits

Deposition Transcript of Philip Botham (Sept. 17, 2024) with Exhibits

Deposition Transcript of Philip Botham (Sept. 18, 2024) with Exhibits

Deposition Transcript of Charles Breckenridge

Deposition Transcript of Philip Botham (June 17, 2020)

Deposition Transcript of Philip Botham (June 18, 2020)

Internal Chevron/Syngenta Documents

CHEV-SJ0015222
CHEV-SJ0016568
CHEV-SJ0022764
CHEV-SJ0048182
CHEV-SJ0052033
CHEV-SJ0070069
CHEV-SJ0086024
CHEV-SJ0087133
CHEV-SJ0096045
CUSA-00011464
CUSA000193960
CUSA-00089490
CUSA-00094490
CUSA-0011497
CUSA-00174168
CUSA-00332251
CUSA-00341060
CUSA-00363346
CUSA-00383597
CUSA-00435211
SNYG-PQ-00481037
SNYG-PQ-06721544
SYNG-PA-01991643
SYNG-PQ-00044965
SYNG-PQ-00124616
SYNG-PQ-00125211
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