Abandoning Science

A look back at the failure to regulate the neurotoxic insecticide chlorpyrifos

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There are many U.S. Environmental Protection Agency (EPA) decisions over the last four years that abandon the underlying principles of protecting health and the environment. The neurotoxic insecticide chlorpyrifos was among the first in 2017 that caught national attention because of EPA's blatant failure to respond to the scientific findings of brain damage in children. It also captured for the nation the ability of an agency, established to rely on science and protect public health, to be politicized and captured by the corporations that it is charged with regulating. In the early days of the Trump administration, EPA officials reversed an Obama administration proposal to ban agricultural uses of this chemical, whose residential uses, for the most part, had been banned nearly two decades earlier. One could point to this case as deserving of immediate attention by a Biden administration EPA, as a test of whether science will govern the process of what was envisioned as a scientific agency. It is one of dozens of decisions that have ignored science with dire consequences. Of course, corrective action on chlorpyrifos and other pesticides should not define progress in an EPA that needs to play a leadership role across government agencies in tackling problems of environmental justice (disproportionately high risks to people in communities of color), farmworker and landscaper (and other service providers) poisoning, pollinator and biodiversity decline, water quality degradation, crop damage and increasing pesticide dependency in genetically engineered crops, and the climate crisis.

EPA continued its politicization of science in the waning days of the Trump administration, when on December 4 the agency announced a proposed interim decision on chlorpyrifos, functionally continuing its registration for many agricultural uses. The interim decision purports to put in place new limitations on use of this pesticide, but they are wholly inadequate to the threat this compound represents—to young children, most concerningly, as well as to farmworkers, critical species and ecosystems, and the public. Chlorpyrifos should not be reregistered for use—i.e., its sale and use should be banned altogether, as Beyond Pesticides has asserted for years.

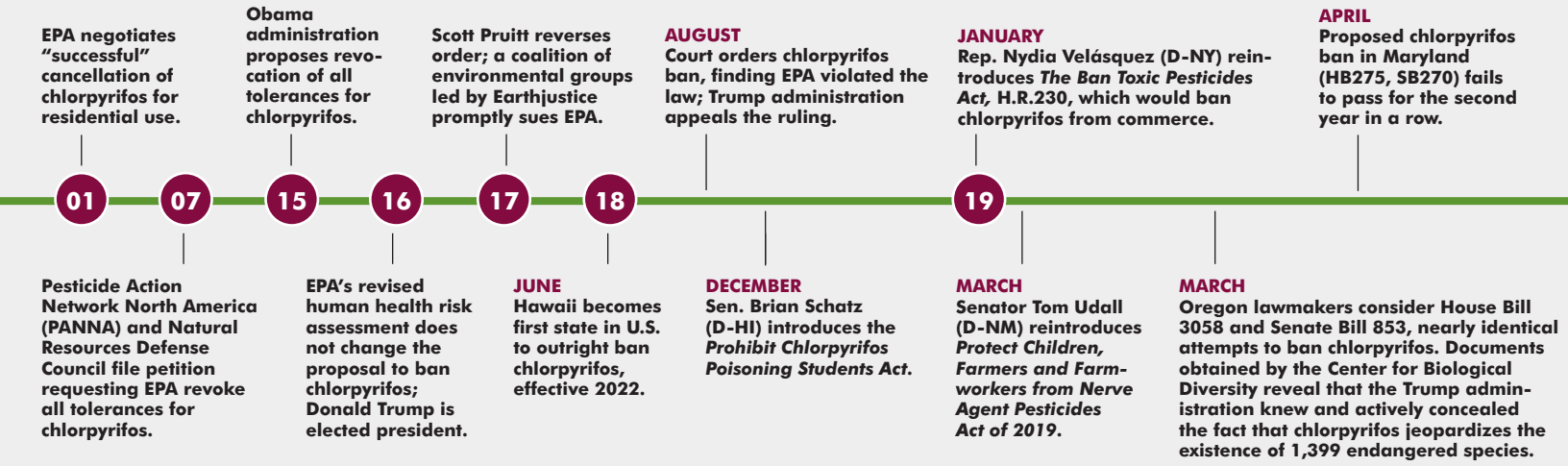
THE PROBLEM WITH CHLORPYRIFOS

Chlorpyrifos is an organophosphate pesticide used on scores of food crops, for mosquito (and other pest) control, and for some turf management (golf courses, especially). The compound is a central and peripheral nervous system poison and is clearly dangerous. It damages the brains of young children, causing impairment to cognitive function, lower IQs, attention deficit disorder, developmental delays, and other learning and developmental disorders. It can cause damage to human reproductive, endocrine, renal, hepatic, and immune function.

Federal and State History

In April 2019, Beyond Pesticides provided a timeline of relevant developments whose highlights are worth reviewing. Beyond Pesticides has reported on the tortuous path of EPA's relationship, as well as legislative, legal, and state responses, to chlorpyrifos.

Since April 2019, there have been more developments.



Chronic exposure has been linked to the development of lung cancer. In addition, chlorpyrifos is toxic to birds, fish, aquatic organisms, and bees. In areas where it is used, chlorpyrifos can contaminate indoor air, surface water, and food crops (most commonly, almonds, cotton, citrus, grapes, corn, broccoli, sugar beets, peaches, nectarines, soybeans, Brussels sprouts, cranberries, alfalfa, peanuts, sunflowers, and tree nuts). Farmworkers and their families, as well as pregnant women in such agricultural areas, are at particular risk for damage from the chemical and its drift.

The Center for Food Safety (CFS) writes: "The interim 'decision' leaves much undecided, including safety thresholds for chlorpyrifos exposure and possible mitigation measures, which EPA is currently negotiating with chlorpyrifos manufacturers." CFS also excoriates this latest decision: "EPA has long been aware of the pesticide's toxicity. While most residential uses of chlorpyrifos were banned nearly two decades ago, the agency permitted its continued use in agriculture, creating a double-standard in which rural kids and farmworkers are left unprotected. People are exposed to chlorpyrifos in food and water, but also through inhalation of spray drift and vapor."

CFS legal director George Kimbrell commented on the interim decision: "True to form, the Trump Administration has placed corporate dollars over public health. If allowed to stand, its proposal to continue registering this neurotoxic insecticide would cause irreparable harm to farmworkers and future generations. Everything possible must be done to ensure the Biden Administration reverses this proposal…"

NEW RESEARCH, OLD PROBLEMS

Beyond the exposure assessment that found brain effects in children exposed to chlorpyrifos, research published in July 2020, "Flawed analysis of an intentional human dosing study and its impact on chlorpyrifos risk assessments," (Sheppard, et al., *Environment International* 143(2020)105905) found that critical data supporting EPA's "safe exposure limit" were flat out wrong. According to the study by University of Washington (UW) researchers, the 1972 "Coulston Study" concluded that the amount of the chemical to which a human could be exposed before adverse effects showed up (the "no-observed-adverse-effect-level," or NOAEL) was *more than twice as high* as should have been determined had the study not ignored critical data. In addition, the study points to the perennial "fox guarding the hen house" issues at EPA, which include using research commissioned, funded, or even conducted by industry as any basis for regulation.

The researchers reanalyzed that human intentional dosing study using both the original statistical methods and modern computational tools that did not exist in the 1970s. (An important side note: such a study is unethical by current research standards.) The new analysis finds two significant flaws: (1) the study design made it less able to identify a treatment effect (an impact of the study subjects' intentional exposure to chlorpyrifos), and (2) the researchers' omission of valid and important data obscured a treatment effect that would otherwise have been identified.

In the study paper, the coauthors say plainly, "The Coulston Study misled regulators by omitting valid data for the key treatment group . . . resulting in a finding of no effect. Our updated analysis indicates that even the lowest dose was unlikely to be a NOAEL. A proper analysis of the Coulston Study would have lowered or eliminated the NOAEL. Either action would have reduced the acceptable dose for chlorpyrifos, and may well have led to more restrictions on its use,


EPA Admin. Scott Pruitt


Sen. Brian Schatz


Sen. Kirsten Gillibrand


Gov. Andrew Cuomo


Rep. Nydia Velásquez


Sen. Tom Udall

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APRIL
Senator Kirsten Gillibrand (D-NY introduces *Safe School Meals for Kids Act* to restrict schools from purchasing or serving food with any detectable amount of chlorpyrifos.

OCTOBER
California announces an early 2020 ban on use of chlorpyrifos.

FEBRUARY
Corteva (formerly DowDuPont) announces it will stop producing chlorpyrifos in 2020 because of declining sales.

AUGUST
A study reveals that research underpinning chlorpyrifos registration by EPA left critical data out of its analysis, resulting in decades of use of a faulty EPA "safe exposure limit."

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MAY
New York State legislature passes a bill to phase out and eventually ban the use of chlorpyrifos.

DECEMBER
NYS Governor Cuomo vetoes the legislature's bill, but orders the state Department of Environmental Conservation to ban aerial applications immediately and all uses by 2021, using rulemaking rather than legislation; this makes it the third state to ban the toxic compound.

MARCH
The Maryland legislature passes a limited ban on chlorpyrifos. Maryland Governor Hogan vetoes the bill in May, preferring regulatory action.

SEPTEMBER
EPA—contravening scientific evidence and its own findings—announces its conclusion that "the science addressing neurodevelopmental effects [of the insecticide chlorphyrifos] remains unresolved.

particularly in scenarios where infants and children were exposed. . . . An earlier reduction in the NOAEL and increased exposure mitigation would have likely reduced the incidence of adverse health effects in children of that era. It is tragic that an omission of valid data from the analysis of the Coulston Study may have adversely impacted public health for at least 15 years."

Put simply: the "acceptable" chlorpyrifos exposure level established by EPA, on the basis of the 1972 research, was much higher than it should have been, and likely led to many, many dangerous exposures for children, in particular. Lead author Lianne Sheppard, PhD, commented, "This has huge public health implications. This study was the basis of policy for over 15 years and because it concluded that the 'no observed adverse effect level' was more than twice as high as it should have been, the standard was a lot less protective than it should have been."

The UW researchers charge that, "Decades of exposure to chlorpyrifos and all the political wrangling and lawsuits surrounding it might have been averted if a 1972 study had been adequately reviewed by the EPA. . . . The EPA also did not re-analyze the study data when new statistical techniques became available a few years later [in the 1980s]." *UW News* reports that if the Coulston data had been reevaluated with the newer statistical tools that became available in the '80s (as should have been done, and as the UW researchers did), "EPA's reviewers would have seen that chlorpyrifos' effect on the body's chemistry accumulated over time and that the study had not discovered the 'no observed adverse effect level' used by regulators to set safe levels of exposure." Dr. Sheppard commented, "All kinds of approvals were allowed for uses that never should have been allowed and quite well wouldn't have been allowed if the Coulston study authors had properly reported their results."

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THE CHALLENGES OF LITIGATING TO FORCE ACTION

EPA has been sued repeatedly for its allowance of chlorpyrifos use and has employed epic levels of foot dragging in responding to petitioners and to court orders. Highlights of the litigation and regulatory landscape include many fits and starts over the past two decades. Chlorpyrifos was first registered as an insecticide in 1965. After wide allowances for use during the 1970s, '80s, and '90s, EPA banned household uses of the compound (except for ant and roach baits) in 2000. Two years later, the agency reduced allowable application frequencies for a number of food crops. A decade after that, EPA created "buffer zones" around agricultural fields close to "sensitive" sites, such as schools, playing fields, parks, public sidewalks, residences, hospitals, and nursing homes.

In 2015, the Ninth Circuit Court of Appeals ordered EPA to respond to a petition by the Natural Resources Defense Council and Pesticide Action Network North America to ban all uses of chlorpyrifos. Following that, EPA proposed to revoke all food tolerances for the compound. In March of 2017, the newly installed Trump administration's EPA contravened the conclusions of its own scientists, as well as those of independent researchers, by reversing that 2015 decision to revoke food residue tolerances because of the chemical's neurotoxic impacts. In a suit brought by a coalition of labor and health organizations represented by Earthjustice, in 2018 the Ninth Circuit Court of Appeals ordered EPA to finalize its ban on chlorpyrifos. In April 2019, the Ninth Circuit gave EPA 90 days to justify a decision to allow chlorpyrifos to remain on the market. In July of that year, EPA announced it would allow continued use of the toxic pesticide.

Absent protective action by EPA, some states have taken action. Hawaii became the first state to ban chlorpyrifos in 2018. In 2019, six states (California, New York, Massachusetts, Washington, Maryland, and Vermont) sued EPA, arguing that chlorpyrifos should be banned because of the dangers of its use to people's health. Also in 2019, the New York State legislature voted to phase out and eventually banned its use. Maryland passed a limited ban in 2020.

In February of 2020, Corteva AgriScience (formerly DowDuPont), the largest manufacturer of chlorpyrifos pesticide products, announced that it would cease production of those products by the end of 2020, citing declining sales as the reason for the move—no doubt fueled by states' actions and momentum against use of the products because of their dire health consequences. The problem behind that welcome news is the difference between one company stopping production and EPA cancellation of the registration of chlorpyrifos. Continued EPA registration permits other generic manufacturers to continue to produce and sell such products.

EPA'S INSTITUTIONAL BIAS IN FAVOR OF PESTICIDES

The coauthors of the UW study note that their reanalysis points to issues of concern beyond those specific to chlorpyrifos. One is that EPA reliance on research results that have not been properly peer reviewed can endanger public health. As they write, "The original analysis, conducted by Dow-employed statisticians, did not undergo formal peer review; nevertheless, EPA cited the Coulston study as credible research and kept its reported NOAEL as a point of departure for risk assessments throughout much of the 1980s and 1990s. During that period, EPA allowed chlorpyrifos to be registered for multiple residential uses that were later cancelled to reduce potential health impacts to children and infants. Had appropriate analyses been employed in the evaluation of this study, it is likely that many of those registered uses of chlorpyrifos would not have been authorized by EPA."

Emeritus professor in the UW School of Public Health's Department of Environmental and Occupational Health Sciences, Richard Fenske, PhD notes that the reasons for the failure of EPA to review the Coulston study—when EPA began a supposedly systematic review of such older studies in 2006 by its inaugural Human Studies Review Board—are a mystery. That said, UW News reports that when EPA began that review of such human-subject studies, the chief manufacturer of chlorpyrifos products (then Dow Chemical) specifically pulled that study from the review process, according to Dr. Fenske, a member of the initial review board. "You can speculate why they did, but they formally asked the Human Studies Review Board not to review this study and so it was never reviewed."

Dr. Fenske also said, "It is a cautionary tale that data being submitted for pesticide registration may not have undergone proper review, and that could be happening today." Dr. Sheppard asserted that, minimally, studies funded by companies developing a chemical that is under review need to be opened to outside scrutiny, adding, "I'm not sure industry should be doing these studies at all. I don't think the fox should be guarding the hen house."

FARMWORKER PARENTS SUING FOR DAMAGES

Meanwhile, in central California, what promises to be a landmark series of lawsuits against Corteva is under way, spearheaded by the case *Alba Luz Calderon de Cerda and Rafael Cerda Martinez v. Corteva Inc., et al*. This first suit, brought by the parents of Rafael Cerda Calderon, Jr. on his behalf, charges that his lifelong disabilities were caused by chronic

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exposures to chlorpyrifos. The parents are suing for general damages, compensatory damages (due to Rafael, Jr.'s loss of earning capacity), medical care costs, and "punitive damages for the willful, reckless, and recklessly indifferent conduct of the Defendants" in intentionally hiding the dangers of their chlorpyrifos products from customers and the public. As with so many dangerous pesticides, absent effective federal regulation, states, cities, and other entities are taking action to protect people from this compound and, as in this case, individuals are seeking redress for harms suffered. In the face of inadequate federal and state laws and a politicized EPA, lawsuits against the manufacturers and users of pesticides may be not only a remedy for harm, but also drive the market to safer products. The $10.8 billion settlement that Monsanto proposed with plaintiffs harmed by glyphosate/Roundup is indicative of future actions. However, these court decisions occur after millions of people are exposed and harmed in ways that are not always directly traceable back to the chemical.

The farmworker case was filed in mid-September in California Superior Court, Kings County, and names not only Corteva, but also, the cities of Huron and Avenal, Woolf Farming Company, Cottonwest, LLC, John A. Kochergen Properties (successor in interest to Alex A. Kochergen Farms), and an "invisible" pesticide applicator as defendants. Plaintiffs are represented by several law firms, led by Calwell Luce diTrapano, PLLC of Charleston, West Virginia. Lead attorney Stuart Calwell reports that the firm is "in the process of reviewing around 200-plus records. We probably got 87 that look like they're provable cases." *AP News* reports that at least 50 additional plaintiffs have emerged and are in the litigation pipeline for similar harms caused by this toxic pesticide.

THUMBS UP TO CONTINUED USE

Then came the 2020 chlorpyrifos interim decision, which proposes to limit uses of chlorpyrifos in some U.S. regions "to better protect human health and the environment," according to EPA. The decision proposes: (1) "label amendments limiting application to address potential drinking water risks of concern," (2) "additional personal protection equipment and application restrictions to address potential occupational handler risks of concern," and (3) "spray drift mitigation, in combination with the use limitations and application restrictions identified to address drinking water and occupational risks, to reduce exposure to non-target organisms."

The text of EPA's decision can be accessed at *bp-dc.org/chlorpyrifosEPA*. A review of the regional application limits (in the tables in section IV of the draft decision, "Proposed Interim Registration Review Decision") shows that the proposed "limits" continue to allow "high-benefit agricultural uses," in the aggregate, on nine crops across 40 states. This is unacceptable for such a dangerous pesticide, to which people can be exposed through diet, water, landscape uses, and/or "use on public health pests, such as mosquitoes, ticks, and fire ants."

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In truth, this decision continues the Trump EPA's anti-science, anti-regulatory track record. One among many examples is that despite the endocrine disrupting effects of chlorpyrifos, this decision asserts: "There is no evidence demonstrating that chlorpyrifos potentially interacts with estrogen, androgen, or thyroid pathways."

Further, Beyond Pesticides reported in 2019 on the administration's concealment of a report showing that 1,399 endangered species are significantly threatened by chlorpyrifos (and two other organophosphate pesticides). This interim decision states, "The proposed mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of chlorpyrifos.… EPA is currently working with the National Marine Fisheries Service (NMFS) under a reinitiated *Endangered Species Act* (ESA) consultation, and NMFS plans to issue a revised biological opinion for chlorpyrifos ***in June 2022*** [emphasis by Beyond Pesticides]. The U.S. Fish and Wildlife Service (FWS) has not yet completed a biological opinion for chlorpyrifos. EPA will complete any necessary consultation with NMFS and FWS for chlorpyrifos prior to completing the chlorpyrifos registration review." Thus, vulnerable wildlife and habitat will continue to be at risk for at least another year and a half (barring any change by the Biden administration), pending a final EPA registration decision on chlorpyrifos.

Beyond Pesticides wrote in 2019, and continues to maintain, that absent effective national protections, "States should ban chlorpyrifos compounds . . . should undertake organic management on state-owned lands, and should support producers in transitioning away from chemical agriculture and to organic, regenerative, and sustainable practices.

CONCLUSION

The question remaining is whether the chlorpyrifos story will provide lessons for transforming our approach to pesticide law and regulation, especially with the viability and profitability of cost-effect organic production practices. Individual chemical bans are not the strategy for a sustainable future. The lessons from chlorpyrifos teach the urgency of shifting to management practices that eliminate all toxic pesticides, given that we have the tools to manage land and produce food without them.