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EPA Denial of Chlorpyrifos Ban Sets Pro-Science Precedent

Activist Petition to Ban Safe and Valuable Pesticide Would Undermine Food Affordability

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Some consumers may wonder why some staples of a healthy diet, such as orange juice and many fruits and veggies, seem needlessly expensive. They might blame farmers or retailers, but much of the blame goes to government regulations that make it increasingly difficult for farmers to produce an affordable food supply. Many of these regulations are driven by environmental activists who use junk science and fearmongering to push unwarranted bans on pesticides. As a result, fewer of these crop-protection products are available to farmers to fight a wide array of crop-destroying insects—both native pests as well as an increasing number of accidentally imported ones. That is why a recent Trump administration decision to deny a petition to ban yet another pesticide is a welcome shift in policy—and a victory for public health, consumers' budgets, and struggling farmers.

In March 2017, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt denied an activist petition to ban the chemical chlorpyrifos, a common pesticide that farmers have safely used for decades. The *New York Times* and other media outlets derided the decision as a Trump administration attack on science.[1] In reality, Pruitt's decision is a repudiation of *junk* science—some funded by the EPA itself—that environmental activists have used to push unwarranted and counterproductive regulations. Pruitt's action sets an important pro-science approach to regulation that the agency should continue to follow.

The petitioners, the Natural Resources Defense Council (NRDC) and the Pesticide Action Network of North America (PANNA), have appealed the decision.[2] They have been joined by seven state attorneys general, led by New York's Eric Schneiderman, who have filed an administrative challenge to the EPA decision.[3] Yet decades of scientific evidence clearly justifies allowing continued use of chlorpyrifos. When used according to label directions, the chemical poses negligible health risks, while providing important public health benefits by making it easier for farmers to produce a plentiful and affordable food supply.

What is Chlorpyrifos? Introduced in 1965, Chlorpyrifos is a common pesticide used in nearly 100 countries around the world for crop protection and mosquito control. It was formerly used in residential settings to control indoor pests, such as cockroaches, as well as outdoors to control lawn and garden pests. In 2001, Dow Agrosciences and other chlorpyrifos manufacturers voluntarily discontinued residential uses, except in cockroach baits, because the cost of registering those uses with the EPA made them unprofitable. Such voluntary deregistration by all producers means those uses are effectively banned. The companies have continued to maintain registrations for many vital agricultural uses.

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Chlorpyrifos falls within the class of chemicals known as organophosphates.[4] Like other organophosphates, it works by inhibiting the effectiveness of an enzyme called cholinesterase, which is necessary for the proper functioning of the nervous system. In very low, dilute doses, the impact of chlorpyrifos on insects' nervous systems is enough to kill them. In humans, exposure has to reach relatively high and concentrated levels for a period of time before significant health effects can occur.[5] Federal pesticide regulation keeps human exposures low enough to avoid health effects on people, while still high enough to kill crop-destroying insects.

Regulatory Background. The EPA regulates pesticides under several laws, which include the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food Drugs and Cosmetics Act (FFDCA). Both of these laws were amended in 1994 with the Food Quality Protection Act (FQPA), which made regulations more stringent.

Before companies can sell pesticides, they must register their products with the EPA under FIFRA, which also requires the agency to conduct reregistration safety reviews of all pesticides every 15 years. This can take years to complete, so the agency often launches a new review shortly after finalizing the prior one. First registered for use in 1965, Chlorpyrifos has been approved and reregistered several times, passing stringent federal pesticide safety standards. The EPA finalized the most recent review of the pesticide in 2006 and then launched the next review in 2009.[6] An overview of this registration process is necessary to understand the stringency of EPA standards and why concerns about chlorpyrifos are overblown.

The EPA must ensure that any pesticide it registers "will not generally cause unreasonable adverse effects on the environment."[7] That mandate includes ensuring both public safety and wildlife protection. This paper focuses on the safety assessment, which is the focus of the NRDC/PANNA petition.

The EPA's safety registration can be divided into three main activities. First, the EPA sets a "tolerance," which involves determining what exposure level it can deem "safe"—the level that poses negligible risks to individuals. Second, the agency must estimate how much exposure the public would experience if the EPA were to register certain uses. Third, the agency uses those two pieces of information to limit the number of registered uses to ensure public exposure will always remain below the "safe" level.

The EPA sets the tolerance under the guidelines of the FFDCA, and the agency defines "tolerance" as "the maximum permissible level of pesticide residues allowed in or on human food and animal feed."[8] The tolerance level is designed to ensure "reasonable certainly of no harm" to public health or the environment.[9] "No harm" implies zero risk, an extremely stringent standard.

The EPA reviews the body of available research to evaluate pesticide safety, and traditionally it has relied on studies that involve rodent tests to determine the tolerance. In these studies, researchers dose rodents at various levels until they find the highest level at

which there are no health effects in the animals identified.[10] Then it uses that data to extrapolate an exposure level for humans at which no health effects would be expected. This "no effect" or "safe level" for humans becomes the agency's point of departure (PoD) for setting the tolerance standard.[11]

A PoD is based on a specific health effect or effects. For example, if a chemical has the potential to cause cancer, the EPA must determine the highest level of exposure that humans can tolerate before suffering an increased cancer risk. For chlorpyrifos, the well-recognized health effect is related to cholinesterase inhibition; accordingly the PoD has long focused on preventing that health effect. There is no compelling evidence that chlorpyrifos causes cancer.[12]

Once the EPA determines a PoD for a chemical, it applies numerous safety factors to keep public exposure far below the no-effect level, usually 10 to 100 times below it.[13] The FQPA required the EPA to be even more conservative by requiring the agency to apply an additional 10-fold safety factor for products to which children might be exposed, unless data are available to demonstrate that children are no more sensitive to the product than adults. For those cases where the 10-fold FQPA safety factor is retained, the allowed exposures are usually 100 to 1,000 times (or more) lower than EPA's determined safety level.

After setting a tolerance, EPA staff must estimate how much the public would be exposed to the chemical after it is registered. This requires that EPA analysts make assumptions about public exposure, and they often vastly overstate potential exposure levels. University of Texas law professor Frank Cross reported in one study on this topic that EPA regulators have assumed farmers apply the full legal limit of all pesticides registered for use on a given crop, when in reality they apply only a fraction of the legal limits. Cross highlights one study that showed farmers in California use about 25 percent of their legal limit for tomatoes and each farmer uses no more than five of 54 licensed pesticide products.[14]

The EPA overestimates exposures to be certain that risks remain negligible even in cases of excessive exposure. For example, the EPA's 2000 risk assessment for the pesticide malathion explained that risk of adverse health effects would be negligible even to a three year-old toddler standing for 20 minutes in a cloud of malathion as it was released from a mosquito fogger truck at the full, legally allowed concentration levels.[15] Of course, such high exposure levels are improbable in real-life situations, but regulators use such scenarios to make sure the chance of significant health effects in real-life exposures remains remote.

Considering all these factors, Cross showed how the EPA's conservative assumptions overstated public pesticide exposure by as much as 99,000 to 463,000 times actual exposure levels, even before the FQPA's more stringent standards were implemented.[16] And, he pointed out, when researchers recalculated risks by considering actual pesticide exposure levels measured by the U.S. Department of Agriculture (USDA), they found that risks were "from 4,600 to 100,000 times lower than the agency estimates."[17]

After those first two steps are complete, the EPA registers only a limited number of uses of each chemical or class of chemicals to ensure total human exposure remains below the

tolerance. It can decide to register a pesticide for farming uses, mosquito control, home uses, or a combination of these, but the estimated total of all registered such uses must ensure the public exposure remains below the tolerance level.

To explain this process, the EPA has described it as filling a cup that is limited in size by the amount of public exposure the EPA will allow. As the EPA registers each use of a chemical, the cup begins to fill, and once it reaches the top, the agency allows no more registrations.

In addition to ratcheting up the safety factors, FQPA includes a couple more provisions that fill the cup even faster. First, it required the EPA to consider all exposures in the aggregate, such as the public's exposure through use in home roach control, lawn uses, food residues, and any trace amounts that may appear in drinking water. Second, if pesticides have similar properties, the EPA groups them and regulates them as a class, limiting the public to a certain cumulative exposure level from a category of chemicals. Basically, that means one cup may be used for categories of chemicals rather than for a single chemical registration. With these provisions in place, the cup fills quickly and fewer registrations are allowed.

As a result of all the safety factors and stringent regulations, the EPA has effectively banned useful pesticides even though risks were low. For example, after FQPA became law, the EPA completed a 10-year study of 230 organophosphates and carbonates pesticides. It concluded that the Act demanded that the agency ban 3,200 uses of pesticide products in these categories and place restrictions on 1,200 other uses. It deemed 5,237 uses as "safe" under the Act.[18] That means the EPA banned or regulated 46 percent of the uses—a substantial increase of regulations using FQPA's risk-based standard.

Moreover, these regulations have caused companies to voluntarily cancel registrations for "minor uses." The EPA defines "minor uses" as registration for crops that have "small acreage" that provides "insufficient economic incentive for pesticide companies (i.e., registrants) to keep their products registered" as well as "pesticides applied for control of disease vectors such as mosquitoes, ticks, cockroaches, rodents, and disease-causing organisms." Basically, regulations have made registering these uses unprofitable, and the number of products available for these minor uses has shrunk.

Syngenta, for example, came to an agreement with the EPA in June 2000 to eliminate many of the minor uses—particularly home-related pest control—for the pesticide diazinon. Syngenta explained that the product was safe when used properly. The company said that agreeing to phase out certain uses was purely a "business decision."[19]

Similarly, in 2000, Dow AgroSciences and other registrants entered into an agreement with the EPA to phase out most home uses of chlorpyrifos, such as for home bug sprays and lawn and garden care products. While environmentalists cast the issue as related to public health, the elimination was simply a business decision by the companies, which could not maintain the registration under the new and unreasonable FQPA regulations. "Unfortunately, we found that continued efforts to retain certain uses of chlorpyrifos in the U.S. no longer made business sense in the current regulatory environment," explained a

Dow representative at the time.[20] The manufacturers maintained registrations for vital agricultural uses.

In fact, chlorpyrifos is one of few chemicals left for farmers to fight a wide range of pests on everything from soy to nuts to oranges. Its elimination would have made food production more difficult and crop damage more widespread. Such factors serve as disincentives for the development of new minor-use pesticides. As a result, it is becoming increasingly difficult for farmers to fight off pests and produce food.

Activist Groups' Chlorpyrifos Petition. Although chlorpyrifos meets the EPA's extremely stringent safety standards, environmental activists continued to hype risk as part of a campaign to ban all uses of chlorpyrifos. Shortly after it was reregistered in 2006, activists used a provision in FIFRA that allows citizens to petition the EPA to change pesticide registration decisions. The Natural Resources Defense Council and the Pesticide Action Network of North America petitioned the EPA in 2007 to revoke the "tolerance" for chlorpyrifos, which would amount to instituting a ban. The law requires the EPA to decide on such requests "after giving due consideration."[21]

The EPA indicated in 2009 that it would consider the petition as part of its reregistration review, which it launched that year.[22] There was little reason for the agency to jump the gun in 2007 and eliminate tolerances per the green groups' request. Chlorpyrifos had just completed an extremely rigorous review that determined it poses very low-level human health risks and was subject to a new registration review in 2009.

In 2011, the EPA issued a Preliminary Human Health Risk Assessment, which it revised after public comments. Then in December 2014, the agency issued a revised health assessment. The comment period for that was held open through April 2015.[23] That spring, PANNA and NRDC sued the agency to force a quicker decision on their petition. Ultimately, the Ninth Circuit Court of Appeals ordered the EPA to inform the court of its schedule by June 31, 2015.[24] The EPA replied later that month that it would propose a rule by April 2016. The following August, the court ordered the agency to make a decision on the petition by October 31, 2015.[25]

On November 6, 2015, the EPA issued a proposed rule accepting the environmentalists' petition to ban the pesticide, while noting numerous times in the *Federal Register* that the courts forced this action prematurely.[26] Specifically, the agency noted:

> At this time, the agency is unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard … EPA's finding that it cannot determine if aggregate exposure from all existing uses of chlorpyrifos are safe, does not necessarily mean that no individual tolerance or group of tolerances could meet the FFDCA 408(b)(2) safety standard.[27]

The *Federal Register* notice indicated most public exposures were below levels of concern, yet the agency was investigating whether there may be isolated cases where public exposure might exceed the standard in a limited number of watersheds. The rule explained:

> EPA's risk assessment supporting this proposed rule indicates that the primary source of risk comes from chlorpyrifos and chlorpyrifos oxon in drinking water in highly vulnerable watersheds (generally small watersheds where the land is agricultural and could be treated with chlorpyrifos (i.e., heavily cropped areas)). However, as explained in this proposed rule, some uses of chlorpyrifos do not by themselves present risks of concern from either food or drinking water and are only a concern when aggregated with all exposures to chlorpyrifos.[28]

The EPA further noted that simple labeling restrictions in key watersheds might resolve any issues with drinking water in agricultural areas. The agency stated:

> In addition, if EPA receives information that would allow it to better refine the location of at risk watersheds and protect such watersheds through appropriate product labeling restrictions, it is possible EPA could conclude that such mitigation would eliminate the need for some or all of the proposed tolerance revocations.[29]

The EPA began a 60-day comment period on the proposed rule and continued its analysis of chlorpyrifos levels in key watersheds. Before it was completed, PANNA sued the agency yet again to force a decision. As a result, in December 2015, the Ninth Circuit directed the EPA to finalize the rule by the end of the following year.[30] The court also required the agency to provide a status report in June 2016 detailing whether any circumstances had emerged that would prevent it from meeting the deadline.

Then, out of the blue, in March 2016, the EPA called a meeting of its Science Advisory Panel (SAP), an independent scientific review committee charged with advising the agency on pesticide-related science. The EPA wanted advice regarding a shift in its entire approach to assessing chlorpyrifos safety. Rather than rely on toxicological data generated from rodent tests, it suddenly wanted to place emphasis on epidemiological research—studies that assessed health impacts in humans exposed to trace amounts of the chemical.

This shift meant the EPA would no longer consider cholinesterase inhibition to be the key health risk for the purposes of setting its PoD for developing a tolerance. The agency wanted to focus on a single epidemiological study that reportedly found a statistical association between chlorpyrifos exposure and developmental issues. Conducted by Columbia University's Center for Children's Environmental Health (CCCEH), this study maintained that children whose mothers had higher exposures to the chemical—as measured in umbilical cords—were more likely to experience developmental delays or neurological problems such as autism.[31]

The study included 254 women and their babies, who were part of a larger study initiated in 1997 on the impact of environmental contaminants on children's health. The women selected lived in New York City, where the use of chlorpyrifos was common to control cockroaches in homes before the chemical was banned for that use (other than in baits) in 2000. The mothers were between the ages of 18 to 35, "who self-identified as black or Dominican." The study included interviews of the women to determine pesticide usage, but

the key marker for exposure was a one-time measurement of traces of the chemical in umbilical cords at delivery. Researchers then conducted exams of the children at ages one, two, and three to measure and track cognitive development and motor skills.[32]

The researchers then conducted a statistical analysis to determine if higher levels of chlorpyrifos in the umbilical cords correlated with reduced neurodevelopment among the children. They reported that the children whose mothers' umbilical cords had the highest levels of chlorpyrifos measured experienced greater developmental delays. Specifically, the study noted:

> Three substantive findings emerged from the study. First, by 3 years of age, significantly greater proportions of highly exposed children scored in the range of mental and motor delays, compared with those with lower exposures. … Second … adverse cognitive and psychomotor effects increased over time and these effects were present in both Dominican and black subjects, which supported the main conclusion of the study. Third, at 3 years of age, children who were exposed prenatally to high levels of pesticides were significantly more likely to score in the clinical range for attention problems, ADHD [Attention-Deficit Hyperactivity Disorder] attention deficit problems, and PDD [Pervasive Developmental Disorders] problems than were children with lower levels of chlorpyrifos exposure.[33]

Statistical associations alone do not prove cause-and-effect relationships. They might help build a case for effects if there is other supporting evidence, such as a significant number of other studies coming to the same conclusions, a biologically plausible explanation for such effects, findings reproduced by other researchers, or a combination of these. None of these factors applied in this case, and similar studies reported no such effects.[34]

Not surprisingly, members of this 2016 SAP meeting raised many concerns about the EPA's reliance on the CCCEH study. A majority of the panel members indicated that the agency's reliance on a single study for its risk assessment was "premature and possibly inappropriate."[35] In addition, panel members raised many other significant concerns about the design and implementation practices of this specific study as well. Concerns included:

- Using blood cord data as a measurement for exposure to infants was not appropriate. The panel noted: "Because many uncertainties cannot be clarified, the majority of the Panel does not have confidence that the CCCEH cord blood data on chlorpyrifos levels can accurately be used in quantitative risk assessment to determine a Point of Departure (PoD)." In addition: "Given the ~5 day terminal half-life of chlorpyrifos, it would seem unreasonable to think that the chlorpyrifos concentration in blood at birth would directly influence the chlorpyrifos blood concentration between 1 and 2 years of age."[36]
- This data set was particularly weak because it involved only one-time measurements, which may not represent actual exposure during pregnancy.
- The study offered inadequate information about "exposure patterns, labor and delivery, and blood collection."

- Much of the data was basically fabricated. Agency officials guesstimated data for a "large fraction" of samples because the chemical exposure was too low to detect in the samples. When researchers found no traces of the chemicals, they used a "default" number rather than zero, which they had to make up without any data to support it.
- The CCCEH researchers did not employ "good laboratory practices," which are government standards designed to ensure sound scientific practices.
- CCCEH researchers failed to make key portions of their data available, which means the study lacked transparency; hence the study could not be reproduced and validated.
- Biological plausibility that the chemical could impact neurodevelopment was questionable because all the levels measured were extremely low: concentrations were all in the "low parts per trillion."

After the SAP meeting concluded, the EPA filed a status report with the Ninth Circuit, reporting that "extraordinary circumstances" warranted a six-month delay in the finalization of the rule. The agency had made progress on the watershed analysis, but also had launched the new review of epidemiological research. In the status report, the EPA noted: "This is the first time EPA has proposed to use epidemiological data instead of acetylcholinesterase inhibition as the point of departure in determining the safe level of an organophosphate pesticide."[37] Rather than wait for the agency analysis, in August 2016 the court ordered the agency to finalize its decision by March 1, 2017.[38]

The EPA released a revised risk assessment in November 2016 that supported its proposed ban.[39] Even after being largely rebuked by the SAP for relying on this single, poorly designed study, the agency found a way to rationalize its risk assessment. The agency noted in the risk assessment that the SAP recommended the agency use what it called a "time weighted average," rather than blood cord data, to assess exposure in the study.[40] Used generally to measure occupational chemical exposures, a "time weighted average" is basically an estimation of exposure based on the amount of time a worker is exposed to a chemical at specific levels.[41]

However, the SAP did not officially recommend that the agency use that approach. The topic was merely raised and discussed by a couple of panel members at the meeting, and it was not included in the written SAP summary report. However, the blood cord data was not reliable, so the EPA needed to rationalize its approach with new data. It is not clear that this approach is appropriate for measuring exposures for an epidemiological study, but because the EPA was in a hurry, it proceeded without a SAP peer review or public comment period.

To that end, agency staff concocted data using a time-weighted average-like approach, and tried to fit it within the results of the CCCEH study. They contacted pest control firms and asked them to recall how these pesticides were applied in homes more than a decade earlier. The agency reported that applicators indicated that chlorpyrifos was mostly sprayed in crevices to fight cockroaches at that time. Then EPA staff guesstimated how much exposure women in these homes might have had from such chemical use. It is not clear how they

could use that data to estimate exposures for the individuals in the study. Perhaps they simply developed numbers based on assumptions that exposure levels were likely lower among women whose exposure occurred after the chemical was discontinued in 2000. In any case, they had no real hard data on such exposures.

How agency officials could consider this data to be better than the cord data is perplexing, as neither measurement seems compelling. In public comments, Ethan Mathews, of the National Corn Growers Association, observed: "Overall, EPA appears to have selectively responded to the SAP's comments in an attempt to put a supportive gloss to a pre-determined outcome, which is not supported by a full analysis of the SAP review."[42]

Some of the public comments called on the EPA to initiate another Science Advisory Panel to review this new approach. However, the activist petition and court order required the agency to issue a final decision by March 31, 2017. On March 25, EPA Administrator Scott Pruitt rightly rejected the activist petition, commenting: "By reversing the previous Administration's steps to ban one of the most widely used pesticides in the world, we are returning to using sound science in decision-making – rather than predetermined results."[43] The director of the U.S. Department of Agriculture's Office of Pest Management Policy, Sheryl Kunickis, applauded the decision, noting: "This is a welcome decision grounded in evidence and science. … It means that this important pest management tool will remain available to growers, helping to ensure an abundant and affordable food supply for this nation and the world."[44]

As the history shows, the NRDC/PANNA petition was flawed from the start. The EPA's unusual and unexpected shift toward reliance on a single epidemiological study was not only perplexing, it was unwarranted. Apparently, ideological activism, rather than science, has driven this debate. Pruitt's rejection of that approach reflects a shift back toward more science-based decision making.

Web of Anti-Pesticide Activism. Significantly, the one study the EPA used to justify its shift away from long-established science appears to be part of an orchestrated effort to push an anti-pesticide agenda. Although it is housed at a university, the Columbia Center for Children's Environmental Health, which produced the study, is not merely an academic organization focused on scientific discovery; it is more akin to an advocacy organization. It appears to be driven more by ideology than by science, and it works in tandem with a network of activists, both inside and outside of government, to promote regulations and chemical bans. Not surprisingly, their research efforts reflect this agenda and these biases.

On its website, CCCEH claims its staff act as "ambassadors of preventive measures to protect children from environmental threats" and that involves "efforts to remove unsafe chemicals and toxicants in our communities." [45]

CCCEH displays a one-sided anti-pesticide ideology that discusses only negative impacts from pesticides and none of their benefits.[46] While claiming that chemicals cause a host of health effects that are unproven, the group never discusses the real and measurable public health benefits they provide. Specifically, CCCEH fails to acknowledge these products'

critical role in helping farmers provide a safe and affordable food supply, as well as in fighting disease-carrying vectors, from mosquitos to ticks to rats.[47]

Modern, high-yield farming methods are crucial to fighting hunger, starvation, and malnutrition. These practices, which include pesticide use, have made it possible for food production to outpace population growth. As a result, people in both developed and developing countries have gained access to more food on a per capita basis. Per capita grain supplies have grown by 27 percent since 1950 and food prices have declined in real terms by 57 percent since 1980.[48] In 1929, before the use of many modern agricultural practices, Americans spent more than 23 percent of their income on food; today, the average American family spends less than 10 percent of its income on food.[49] That is quite an accomplishment, yet CCCEH ignores these realities.

CCCEH's collaborations also raise questions about its independence and research goals. The group notes that it is funded in part by the EPA itself, which then uses the research as a basis for advancing regulations. According to its website, CCCEH was launched thanks to funding by EPA and the National Institutes for Environmental Health Sciences (NIESH) grants.[50] While there is certainly nothing wrong with private organizations funding advocacy efforts, it is a conflict of interest for regulatory bodies such as EPA to fund efforts designed to promote the agency's own regulatory agendas. And it is not surprising that CCCEH receives funding from NIESH, a similarly focused, anti-chemical advocacy center housed inside the U.S. Department of Health and Human Services.[51]

The organization also works closely with other environmental activist and lobbying organizations that share its anti-chemical ideology. Among the "partner organizations" on their website are both PANNA and NRDC—the groups petitioning for the ban.

CCCEH also promotes questionable research and other similarly situated, quasi-activist organizations. For example, its website highlights recent publications from another activist-oriented group housed within the World Health Organization (WHO)—that makes many unsupportable claims about pollution and children's health.[52] For example, in a March 2017 news release, the WHO claimed that 1.7 million children die every year from "pollution," with the implication that "industrial pollution" and free enterprise are to blame. They maintain that the "solution" lies in "sustainable development"—government management of the economy—including government regulation of fossil fuels, pesticides, and other economic activity. [53]

But the "pollution" to which they refer includes untreated drinking water and heavy smoke related to rudimentary energy sources—challenges related to low-levels of economic development. Hence, the problem is not industrial activity, but the lack of it.

CCCEH's ideological leanings, financial support, and organizational alliances appear to clearly have an impact on its research. For example, the group states on its website that it focuses on "generating new findings" that link chemicals to developmental problems, which they can then use in various campaigns to eliminate these chemicals in commerce.[54]

In other words, CCCEH researchers are not necessarily looking to produce unbiased results. Rather, its analysts appear to be engaged in a process known as "data mining" to generate positive associations. Data mining involves working and reworking of data and assumptions until it generates positive associations, which can happen either by mere chance or because of researcher bias, whether intentional or not. The problem of such "data mining" can be so bad that James Mills of the National Institute of Child Health and Human Development lamented in a 1993 article in the *New England Journal of Medicine*: "If you torture your data long enough, they will tell you whatever you want to hear."[55]

Although these studies do not prove cause and effect, they generate headlines and concerns that have policy implications. CCCEH researchers are quick to make highly suspect claims about the associations they generate. In a May 2016 news release, one CCCEH researcher claimed that a statistical analysis CCCEH conducted "provides evidence" that the chemical Bisphenol A may be a significant contributor to the nation's "obesity epidemic."[56] This statistical finding is not compelling, as there are scientifically robust findings that explain increased obesity, such as the fact that people of all ages are eating more calories.[57] Moreover, that claim is contradicted by a substantial body of research on the topic showing that human exposure to BPA is simply too low to have any such impacts.[58]

CCCEH research also lacks certain quality control measures. Although they are funded by government and use their research to influence public policy, CCCEH researchers choose to not comply with government research standards known as "good laboratory practices" (GLP). The U.S. Food and Drug Administration originally established GLPs in 1978 to address fraudulently produced results submitted by industry to government agencies for the drug approval process. Industry must apply GLPs when conducting research for submission to regulatory bodies such as EPA for the purpose of ensuring, "uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) nonclinical safety tests."[59]

GLP studies undergo a different, more rigorous form of peer review than is commonly done for journal-published studies. For GLP studies, research labs must establish a "quality control unit"—a team of researchers who are independent of the individuals implementing the study. The quality control unit reviews study design protocols and then continues to monitor and review the research as it proceeds.[60] In addition, government agencies conduct additional reviews of the final study once it is submitted. These procedures ensure that the data for GLP studies is transparent and allow for reproducibility.

Not all privately conducted research needs to apply these standards, but since CCCEH is government-funded and its mission focuses on influencing public policy, its research would prove more helpful if its researchers followed GLP. But following GLP would make the research very transparent and more easily challenged, which may explain why CCCEH does not bother to follow these practices.

Clearly, CCCEH is not simply an unbiased scientific research group. Its research is riddled with methodological problems and likely tainted by researcher bias. CCCEH's flawed research does not warrant the EPA's shift away from the well-understood science that

supports the safe use of chlorpyrifos. Moreover, because they never consider benefits associated with chemicals, CCCEH's policy prescriptions are more dangerous to public health than the risks they allege.

Why We Need Chlorpyrifos. While the risks alleged about chlorpyrifos safety are speculative, its benefits are well proven. It helps farmers to produce an affordable and healthy food supply. Yet chlorpyrifos is one among a shrinking number of products available for farmers to fight serious pests that otherwise destroy many crops. Public comments filed in response to the November 2016 EPA chlorpyrifos risk assessment include numerous statements from farmers and university agricultural experts that reveal the extensive value of this chemical in crop protection.[61]

Citrus growers are among those with the most to lose from a chlorpyrifos ban. The national orange crop has shrunk in recent years, because of a bacterial disease transmitted by an insect known as the Asian citrus psyllid, which was accidentally introduced into the United States from Asia. Discovered in 2005, these insects transmit a bacterium that causes a disease known as huanglongbing (HLB), which prevents proper ripening of fruit.[62]

Referred to as "citrus greening," this disease has taken a heavy toll on the size of citrus crops, particularly in Florida. HLB "has reduced our production by almost 25 percent over the past decade," explains Michael W. Sparks, the CEO of Florida Citrus Mutual, in comments to EPA. The situation is so bad that growers are abandoning the citrus business and the industry, which supports 62,000 jobs, "is in a crisis situation," according to Sparks. According to Florida Agriculture Commissioner Adam Putnam, this disease has reduced orange production by 70 percent compared to 20 years ago. "Our brightest minds are working to find a solution, but until then, we must support our growers and provide them every tool available to combat this devastating disease," he told reporters.[63]

Chlorpyrifos is a key tool in efforts to save Florida's citrus industry, as it helps keep psyllid populations in check. Research has shown that one-time winter application of chlorpyrifos helps reduce overwintering populations of the Asian citrus psyllid, "for up to 6–7 months" while maintaining populations of other insects that feed on the citrus psyllid.[64]

Without access to chlorpyrifos, the Asian citrus psyllid may soon become a major problem in California as well. The citrus psyllid is present there now and expected to become more common on California's commercial citrus crops, explains University of California, Riverside Entomology Professor Joseph G. Morse in comments to the EPA. Right now, chlorpyrifos is helping control ants that destroy beneficial insects that otherwise would feed on the citrus psyllid. Farmers only need to use chlorpyrifos about once a year, applying it to tree trunks and soil, to keep the ants under control, and those applications have little impact on beneficial species. "Thus, chlorpyrifos is an essential material, which allows us to maximize biological control and greatly reduce the number of chemical treatments that would be needed otherwise," Morse explains. And right now, he noted, it's the only effective product available for controlling the ants.[65]

Citrus crops are just one example of the important role that chlorpyrifos plays in agriculture. Other commenters have pointed out numerous valuable and critical uses of chlorpyrifos. University of Arizona entomologist John Palumbo, in comments to the EPA, said it is key to affordable production of fruits and vegetables in Arizona and California. "I am concerned that the proposed actions would seriously impact their [farmers'] ability to economically produce crops," he noted.[66] He further explained that banning chlorpyrifos would likely force growers into "using less effective compounds that would need to be applied at much higher frequencies."[67] In other words, without chlorpyrifos, farmers would need to use more pesticides to protect crops.

These problems are just the tip of the iceberg, as multiple comments reveal serious impacts for a wide range of crops. Commenters also addressed adverse impacts for alfalfa,[68] almonds,[69] corn,[70] peanuts,[71] cotton,[72] soybeans,[73] wheat,[74] cranberries,[75] and other products. Elimination of chlorpyrifos would have widespread impacts in many agricultural sectors, and that would eventually affect consumers by raising the prices of healthy foods.

Conclusion. EPA Administrator Scott Pruitt's action in denying the petition to effectively ban chlorpyrifos was clearly a defense of sound science, halting an activist-driven effort to use junk science in order to justify an unwarranted chemical ban.

By reversing course, the EPA turned away from formulating policy based on the kind of agenda-driven research for which the Columbia University's Center for Children's Environmental Health—which is partly funded the EPA—has become well known. The CCCEH study the EPA had previously cited to justify banning chlorpyrifos was not based on any new, compelling science.

More importantly, a chlorpyrifos ban would be ill-advised. The benefits of products like chlorpyrifos in making food more affordable by helping farmers fight damaging pests and related disease far outweigh the very low and manageable health risks.

Notes

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https://ag.ny.gov/sites/default/files/2017_06_05_objections_final.pdf.
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