CENTER FOR
FOOD SAFETY

March 24, 2025

Charles Smith, Director, Registration Division
Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Submitted via Regulations.gov

Re: Comments on Petition for Rulemaking to Clarify Section 24 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136v; Docket No. EPA-HQ-OPP-2024-0562

Dear Mr. Smith and the Office of Chemical Safety and Pollution Prevention:

On behalf of itself and its 970,000 members and supporters, Center for Food Safety (CFS) appreciates this opportunity to comment on the Petition for Rulemaking to Clarify Section 24 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136v. CFS is a nonprofit public interest organization whose mission is to empower people, support farmers, and protect the environment from the harmful impacts of industrial agriculture. CFS has members across the country, including many thousands of conservationists, consumers, and farmers, and maintains offices in Portland, Oregon, San Francisco, California, and Washington, D.C. CFS is a recognized national leader on the issue of industrial agriculture and pesticides particularly. CFS's pesticide program has long advocated for rigorous, science-based safety testing and proper regulation of pesticide product uses, including timely review of the possible health risks posed by pesticides. CFS and its members are concerned about the impacts of industrial agriculture, specifically pesticide use, on biodiversity and human health.

Petitioners are 11 state Attorneys General who seek a rulemaking by EPA that would render state-required human health warnings on pesticide labels unlawful unless they conform to EPA's human health findings. EPA must reject this misguided effort as an illegitimate infringement of states' rights and contrary to FIFRA on multiple grounds. First, differing expert views of a pesticide's harmful effects within and outside the Agency mean there is no unitary standard against which a state warning could be judged unlawful. This is evidenced by differing assessments of the toxicity of glyphosate and/or other pesticides by three EPA divisions, an EPA Scientific Advisory Panel, and by NIH's expert agency on toxic substances. Moreover, FIFRA contemplates constantly evolving science and thus requires

registration review every 15 years to ensure that the safety standard determination ("unreasonable adverse effects") is still met.

Second, FIFRA expressly reserves states' rights to protect people and the environment above and beyond the federal standard. There are many reasons why states may want to be more protective, including that the findings of EPA pesticide risk assessments based on low, ideal-world exposure conditions must not be binding upon states that wish to warn of risks ensuing from the higher exposures that frequently occur in real-world farming practice. Further, states must be free to warn of harm like cancer for which the risk is often never zero, but rather increases with exposure level, and for which EPA has not established anything approaching an effective risk threshold.

Third, states' rights to warn must not be abridged because warnings serve the important policy goal of saving lives, in two major ways. Warnings such as those required by California's Proposition 65 incentivize manufacturers to switch to safer ingredients in their products. Also, the most important factor incentivizing pesticide applicators to wear exposure-reducing, life-saving personal protective equipment are governmental warnings of health risks like cancer and reproductive impairment, which are virtually never required by EPA's pesticide division. Ironically, depriving states of their right to warn would likely drive some to more extreme measures such as cancellation of pesticides or their uses, a power reserved to the states under federal pesticide law.

While pesticide labeling reform is badly needed, it must involve *greater* rather than less transparency. Current label warnings are keyed to the amount of a pesticide needed to kill a rat, and do not convey even that information effectively. Lacking entirely are warnings of cancer and other serious health impairments, despite, for example, dozens of EPA-approved pesticides that are "likely to be carcinogenic to humans" in use today.

Finally, Petitioners have expressed no legitimate interest in the broad rulemaking they seek, which appears to be motivated by antipathy to private tort actions involving glyphosate and undertaken on behalf of pesticide companies. The use of glyphosate and other pesticides is not threatened by the *status quo*; whereas states could undoubtedly save lives by warning of specific pesticidal human health threats that EPA's pesticide division fails to acknowledge and/or warn against.

For the legal and policy reasons below, EPA must not grant this petition.

I. REQUESTED RULEMAKING IS CONTRARY TO FIFRA

Petitioners seek an amendment to EPA's regulation on false or misleading statements, which implements FIFRA Section 136(q)(1)(A), which in turn states that a pesticide is misbranded if "its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular." EPA's regulation, 40 C.F.R. § 156.10(a)(5), repeats this definition and provides

"examples of statements or representations in the labeling which constitute misbranding." Petitioners would have EPA add an additional "example," namely:

> (xi) Statements or conclusions regarding the product's human health effects, including the likelihood of causing cancer, birth defects, or reproductive harm, that are different from EPA's findings and conclusions stated in its human health risk assessment conducted during the registration review of the product's principal active ingredients.

Petition at 2. This request has several limitations, namely: 1) it is related only to human health effects, including likelihood of cancer; 2) it focuses solely on EPA's findings in its human health risk assessment conducted specifically "during the registration review" of the product's active ingredient. The requested amendment therefore leaves out any statements as to ecological effects, and any EPA findings or conclusions during *other* EPA assessments, such as initial registration, instead specifically naming "registration review," which is a particular review of already-registered products that Congress requires every 15 years. 7 U.S.C. § 136a(g). There is a clear motive for this strangely narrow request: to benefit the pesticide industry, as outlined below.

However, the human health risk assessment (like any other assessments that are part of the larger registration process) is not a final orders of EPA, nor do they have independent effect under FIFRA or impose requirements. 7 U.S.C. §§ 136a(c)(5) (determination as to whether use of pesticide will cause "unreasonable adverse effects" is informed by risk assessments as well as benefits in a cost-benefit analysis).

Nor does the requested amendment implicate EPA's "misbranding" authority under FIFRA. FIFRA defines misbranding as bearing "any statement…which is false and misleading in any particular," and *inter alia,* as when "the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(G). The fact that pesticides are *registered* does not mean they are not misbranded, hence pesticide manufacturers' continuing duty to comply with labeling requirements and "report incidents involving a pesticide's toxic effects that may not be adequately reflected in its label's warnings." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 438 (2005). While a statement implying safety inaccurately *would* be misbranding, it does not work the other way around: a factual statement that does not overstate safety is *not* misbranding. *See, e.g.*, *Nat. Res. Def. Council v. EPA*, 38 F.4th 34, 45-52 (9th Cir. 2022).

Further, whether a particular pesticide product is "misbranded" is a factual determination that depends on whether the warnings on the label are enough to protect public health and the environment. S. Rep. No. 92-838, at 14 (1972). Such determinations are contemplated through FIFRA's "stop sale or use" authority to EPA, which like other enforcement orders are reviewable either by an ALJ or federal court. 7 U.S.C. § 136k, 136l,

136n(c). Moreover, FIFRA does not prevent a state from enforcing FIFRA's labeling rules, such as imposing its own sanctions on pesticide manufacturers that sell misbranded pesticides. *Id*. at 442.

The petitioned regulation would also upend FIFRA's explicit recognition of the states' ability to regulate pesticide use beyond EPA's registration and to impose "duty to warn" protections for residents that do not differ from FIFRA's requirements. FIFRA, like other environmental statutes, contemplates federal and state cooperation and allows states to regulate above and beyond the federal floor. *See Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991); 7 U.S.C. §§ 136u, 136v(a) (stating that a "State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extend the regulation does not permit any sale or use prohibited by this subchapter"), 136w-1 (state primary enforcement).

States are free to be *more* protective than EPA, just not *less* protective. *Id*. § 136v(a); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). Even under FIFRA's express preemption clause, *Bates* held that state laws requiring reasonably safe products were not "requirements" for "labeling or packaging" such that they would be preempted under the FIFRA clause. *Id*. at 444. Further, FIFRA only prohibits "state-law labeling and packaging requirements that are '*in addition to or different from 'the* labeing and packaging requirements under FIFRA." *Id*. at 447. State laws that impose common law duties equivalent to FIFRA's misbranding prohibition are thus not preempted. *Id*.

Examples of ways in which the requested rulemaking is contrary to FIFRA and sound policy are provided below.

II. PETITIONERS LACK LEGITIMATE INTEREST IN REQUESTED RULEMAKING

Petitioners have expressed no legitimate interest in seeking this rulemaking. In the introduction (Identity and Interest of Petitioners), they state that agriculture is important to their states and make mostly false assertions about the putative benefits of the herbicide glyphosate and glyphosate-resistant crops (*see* Addendum). Yet there is absolutely no threat to their states' agriculture, nor to their farmers continued use of their pet herbicide, that the rulemaking would address. They reference a "court-made gap" in FIFRA's regulatory framework that affects "countless" pesticides but provide no evidence of a "gap" nor how this putative gap affects or disadvantages their states' farmers or agriculture in any way. That Petitioners take a dim view of private tort actions regarding glyphosate ("needless litigation") is irrelevant to the rulemaking they seek. And it is not Petitioners' job to represent the interests of the pesticide "industry," as they openly purport to do, with respect to pesticide labeling. In the end, this petition is nothing more than the effort of 11 state attorneys general to rob 39 other states (and their own) of the right to make critical policy decisions on pesticides to protect the health of their citizens. But this is expressly protected by FIFRA. *See supra*; 7 U.S.C. §§ 136u, 136v(a) (states may regulate for additional safety, but not be less protective); 136w-1 (state primary enforcement).

Although the rulemaking Petitioners seek would be extremely broad—affecting all state policy regarding all pesticides in every state of the Union—it is clearly grounded in antipathy to a single state's policy with respect to a single pesticide: the state is California and the pesticide is glyphosate.

Petitioners may have the naïve, mistaken view that regulatory decisions are purely a scientific matter, that science always delivers black and white conclusions, and that EPA's Office of Pesticide Programs (OPP) is a neutral arbiter of the science on pesticide toxicity. Thus, they fail to understand that competent scientists can have differing views on the toxicity of a particular chemical; that EPA's OPP routinely approves quite harmful pesticide uses; and that human health-related warnings can serve important state policy objectives – and save lives. It would be contrary to FIFRA and unlawful under the Administrative Procedure Act (APA) to abridge states' rights to warn, and certainly not to serve the financial interests of the pesticide industry. 5 U.S.C. § 706(2).

III. SOUND POLICY AND SCIENCE REQUIRES DENIAL OF PETITION

A. Differences Among Competent Authorities Within and Outside of EPA

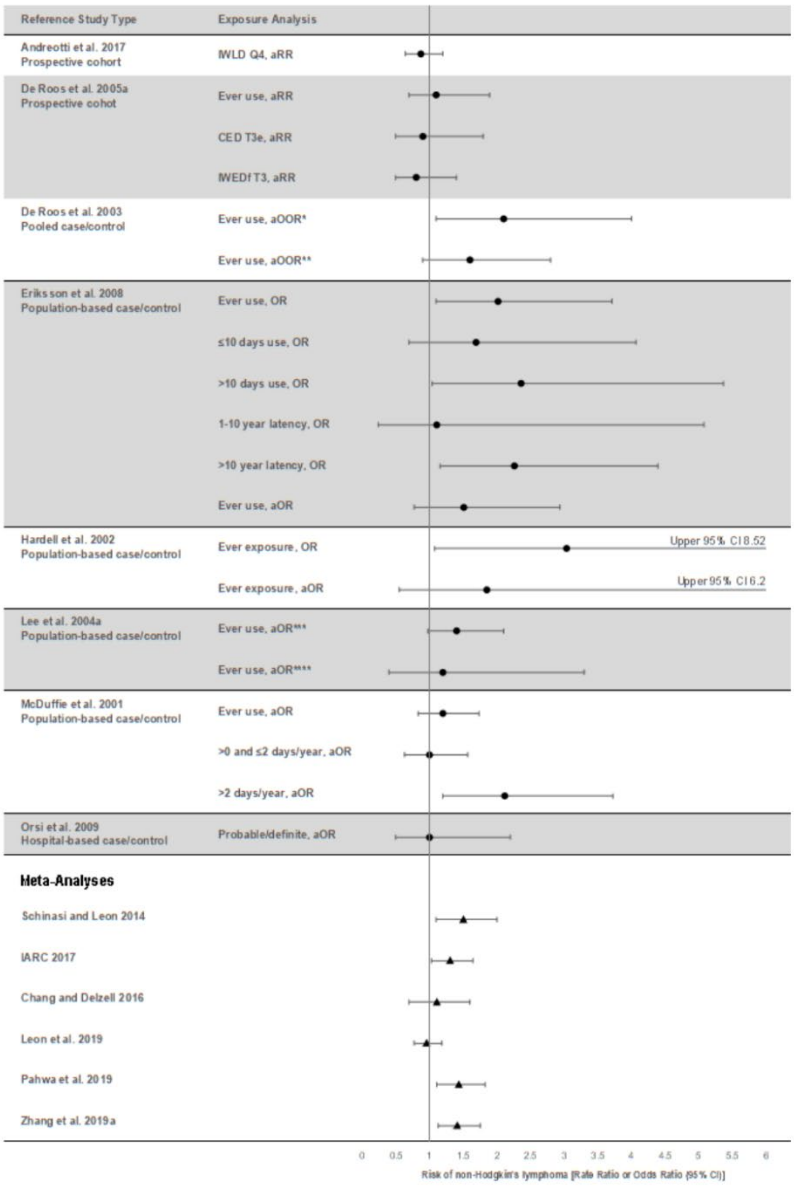
Petitioners seek to prohibit any warnings on pesticide labels that deviate one iota from EPA's human health findings. But EPA is a large agency, and different divisions and scientists within the Agency may well disagree on the health harms of a particular chemical or pesticide. As explained above, a factual statement that does not *downplay* safety risks is not "misbranding" under FIFRA, and EPA's one risk assessment for human health harms is not an order with the force of law. *Supra*; 7 U.S.C. §§ 136(q)(1)(G); *compare* 136a(c)(5) *with* § 136k, 136l, 136n(c).

Take the example of glyphosate. EPA's Office of Pesticide Programs (OPP) classified glyphosate as "not likely to be carcinogenic," but EPA's Office of Research and Development (ORD) harshly criticized OPP's draft evaluation of glyphosate's carcinogenicity (EPA ORD 12/14/15), and ORD scientists favored classifying glyphosate as "likely to be carcinogenic to humans," or at least as having "suggestive evidence of carcinogenicity" (EPA ORD 12/7/15). OPP applied the "not likely" designation – which requires "robust" evidence that the pesticide does not cause cancer (EPA 2005, p. 2-57) – despite being unable to conclude that glyphosate does not cause non-Hodgkin lymphoma,[1] the cancer most associated with glyphosate (see Figure below). This blatant contradiction, together with numerous other violations of the Agency's Guidelines for

[1] After discussing epidemiology studies and meta-analyses, most of which showed an association between glyphosate exposure and NHL, EPA concluded as follows: "a conclusion regarding the association between glyphosate exposure and risk of NHL [non-Hodgkin lymphoma] cannot be determined…" (EPA OPP 2017b, p. 68).

Carcinogen Risk Assessment (EPA 2005) that OPP claimed adherence to (EPA OPP 2017a, p. 15), led the Ninth Circuit Court of Appeals to rescind EPA's latest human health assessment of glyphosate in 2022 (CFS 2022). Thus, the World Health Organization's International Agency for Research on Cancer (IARC) is far from alone in recognizing glyphosate's carcinogenic potential (Guyton et al. 2015, IARC 2017), the evidence for which has only accumulated in recent years (e.g. Zhang et al. 2019, Leon et al. 2019, Weisenburger 2021, Chang et al. 2023, Rana et al. 2023).

Figure 2-4. Risk of non-Hodgkin's Lymphoma Relative to Self-Reported Glyphosate Use or Exposure



*Logistic Regression; **Hierarchical regression; ***Non-Asthmatic farmers; ****Asthmatic farmers

a = adjusted; CED = cumulative exposure; IWED = intensity-weighted exposure days; IWLD = intensity-weighted lifetime days; OR = odds ratio; Q4 = 4th quartile; RR = rate ratio; T3 = 3rd tertile

Excerpted from: ATSDR (2020), p. 116. Epidemiology studies on glyphosate use and incidence of NHL in applicators. Filled circles to the right of the vertical line represent increased risk of NHL in glyphosate-using farmers. Meta-analyses represent the central tendency of a group of underlying epidemiology studies.

That EPA's pesticide division (OPP) did violate those Cancer Guidelines was demonstrated not only by the Ninth Circuit, but also by EPA's Office of Research and Development (ORD) (EPA ORD 12/14/15, 12/7/15), and by a FIFRA Scientific Advisory Panel of outside experts that EPA convened to assess OPP's draft glyphosate cancer evaluation (FIFRA SAP 2017, pp. 18, 21). These Cancer Guidelines provide essential rules for data interpretation as well as criteria for classifying chemicals into one of five groups based on the strength of evidence that they cause or do not cause cancer. The Guidelines were drafted by EPA's Risk Assessment Forum, an interagency "standing committee of senior EPA scientists which was established to promote Agency-wide consensus on difficult and controversial risk assessment issues and to ensure that this consensus is incorporated into appropriate Agency risk assessment guidance."[2] Similarly, ORD is a non-regulatory division of EPA that is better able to deliver impartial toxicity information than arms of EPA involved in regulation, like OPP:

> "The placement of the IRIS [Integrated Risk Management System] program in ORD is *intentional*. It ensures that IRIS can develop *impartial* toxicity information *independent of its use by* EPA's program [e.g. OPP] and regional offices...."[3]

ORD assessments are explicitly described by EPA as appropriate for use by "state and local health agencies, other federal agencies, and international health organizations."[4] Thus, a state might justifiably choose to add health warnings to pesticide labels based on the impartial toxicity information provided by EPA's ORD.

OPP also differs from other EPA divisions with respect to various other pesticidal harms, which are investigated primarily via animal feeding trials, since it is unethical to conduct human experimentation. For instance, OPP once regarded the kidney as the organ most sensitive to damage from glyphosate, based on a registrant-submitted rat study (EPA OPP 7/21/82, EPA OPP 3/3/83). ORD has expressed high confidence in the quality of that study as evidence of glyphosate's low-dose kidney toxicity (1/31/87), but OPP illegitimately dismissed it in 1993, enabling a huge 20-fold increase in the maximum "safe" level of glyphosate exposure (EPA OPP 1993, pp. 15-16, 19). EPA's Office of Water (EPA OW), which administers the National Primary Drinking Water Regulations, also cites "kidney problems"

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[2] https://archive.epa.gov/raf/web/html/index.html, last visited 3/20/25.
[3] https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system, emphasis added, last visited 3/20/25.
[4] Ibid.

as well as "reproductive difficulties" as potential human health effects from consuming water contaminated with glyphosate above the maximum contaminant level (MCL).[5]

Outside of EPA, the Agency for Toxic Substances and Disease Registry (ATSDR), a division of NIH's Centers for Disease Control and Prevention, published a Toxicological Profile for Glyphosate (ATSDR 2020). Like ORD's assessments, ATSDR Profiles present toxicological information for "health professionals at the Federal, State and local level; interested private sector organizations and groups; and members of the public" (Ibid., Foreword). ATSDR discussed numerous studies showing that low oral doses of glyphosate and glyphosate formulations have adverse reproductive, developmental and endocrine effects in rodent experiments, particularly in males (ATSDR 2020, pp. 74-80). Reproductive effects include testicular degeneration, increased sperm abnormalities and delayed first estrous in females (Ibid., pp. 75-76). Developmental anomalies in offspring following exposure *in utero* and directly after birth include altered testes morphology, sharply reduced sperm counts, thinning of seminiferous tubules, increased anogenital distance, and smaller fetal size in females (Ibid., pp. 77-80). Reduced blood levels of testosterone were indicative of adverse endocrine effects in young male rodents (Ibid., p. 71). In contrast, OPP acknowledges none of these low-dose kidney, reproductive, developmental or endocrine effects.

Finally, EPA's Office of Water lists potential effects from long-term exposure to several pesticides besides glyphosate in drinking water. Both the effects and the safety thresholds established by EPA OW can differ sharply from those of OPP. As one example, for atrazine, the most sensitive target of toxicity identified by OPP is the kidney (EPA OPP 2018, p. 63, Table 4.7), while for EPA OW it is the cardiovascular or reproductive systems.[6] OPP's safety threshold[7] of 0.0676 mg/kg bw/day (Ibid., p. 63) is over 600-fold higher (less protective) than the exposure at EPA OW's atrazine MCL of 0.003 mg/liter.[8] In line with EPA's Office of Water, NIH's Agency for Toxic Substances and Disease Registry highlights atrazine's reproductive impacts, also noting potential damage to the liver, kidney and heat

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[5] https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations, last visited 3/20/25.

[6] https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations/.

[7] In EPA parlance, the oral "chronic reference dose" or "RfD," which is the maximum amount of a toxicant that can be consumed daily in food/water, for a lifetime, without adverse effects; formerly called "acceptable daily intake" or "ADI."

[8] https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations/. The notation "mg/kg bw/day" = milligram [atrazine] per kilogram body weight per day. Using standard EPA assumptions, a 60 kg adult would consume 2 liters of water per day containing 0.006 mg atrazine (2 liters x 0.003 mg/liter atrazine = 0.006 mg). On a per kg body weight basis, 0.006 mg/l divided by 60 kg = 0.0001 mg/kg bw/day. EPA OW's safety threshold is thus over 600 times lower (more protective) than OPP's 0.0676 mg/kg bw/day.

(ATSDR 2003, p. 5). California's Prop65 likewise classifies atrazine as a female reproductive and developmental toxin.[9]

Competent scientists can reach different conclusions in the complex field of toxicology. Factual statements about risks are not "misbranding" under FIFRA, nor can a state be barred from using its discretion to warn of human health risks recognized by one EPA division, such as the Office of Research and Development or the Office of Water, or by NIH's expert agency on toxic substances, just because EPA's pesticide division does not acknowledge them.

B. Under FIFRA, States Retain the Right to Warn of Health Risks of Real-World Farming Practice

The necessity of federalism and the robust role reserved to the states in FIFRA is illuminated by the difference between EPA's assessments and the real-world use of pesticides. EPA risk assessments of and registration decisions on pesticides assume low exposure levels in an ideal world where nothing goes wrong, the weather is typical rather than extreme, and applicators comply with the letter with every single prescription on the label. But in the real world, accidents happen: the hose on a backpack sprayer disconnects, dousing the applicator with the pesticide; or a rubber glove rips while tank-mixing, exposing the hand to concentrated pesticide solution. In the real-world, nature cannot be controlled: unpredictable gusts of wind blow spray back onto the applicator, or a farmer inhales pesticide that vaporizes in high temperatures. And sometimes it is difficult or even risky for applicators to wear all the personal protective equipment (PPE) prescribed on the label, such as long-sleeved shirts, boots, aprons and respirators (Garrigou et al. 2020). Reasons given for not using PPE include discomfort (Van Wely 2017), impairment of work productivity (Snipes et al. 2016), and PPE's exacerbation of hot, humid conditions, imposing physiological burden and heat stress, with possible adverse health consequences (Nigg et al. 1992, 1986; Grimbuhler and Viel 2018).

In each of these scenarios, applicators can be exposed to far more pesticide than anticipated by EPA in its risk assessment. Higher exposures in such circumstances can cause or increase the probability of harm that the ideal-world exposures modeled by EPA for making safety determinations do not. EPA chooses to ignore such high-dose exposures in deciding whether pesticides and their various uses are safe or hazardous.

Another real-world harm that states may want to protect against, above and beyond what EPA does, is the impact of the *whole* pesticide product formula, not just the active ingredient. Most of EPA's required tests for impacts to human health and the environment are based on the active ingredient, rather than the whole formula of the pesticide, which includes "inert" ingredients, some of which are designed to make the pesticide more effective, aka more dangerous. *See generally*, 40 C.F.R. Part 158. As Donna Farmer, chief toxicologist for Monsanto, stated back in 2003: "The terms glyphosate and Roundup

[9] https://oehha.ca.gov/chemicals/atrazine.

cannot be used interchangeably nor can you use 'Roundup' for all glyphosate-based herbicides any more. For example you cannot say that Roundup is not a carcinogen…we have not done the necessary testing on the formulation to make that statement. The testing on the formulations are not anywhere near the level of the active ingredient." (Farmer 2003).

This is why Congress reserved to the states the right to regulate pesticide use above and beyond EPA: namely, to warn of human health risks that applicators incur in real-world farming practice, but to which EPA, in its implementation of FIFRA, is blind. State bans on chlorpyrifos are examples (California, Hawaii, Oregon, etc), as are state designations of pesticides as "restricted use" or imposition of further restrictions their outdoor uses (although registered under FIFRA).[10] If states can ban active ingredients and/or uses of pesticides outright, it is clear they also retain the right under FIFRA to require warnings about human health risks.

C. States Retain the Right to Warn of Health Risks Such As Cancer

For the reasons explained above, states retain the ability under FIFRA to provide additional remedies for violations of FIFRA's requirements, beyond just misbranding, even if they do not expressly incorporate FIFRA's standards as elements of a cause of action. *Bates*, 544 U.S. at 442-445. This includes common law rules and laws that require manufacturers of products to market reasonably safe products and warn against harms, such as cancer, from using said product. *Id.* at 444.

The acceptable risk of cancer for EPA may not be protective enough for a given state, and FIFRA preserves that state's right to be more protective than EPA. When carcinogenic chemicals induce cancers by mutating genes, or the mode of action is unknown, EPA calculates the risk of cancer using a low-dose, linear extrapolation approach (EPA 2005, Sections 3.3.1, 3.3.3). This approach assumes there is no threshold below which a carcinogenic agent is unable to cause cancer. The risk of cancer increases linearly (proportionally) with the level of exposure, starting with zero (EPA 1/31/25).

Petitioners may be ignorant of the fact that OPP regards 204 pesticides as raising carcinogenic concerns: 129 are either possible human carcinogens or have suggestive evidence of carcinogenicity, while 67 are likely to be carcinogenic to humans or probable

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[10] *E.g.*, https://www.xerces.org/blog/states-make-way-for-pesticide-reforms; https://environmentamerica.org/oregon/center/articles/will-oregon-become-the-13th-state-to-save-the-bees/. New Jersey's Hazardous Substance Fact Sheet for paraquat says: "Paraquat may be a carcinogen in humans. There may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level." *See* https://nj.gov/health/eoh/rtkweb/documents/fs/1458.pdf. In contrast, EPA classifies paraquat as Group E - Evidence of Non-Carcinogenicity for Humans.

human carcinogens (EPA OPP 2023).[11] With rare exceptions, OPP only calculates the *risk of cancer*[12] when the pesticide is designated carcinogenic to humans or a likely/probable human carcinogen (EPA 2005, Section 3, pp. 3-1 to 3-2). As noted above, cancer risk increases with exposure. EPA calculates the risk of cancer for consumers based on the amount of a pesticide's residues in food and water. Users of a pesticide have far higher exposure and cancer risks because they absorb the pesticide through their skin and inhale fine mist or vapor. EPA calculates cancer risks for various pesticide mixing and application scenarios that involve differing levels of exposure. The Agency's official "benchmark level of concern" is one additional cancer victim among one million exposed to the pesticide (1×10^{-6}); risks below this level are deemed "negligible" (EPA 2013, p. 40025-40026). Whatever one's view of this "benchmark," in practice OPP approves pesticide uses that result in far higher cancer risks. We discuss three examples below: iprodione, thiophanate-methyl and cyanazine.

Iprodione: OPP estimates that in various exposure scenarios, the "likely carcinogenic" fungicide iprodione results in cancer risks from 120 to over 7,000-fold greater than EPA's nominal 1 in 1 million "benchmark level of concern." Drinking water and food contaminated with iprodione can cause up to 1.2 additional cases of cancer among 10,000 exposed to it (EPA OPP 12/20/21, p. 19, Table 2).[13] Up to 3 of 10,000 homeowners who are exposed to the fungicide after it has been applied to their lawns (turf) can expect to contract cancer (EPA OPP 12/20/21, p. 21, Table 4). For every 1,000 commercial landscapers who mix, load and apply wettable powder (WP) formulations of iprodione for broadcast spraying on turf using backpack sprayers, OPP estimates that up to 7 will become cancer victims; and this 7 in 1,000 cancer risk estimate assumes the landscapers

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[11] EPA OPP places pesticides into one of five hazard categories: "Not likely to be carcinogenic to humans," "inadequate information to assess carcinogenic potential," "suggestive evidence of carcinogenic potential," "likely to be carcinogenic to humans," or "carcinogenic to humans," based on the strength of the evidence for carcinogenic potential (EPA 2005, Section 2.5). Some older pesticides are designated using a 1986 classification system, e.g. "probable human carcinogen" or "possible human carcinogen" (EPA 2023). Note that the 67 pesticides that are likely/probable carcinogens excludes 8 others that are likely carcinogenic at high but not lower doses. Not all pesticides in EPA's list are currently in use.

[12] The 5 ***hazard*** classifications detailed in the last footnote reflect the likelihood or unlikelihood that the pesticide is able to trigger carcinogenic changes, without considering exposure level. The ***risk*** of cancer depends upon the level of exposure to a carcinogen. This approach follows a fundamental principle of toxicology: risk = hazard x dose, equivalent to risk = toxicity x exposure (EPA 1/30/25).

[13] See Refined food & water (turf EDWC is 125 ppb): 1.2×10^{-4}. EDWC = estimated drinking water concentration. $1.2 \times 10^{-4} = 1.2 \times 1/10{,}000 = 1.2$ in 10,000 risk of cancer.

are wearing "baseline apparel and chemical-resistant gloves" (EPA OPP 12/20/21, pp. 24-25, Table 6).[14]

Thiophanate-methyl: A second example is thiophanate-methyl, a fungicide that breaks down to the more persistent carbendazim (aka MBC). Up to 4 of 10,000 people who drink water contaminated with MBC from application of thiophanate-methyl to ornamentals will contract cancer, according to EPA (EPA OPP 8/27/20, pp. 9-10).

Cyanazine: A third example is cyanazine, an herbicide introduced in 1971 and used in the tens of millions of pounds annually on corn and cotton over the next three decades (EWG 1995).[15] In the mid-1980s, EPA discovered that cyanazine was teratogenic, and required a label warning that it "may be hazardous to your family's health" because cyanazine "cause[s] birth defects in laboratory animals" and "[e]xposure of women of child-bearing age to cyanazine should be avoided" (EPA OPP 1984, p. 6). In 1994/1995, over two decades after its introduction, OPP realized that cyanazine was a more potent carcinogen than any other widely used pesticide (EWG 1995), and on that basis accepted its manufacturer's proposal to phase it out over the next seven years (EPA OPP 2000).[16] EPA estimated that an average of up to 1.2 commercial applicators would contract cancer among every 100 exposed while mixing, loading and applying it to corn via ground boom (EPA OPP 1994, pdf pp. 1, 27, Table 9).[17] This 1.2 in 100 cancer risk is 12,000 times OPP's putative 1 in 1 million "benchmark level of concern."

The acceptable degree of cancer or other health risk is not a scientific question; rather, it is a policy matter[18] that falls squarely within states' rights. Should a state object to an EPA-approved pesticide use that can result in 1 or more cancer victims among 100,000, 10,000, 1,000 or 100 exposed to it, the state's right to ameliorate the situation must not be abridged in any way. One response would be to simply deny state registration of the pesticide; a second would be to prohibit the high-risk uses of the pesticide, but not others. A state might also choose to impose usage restrictions more stringent than those of OPP, in

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[14] See entry under "WP" for Landscaping (turf; broadcast): $7 \times 10^{-3} = 7 \times 1/1{,}000 = 7$ in 1,000.

[15] https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2019&map=CYANAZINE&hilo=L&disp=Cyanazine.

[16] EPA's OPP rarely bans a pesticide without first obtaining approval to do so from the manufacturer and normally allows continued use of "existing stocks" for several to many years after cancellation of the registration.

[17] Page 1: "The excess individual cancer risk estimates range from 10^{-6} to 10^{-2} for typical use of atrazine, simazine and cyanazine." Page 27: Cancer risk of 1.2×10^{-2} for Corn – Commercial/Ground boom: M/L/A – open/open, assuming dermal absorption of just 2%. M/L/A = mixing/loading/applying; open/open refers to open loading systems and a tractor with an open rather than a closed cab (p. 13). $1.2 \times 10^{-2} = 1.2 \times 1/100$ or 1.2 in 100.

[18] As EPA's Office of Water states in another context: "The target cancer risk level used in determining if there is an unacceptable risk level is a policy decision" (EPA 2025, p. 54).

hopes of reducing exposure and the associated risk. States have the authority under FIFRA to do any of these things. One example is New York State's refusal to register the herbicide fluthiacet-methyl, classified by EPA as a probable human carcinogen. The state held that registration of a product classified as likely to be a human carcinogen was not warranted unless it either replaces a product that poses greater risks or the need for the product is significant (NYS 2000).

Because "states are independent sovereigns in our federal system, [the Supreme Court has] long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Bates*, 544 U.S. at 449 (internal citations removed). But the rulemaking Petitioners seek would deny to states their "areas of traditional state regulation" like the less extreme option of a warning, rather than one that entails prohibition or restriction of use. *Id*. States have a "long history of tort litigation against manufacturers of poisonous substances" which adds force to the FIFRA federalism scheme which the Petition seeks to upend. *Id*.

A state might opt for a warning over the other options for several sound policy reasons within their rights to protect their residents: if the pesticide or its particular uses were deemed too valuable to cancel altogether, or if additional usage restrictions were considered infeasible. A state might decide that warning of a particular health harm, such as cancer, would incentivize compliance with exposure mitigation measures, such as personal protective equipment, reducing risk (see next section). A state might also choose a warning over prohibition in hopes of avoiding a potential lawsuit against the state by the pesticide's manufacturer. The latter scenario played out when Monsanto sued the State of Arkansas for not approving the company's volatile XtendiMax herbicide (Steed 2017), one of several dicamba formulations that since 2017 has rampantly drifted to damage millions of acres of crops across the country (EPA OPP 12/15/21), and has been banned twice by courts in lawsuits brought against the EPA for violating federal pesticide law (Freese 2024).

D. Label Warnings Save Lives

Warnings can have at least two life-saving effects. They can motivate pesticide manufacturers to develop less hazardous alternatives, and they incentivize applicators to reduce exposure and hence risk by wearing protective gear, known generally as personal protective equipment.

1. *Warnings incentivize manufacturers to develop safer products*

An example of the former is California's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act, which was enacted as a ballot initiative in 1986 by over two-thirds of California voters frustrated with government inaction on regulating toxic chemicals (see Tabuchi 2025 and Ohayon et al. 2025 for the following discussion). Proposition 65 requires companies to warn the public about the presence of chemicals in their products that are known to the State of California to cause cancer or developmental or reproductive harm. California's Office of Environmental Health Hazard Assessment (OEHHA) administers Proposition 65, which now lists roughly 900 chemicals in one or more of the three

categories. Ohayon et al. (2025) conducted interviews with senior personnel at major manufacturers across a range of sectors, including the pesticide industry, and found that the law has strongly incentivized removal of Proposition 65-listed chemicals from their products to avoid warnings, and has also increased transparency regarding the chemical composition of products throughout the supply chain. In short, Proposition 65 has made a full range of consumer products safer and thus saved lives.

Not all products containing Proposition 65-listed carcinogens trigger the warning requirement. A warning is not required if lifetime use of the product poses no significant risk. To this end, OEHHA often establishes a "no significant risk level" (NSRL) of exposure, also called the safe harbor level, below which a warning is not required. For example, the NSRL for glyphosate is 1,100 ug/day (OEHHA 2018). Because the exposure of a typical home user of a dilute, ready-to-use glyphosate-containing weedkiller product falls below the NSRL, that product would not require a Proposition 65 warning (OEHHA 2021, p. 7).

2. *Warnings incentivize users to adopt safer practices*

Use of personal protective equipment (PPE) while mixing, loading and applying pesticides can reduce applicators' exposure and health risks substantially. PPE includes limb-covering shirts and pants, chemical-resistant gloves, rubber boots, coveralls, safety goggles and respirators. For instance, EPA estimates that workers reduce their inhalational exposure by 90% when wearing a PF10 respirator, and their body exposure by 75% when wearing "double layer" clothing (i.e. long-sleeve shirt, long pants, shoes and socks, coveralls) (EPA OPP 2021, p. 14).

However, numerous studies demonstrate low compliance with PPE requirements. For instance, in a study of 220 Wisconsin dairy farmers, investigators surveyed the farmers' compliance with PPE requirements for 15 different restricted use pesticides on their first pesticide application of the 1997 growing season. Only 2.5% to 8.8% of the farmers wore all the personal protective equipment required for three of those most commonly used: dicamba, atrazine and cyanazine. For these same pesticides, from 38.6% to 56.9% of farmers wore none of the required PPE (Perry et al. 2002). Many thousands of farmers used cyanazine in the early 1990s, when it was applied to a fifth of all corn nationwide.[19] If the low PPE compliance in the Wisconsin study was typical of all U.S. corn farmers, then this one pesticide alone must have led to numerous cancers and likely many deaths, given cancer risks of up to 1.2 in 100 (see discussion above).

In a study of PPE use by farmworkers who mixed or applied pesticides in Washington State, Strong et al. (2008) found that 35% and 45% rarely or never wore gloves or protective boots, respectively, while only 38% and 41% wore them usually or always.

[19] See figures for cyanazine application to corn from 1990-1994, accessible from files at: https://usda.library.cornell.edu/concern/publications/2n49t1699?locale=en#release-items.

Reynolds et al. (2007) found that a "substantial portion" of Keokuk County, Iowa farmers "did not use gloves even for mixing" pesticides, an activity that involves high dermal exposure, and that even when used, they were often made of cloth or leather, which do not offer meaningful protection. In a study of fungicide use by orchard farmers in North Carolina and Iowa, Hines et al. (2007) found that a third or more of farmers did not wear rubber gloves, roughly half did not use respirators, while two-thirds did not don protective outwear and two-thirds did not wear rubber boots. Garrigou et al. (2020) reviewed dozens of additional studies documenting low PPE use, and made the important point that because some hazardous pesticides are only approved on the assumption that wearing PPE will limit exposure and thus risk, real-world use involving low compliance with PPE "requirements" likely results in substantial pesticide-induced disease.

As might be expected, among the strongest factors motivating applicators to wear PPE are concern for one's health and knowledge of pesticides' harmful impacts. Damalas and Abdollahzadeh (2016) found that the two strongest determinants of Greek cotton farmers' use of personal protective equipment when they apply pesticides were having had a past poisoning episode and a perception of pesticides as being hazardous substances. In a survey of nearly 2,000 California farmers, Schenker et al. (2002) found that concerns about cancer were the strongest factor incentivizing use of better personal protective equipment,[20] defined as using three of five types of protection for more than half the time when using pesticides. Kearney et al. (2015) found that 60% of 129 North Carolina farmers they interviewed (strongly) agreed that they were concerned about getting cancer from using agricultural chemicals, and 27% were concerned about reproductive impairment. The two factors that most strongly influenced these farmers' decisions to wear PPE were desire to avoid injury and, tellingly, government warning stickers or labels.

Collectively, these studies demonstrate shockingly low compliance with even the most basic personal protection measures, meaning excessive exposure to pesticides for many thousands of farmers and farmworkers, and risks of cancer and other adverse health effects far greater than estimated in some of EPA's ideal-world, low-exposure risk assessments that fail to fully capture the risks as intended by FIFRA. The studies also corroborate the common-sense notion that warning of serious health hazards – such as cancer and reproductive impairment – strongly motivates applicators to make use of exposure-reducing personal protective equipment. Yet Petitioners seek to drastically limit states' rights to save lives by requiring pesticide products carry "government stickers and labels" with human health warnings, despite their demonstrated effectiveness.

[20] More strongly predictive than other factors associated with PPE use, including more days spent using pesticides, younger age and male sex.

E. Consumers Deserve More, Not Less, Transparency About the Health Risks of Pesticides

While Petitioners seek to restrict warnings, pesticide safety experts have long advocated more and better toxicological information on pesticide labels, conveyed more effectively to the user. Pesticide labels carry one of three signal words – caution, warning or danger – that are intended to signify low, moderate and high toxicity, respectively. However, in a study investigating consumer comprehension of these terms, Hosni et al. (2024) found that barely more than half (54%) were able to correctly link the signal word to the toxicity level it designates. The deeper criticism of signal words is that they designate only the level of ***acute*** toxicity (i.e. the amount needed to kill a lab rat in a single dose), leaving the risks of cancer and other chronic diseases entirely out of consideration; in other words, signal words "do not reflect any effects from long-term exposure (i.e. cancer, birth defects or reproductive toxicity) that may occur at levels below those that cause death" (NPIC 2008).

Moreover, pesticide labels convey very little information regarding ***specific*** health hazards, and rarely if ever more serious ones. Representative labels for products containing the likely human carcinogens iprodione and thiophanate-methyl (see discussion above) say nothing about cancer risk. Instead, thiophanate-methyl users are only warned of "moderate eye irritation" and that the product is "harmful if swallowed" (Nufarm 2018). An iprodione product is "harmful if absorbed through skin or inhaled" and "may cause allergic reactions in some individuals" upon prolonged skin contact (OHP Label undated). These product labels contain copious instructions to wear all manner of PPE but fail to give the cancer warning that would incentivize their use.

Deficient human health warnings on pesticide labels must be seen in the broader context of pesticide disinformation, both advertising aimed at the public and more technical information. An example of the former is Monsanto's fraudulent advertisements claiming its Roundup herbicide was "practically non-toxic" and "less toxic to rats than table salt." The State of New York's Attorney General banned these and other fraudulent claims regarding Roundup's putative environmental safety, and fined Bayer/Monsanto for making them, on at least three occasions, most recently fining the company $6.9 million (NYS AG 1996, 1998, 2023). An example of technical disinformation can be found in the Safety Data Sheet (SDS) for an iprodione product, which concedes that iprodione causes liver and testes tumors in rat studies but claims the tumor findings "are not relevant to humans" (OHP SDS 2017). This directly contradicts the findings of EPA's human health assessment of iprodione, conducted in support of registration review, which classified iprodione as a "'likely' ***human*** carcinogen based on an increased incidence of liver tumors in both sexes of the mouse and an increased incidence of Leydig cell [testes] tumors in male rats" (EPA 5/22/20, p. 6, emphasis added).

Rather than seek to prohibit human health warnings, Petitioners would serve their residents far better by demanding that pesticide labels do not deceive users by denying

human health threats, like that of iprodione, that even EPA's pesticide division acknowledges.

For all the reasons discussed above, **we urge the EPA to reject Petitioners' request** that the Agency enact a rule under FIFRA to prohibit states from protecting their residents by adding human health warnings to pesticide labels.

Sincerely,

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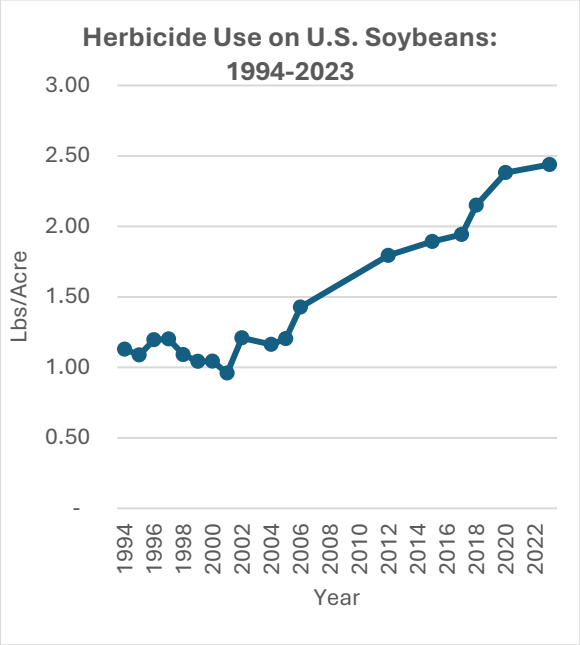
Amy van Saun, Senior Attorney
CENTER FOR FOOD SAFETY

Addendum on Glyphosate and Herbicide-Resistant Crops

Below we rebut several false and/or badly outdated claims made by Petitioners regarding the putative benefits of glyphosate and glyphosate-resistant crops. We also demonstrate that herbicide-resistant crops are a seductive but entirely unsustainable innovation that has been as detrimental to the true interests of farmers and rural communities as to public health and the environment.



Source: USDA NASS Agricultural Chemical Use reports

First, the glyphosate-resistant crop system has not reduced, but rather dramatically increased use of chemical weedkillers (Benbrook 2012). After a brief honeymoon period in the late 1990s (see graph), exclusive reliance on glyphosate with resistant corn, soybeans and cotton predictably drove an epidemic of glyphosate-resistant weeds that by 2017 had infested 120 million acres of cropland (Pucci 2018). In order to control these weeds, farmers supplemented glyphosate with additional herbicides. In 2017, Monsanto introduced soybeans and cotton resistant to dicamba (as well as to glyphosate and a third herbicide, glufosinate), leading to a massive increase in use of this volatile chemical (see below). The toxic spiral of spraying more weedkillers in response to increasing weed resistance is reflected in the remarkable 34% rise in annual farm herbicide use from just 2005 to 2012 (EPA OPP 2017, Table 3.2). It also helps explain why on a per acre basis, over twice as much herbicide is being sprayed on soybeans today as in 1994, just before the introduction of genetically engineered glyphosate-resistant crops (see graph). Agriculture will become still more chemical-intensive if Bayer is allowed to introduce corn and soybeans resistant to five herbicides, which are waiting in the wings (Held 2020, White 2024).

Second, it has been many years since glyphosate "effectively manage[d]" farmers' most challenging weeds, like Palmer amaranth and waterhemp, which have developed glyphosate resistance in states across the country[21] (Brown 2021). To the extent weeds are being controlled, it has come at a very steep price for farmers, rural communities and the

[21] For a list of glyphosate-resistant weed populations, see https://www.weedscience.com/Pages/MOA.aspx?MOAID=12.

environment. Since 2016, a huge upsurge in use of dicamba[22] to control glyphosate-resistant weeds has led to the most extensive and costly herbicidal drift injury in the history of American agriculture.[23] Millions of acres of soybeans as well as fruit orchards, vegetable crops, trees and natural areas have been impacted, often with devasting consequences (see photos below; Bradley 2017, NWF 2020, EPA OPP 12/15/21, PRN 2024). Dicamba drift has also killed off flowering plants, driving steep drops in honey production and shutting down beekeeping operations in hard-hit areas like Arkansas and Missouri (Charles 2017, Gray 2018) and other parts of the country (Gross 2019). Dicamba drift damage has spurred numerous lawsuits against Bayer/Monsanto, resulting in multimillion dollar settlements or decisions, in one case for decimating Missouri's largest peach orchard (Gillam 2020, Hettinger 2020). It has pitted dicamba users against dicamba drift victims, tearing apart the fabric of rural communities (Unglesbee 2018), and instigating vandalism and murder (Koon 2017, Bunge 2020). This dicamba debacle is a direct consequence of the glyphosate-resistant crop system blithely touted by Petitioners.

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[22] https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2019&map=DICAMBA&hilo=L&disp=Dicamba.

[23] Unglesbee E (2017). States grapple with dicamba, DTN Progressive Farmer, 9/20/17, quoting North Dakota State University pesticide specialist Andrew Thostenson: "We've never observed anything on this scale in this country since we've been using pesticides in the modern era." https://www.dtnpf.com/agriculture/web/ag/crops/article/2017/09/20/state-pesticide-regulators-face-2018.

Dan Charles NPR

Arkansas farmer David Wildy inspects a field of soybeans that were damaged by dicamba in 2017.

Source: Charles D (2018). The EPA says farmers can keep using weedkiller blamed for vast crop damage. NPR, 11/1/18. https://www.kpbs.org/news/2018/11/01/the-epa-says-farmers-can-keep-using-weedkiller.

Third, the National Academy of Sciences long ago put to rest the false notion that glyphosate and glyphosate-resistant crops increase yields (NAS 2016, p. 64). What this crop system ***has*** done, however, is increase concentration of farmland in ever fewer hands. USDA agricultural economists established that by reducing labor in weed management, glyphosate-resistant crops are one "driver of consolidation" that can "lead to increased farm size" (Macdonald et al. 2013, pp. 22, 26-28).

SHRIVELED: At last count, the Flamms say, they likely will lose 500 to 600 peach trees this year, due to damage suspected from growth-regulating herbicides. In addition, loss of leaves have led to sunburned apples, which can only be sold for juice.

Source: Lee, C (2018). Orchard growers raise dicamba red flags, Farm Progress, Nov. 21, 2018. https://www.farmprogress.com/crops/orchard-growers-raise-dicamba-red-flags

Fourth, the National Academy of Sciences also tells us that the glyphosate-resistant crop system does not "encourage farmers to adopt conservation tillage," or reduce soil erosion, as Petitioners claim (NAS 2016, p. 98). USDA data show clearly that soil erosion rates declined steeply in the 1980s, prior to the introduction of glyphosate-resistant crops, then virtually flatlined in the two decades (mid-1990s to 2017) during which glyphosate-resistant corn, soybeans and cotton became dominant and glyphosate use skyrocketed (USDA NRI 2020, p. 2-8). Vigorous federal policies promoting soil conservation are largely responsible for greater use of conservation tillage and reduced soil erosion (NAS 2016, p. 98; Freese et al. 2015).

Finally, the Petitioners' implication that the rulemaking they seek is somehow needed to fend off a threat to the continued availability of glyphosate or any other pesticide is unfounded. As detailed above, EPA OPP has long approved pesticides that are likely/probable human carcinogens or pose other chronic health threats, and shows no sign of altering course. Given this reality, Petitioners' efforts to outlaw human health warnings on labels will cost the lives of the citizens they are appointed to protect.

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