March 16, 2025

Charles Smith, Director, Registration Division
Environmental Protection Agency, Office of Pesticide Programs,
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: Petition Seeking Rulemaking to Modify Labeling Requirements for Pesticides and Devices, Docket ID# EPA-HQ-OPP-2024-0562

Mr. Smith:

These comments are submitted on behalf of the Heartland Health Research Alliance (HHRA), a non-profit organization conducting and supporting public health research on the impacts of farming systems and technology. HHRA is the sponsor of the Heartland Study, a large, multi-center birth cohort study in the Midwest focused on the impacts of prenatal herbicide and other pesticide exposures on reproductive outcomes, the health of newborns, and the impacts of early-life pesticide exposures on children's development.

These comments were prepared by Dr. Thomas Green, HHRA's Board Chair, and Dr. Charles Benbrook, former ED of HHRA.

Thomas Green founded and led for many years the Wisconsin-based Integrated Pest Management (IPM) Institute. He has contributed to many federal and state efforts to promote IPM adoption in both agricultural and non-ag settings. The IPM Institute works with multiple food companies and organizations to advance innovation in farming and pest management systems.

Under a consulting contract with HHRA, Dr. Benbrook is leading an HHRA project focused on the presence and risks associated with pesticide residues in organic and conventionally grown food. Dr. Benbrook has worked on pesticide regulatory law and policy, pesticide risk assessment science, and the impacts of pesticide use on farmers and public health since the late 1970s. He has served as an expert witness in pesticide litigation for 25 years, and most recently litigation on Roundup and non-Hodgkin lymphoma, paraquat-Parkinson's disease, and chlorpyrifos-neural development. Preemption efforts and "failure to warn" issues have been among the pesticide policy issues that Dr. Benbrook has been involved with since the early 1980s.

Summary

The current effort to eliminate "failure to warn" claims in pesticide efficacy and human health litigation is unfolding in multiple venues:

- The Attorneys General petition addressed in these comments.
- The U.S. Congress via an expected 2025 farm bill provision.
- An effort in at least 20 states to amend state law.
- A complicated scheme to re-litigate the Bates et al. v. Dow AgroSciences SCOTUS decision.
- Possibly, one or more Executive Orders.

Bayer/Monsanto, Syngenta, and pesticide industry associations and surrogates are funding and carrying out efforts to change the way federal EPA and states cooperate and coordinate pesticide regulatory and labeling activities. Most of their arguments in support of proposed changes are irrelevant ("feed the world"), and/or factually inaccurate (without new laws and action eliminating "failure to warn" claims, farmers will lose access to glyphosate-based herbicides).

The proposed changes in law and policy will unravel key aspects of how FIFRA is designed to promote safe pesticide use, and will lead to a number of unintended and negative consequences. In the key *Bates v. Dow* Supreme Court case, Justice Stevens, wrote for the majority and noted that "Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA." All nine justices concurred, including Justice Thomas and Scalia. The opinion explained that:

> "By encouraging plaintiffs to bring suit for injuries not previously recognized as traceable to pesticides such as [the pesticide there at issue], a state tort action of the kind under review may aid in the exposure of new dangers associated with pesticides. Successful actions of this sort may lead manufacturers to petition EPA to allow more detailed labelling of their products; alternatively, EPA itself may decide that revised labels are required in light of the new information that has been brought to its attention through common law suits. In addition, ***the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement***." [Emphasis added]

In the rush to change laws and policy to shield pesticide manufacturers from liability arising from their past decisions and stewardship behavior, or lack thereof, advocates of this petition have not thought through, nor addressed several problems such changes will trigger. These include the limited ability to detect in pre-market testing all of the adverse outcomes and human health harms that may arise as a result of how a pesticide is used in the real world. There will also be an ongoing need to identify and address newly recognized high-risk exposure scenarios via future label amendments.

The proposed changes also call for rethinking and clarification of state versus federal regulatory roles and responsibilities, and how risk mitigation measures will be shared between EPA-approved labels applicable nationwide, versus state-proposed "special local need" and "emergency exemption" labels.

The petition's end goal is clearly stated: protect pesticide manufacturers and registrants from facing litigation when their products do not work as claimed and advertised, when they trigger disease or health problems among exposed individuals, and/or damage personal property (crops growing in a field, backyard gardens, rose bushes, pets, livestock).

The pesticide industry has been seeking essentially the same changes in federal and state laws since the early 1980s. The same arguments have been advanced by those supporting such changes. To date, such arguments have been found unpersuasive for basically the same reasons.

In shaping the modern FIFRA statute, Congress, farmers, and the pesticide industry were in general agreement that federal EPA could not be expected to effectively deal with the vast diversity of pesticide use patterns and application methods that will be needed in the ag and non-ag sectors across all 50 states. Accordingly, Congress provided for a meaningful state role ***in some aspects of pesticide risk assessments and labeling***.

The roles of states codified in FIFRA were designed to accomplish two goals:

1. Allow for some different ways a pesticide can be lawfully applied in a given state, in addition to the uses already sanctioned on the pesticide's federal, EPA-approved label. Or, allow uses on a different crop, or to address a different, non-ag pest management challenge.
2. Provide states with a mechanism to impose additional risk-mitigation measures and warnings on the use of a federally registered pesticide in a state, because of known, high-risk application scenarios unique to a state (e.g., farm worker exposures, applications near wildlife refuges populated with tens of thousands migratory birds, or mitigating risks in parts of a state with karst geography, where the risk of a pesticide leaching down into groundwater is markedly heightened).

Congress added authority in FIFRA for states to propose and secure EPA approval of Section 18 "emergency exemption" supplemental labels, as well as Section 24 "special local need" labels. Such added uses create the capacity for states, the pesticide industry, pest managers, and federal EPA to act quickly when a new pest problem emerges that threatens serious crop losses, or when a documented poisoning episode leads to the recognition of a high-risk application scenario. Such high-risk scenarios arise both on farms and ranches, and in buildings and urban settings.

Farmers, landscapers, and pest managers throughout the US have benefited for over 50 years from the ability to work with state regulatory authorities, researchers, and farm organizations in identifying the need for state-sponsored, supplemental labels.

The current effort by the pesticide industry seeks to forbid “failure to warn” claims grounded in state-law obligations. It would vest all responsibility for legally labeled pesticide uses in federal EPA. Hence, any additional or different language on supplemental state labels would be vulnerable to challenge as “different” from EPA-approved, federal labels.

Moreover, state regulators would still be encouraged, and in some cases aggressively pushed, to grant approvals via supplemental labels for new uses of federally registered pesticides, but would be blocked from imposing any new or different risk-mitigation measures deemed necessary to prevent “unreasonable adverse effects on man or the environment” stemming from newly approved uses on state supplemental labels

The reforms now sought in multiple venues will have profound and hard-to-predict consequences, some of which will surely make it harder for pesticide companies to formulate and label products designed to be both effective and safe in niche, but possibly high-risk markets in a given state.

This would create a dangerous imbalance in state-federal pesticide law and regulation. States would retain pathways to approve new and different uses of pesticides, including some in high-risk situations, but lack access to the tools needed to mitigate possibly high and unacceptable risks.

It is Never Just One Risk, and Exposure Levels and Patterns Matter

One other key, unintended effect of the proposed changes in FIFRA and state pesticide law must be considered by farmers, regulators, and public health scientists.

The Attorneys General petition preempts any state consideration of pesticide hazards and risk levels, and the need for risk mitigation measures, that differ from a final EPA human health risk assessment and/or cancer classification decision. But EPA only issues a final human health risk assessment every 15-25 years. Once a final human health risk assessment is issued at the end of a pesticide reregistration cycle, the Attorneys General petition would lock state regulators into the judgements made in it, and prohibit state efforts to mitigate newly recognized risks not addressed in the most recent, final EPA human health risk assessment.

This would delay any meaningful opportunity to address new high-risk scenarios for perhaps one to two decades, even when risks become obvious and extreme.

This makes no sense in an era when there are often major changes in pesticide use patterns, exposures, and risks over a span of just a few years (e.g., major changes in herbicide use in the Midwest since 2016). Plus, new scientific tools are shortening the time it takes to trace adverse health effects to specific application scenarios, and will

help identify the pesticides responsible for “unreasonable adverse effects on man...” Shouldn’t policy provide mechanisms for new science to accelerate efforts to reduce exposures and risks?

All EPA human health risk assessments draw upon both toxicology data ***and*** exposure data to estimate risk. When EPA makes a determination that a pesticide will not cause any “unreasonable adverse effects” among people, it does so relative to a narrow, specific adverse effect. ***Plus, the EPA’s scientific judgements and risk mitigation decisions are based on their best estimate of maximum exposures stemming from legal, labeled uses***. An EPA risk assessment predicts that a labeled pesticide use will be safe up to a given level of exposure, ***and not at any and all levels of exposure***.

It is widely accepted that the dose makes the poison. So too do the tissues exposed and the timing of exposures. The way some pesticides are used in certain states expose some applicators, mixer-loaders, and farm workers to markedly higher levels of exposure than projected by federal EPA and incorporated in final human health risk assessments.

But adoption of the proposed changes would, in effect, prohibit state regulators from imposing added label directions, precaution statements, and warnings to prevent or mitigate high and risky exposures occurring in a state. This is because EPA approved labels are assumed to only allow “safe” applications relative to all possible, adverse health outcomes.

In the real world, this is a dangerous assumption. Different routes of exposure – inhalation versus dietary versus dermal – matter and alter risk outcomes and risk levels.

Different timing of exposures – during pregnancy versus when a person is taking an immunosuppressive drug, or battling cancer – matter greatly in determining whether an adverse health outcome might be triggered.

The tissues exposed matter a great deal– stem cells versus lung tissues, versus dopaminergic neurons in the brain. The tissues exposed markedly alter the kinds of human health risks that pesticide exposures might contribute to, as well as the dose levels likely to be associated with novel adverse effects, especially among heavily and frequently exposed individuals.

By locking in all state and federal risk assessments and regulatory decisions to the maximum exposure thresholds set by EPA, it is likely that many high-risk uses and exposure scenarios, and adverse health outcomes, will remain out of sight, out of mind. Is that among the goals sought by those promoting these changes in FIFRA and state laws, or just an unintended and unexplored outcome?

The Attorneys General proposal, if adopted, will fundamentally undermine the ability of states and EPA to identify and mitigate high-risk pesticide use scenarios in essentially all states. For this reason, we urge EPA to reject this petition.

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I. ASSESSMENT OF THE ATTORNEYS GENERAL PETITION

The Attorneys General letter dated August 7, 2024 and their petition propose that the EPA overrule via rulemaking key provisions in federal law and Supreme Court precedence. The impacted provisions of law govern how state and federal pesticide regulators cooperate in achieving the environmental and public health goals embedded in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

The consequences of the proposed changes will be significant and hard to predict. But the changes will surely relieve pesticide manufacturers of one of the important imperatives for them to comply with FIFRA requirements. Farmers and rural communities will be among those directly, and negatively, impacted if EPA were to alter its operating regulations as proposed in the Attorneys General petition.

Such major changes in law and policy governing the role of state law and regulatory activities in assuring pesticides are used safely will alter the ability of individuals adversely impacted by pesticides to seek compensation. While the petition focuses on adverse impacts on human health, the changes will also curtail the ability of farmers and other pest managers to seek compensation when a pesticide does not work as claimed, or causes a problem on or near a farm, such as killing pets or livestock. And significantly, the changes would also undermine the ability of Attorneys General, civic organizations, farmers, and landowners in Midwestern states to seek compensation for crop, tree, and vine damage caused when dicamba, 2,4-D, or other volatile herbicides move off-target with the wind.

Claims alleging health risks and damage to personal property would face a more difficult evidentiary and legal burden. The significant beneficiaries of such changes will be pesticide registrants who would argue in court, as they have mostly done unsuccessfully for years, that a federally approved pesticide product label is proof their product will be safe when applied in accord with label directions. Moreover and as a result, if a problem does occur, registrants will assert in court that any alleged problem must have arisen from applicator error or some other version of blame the victim or some other innocent party.

A Multi-Prong Effort

The EPA, and all concerned parties should be mindful of the fact that the effort to rid pesticide litigation of “failure to warn” claims is unfolding in multiple venues, and in each, the effort is predominately driven by multinational pesticide registrants and industry surrogates. The multiple venues include;

- This proposed EPA rulemaking;
- Efforts in over 20 states to convince state legislatures to pass a bill that would make it no longer possible for individuals, farm enterprises, farm workers, rural residents, municipal organizations (e.g., water treatment plants, agencies

managing public parks, highway commissions), pesticide plant workers, or businesses that are allegedly and adversely impacted by pesticides to seek redress in courts based, in whole or part, on a "failure to warn" claim;

- The US Congress, which will make another effort to pass the long-delayed, five year farm bill in 2025. An effort is expected to include a preemption provision in the farm bill similar or identical to the preemption provision in the farm bill passed out of the House Committee on Agriculture in 2024;
- The Supreme Court (again), via steps by lawyers and law firms working on the Roundup-NHL litigation; and
- Other possible legislative and/or rule-making processes, or via an Executive Order or Orders.

A. Preemption 101

What exactly would be preempted? State laws allow individuals or businesses to seek compensation under state consumer protection and negligence laws when they experience economic losses or personal injury as a result of a faulty product design or manufacturing, and/or inadequate directions for safe use and warnings. "Failure to warn" causes of action grounded in state law would no longer be allowed in pesticide litigation. The risk assessment judgements and risk mitigation measures contained in EPA-approved, federal pesticide labels would supersede and nullify any responsibilities or obligations under state law, including "failure to warn" claims.

If federal pesticide labels were always able to deal effectively with the unique exposure scenarios and risks arising from how pesticides are used in all 50 states, such preemption of state laws might not significantly undermine attainment of core FIFRA goals. But clearly, no one believes that federal EPA has access to the information and knowledge required to accurately project all possible pesticide risks and adverse impacts nationwide. It is hard to imagine that the Attorneys General of nearly a dozen states have such confidence in federal EPA.

The letter and petition claim that ***ambiguity in the requirements set forth in FIFRA*** justifies EPA rulemaking to clarify what constitutes the misbranding of a pesticide. In fact, there is little ambiguity about what constitutes misbranding of a pesticide. The FIFRA statute and EPA operating regulations clearly spell out the roles and responsibilities of registrants, federal EPA, and states in assuring pesticides are not misbranded, and what happens when they are.

Some pesticide registrants do not agree with certain of their obligations under FIFRA and oppose how state law impacts their exposure to liability risk. Pesticide industry organizations and advocates have tried for decades to block "failure to warn" claims in pesticide litigation by asserting that when EPA issues a federal pesticide label, the EPA is, in effect, confirming their products are safe when used as directed, and therefor companies should not have to face "failure to warn" claims in courts of law.

The current Attorneys General petition is ***one node of a new multi-prong effort to achieve federal preemption and end the role of "failure to warn" claims in toxic tort and product performance litigation***.

Today, the large damage awards granted by some juries in recent litigation over Roundup and cancer have stimulated an effort to rid pesticide litigation of "failure to warn" claims grounded in state law. Cutting to the core of the Attorneys General petition, the goal is to assure in the future, courts will rely more heavily on federal EPA risk assessments and label determinations, while undermining the importance of state law and pesticide regulatory activities.

Over the years, however, it has actually been more common for pesticide registrants and industry advocates to encourage Congress and state legislatures to ***expand the avenues through which state regulatory authorities can approve additional uses of pesticides not covered by the labels approved by federal EPA***. Among the arguments they have advanced in support of expanded reliance on state actions is that in-state pest management experts, farmers, researchers, and regulators are more familiar with how pesticides are used in a state, as well as with the factors giving rise to high-risk application scenarios that are unique in a state.

In its first paragraph, the petition states that "The label reviewed and approved by EPA is to control". Presumably, there is an error in this sentence, and the intent was to say the EPA label is "in control". The petition than acknowledges that state regulators can restrict or deny the use of a federally labeled product in their state, "but cannot impose..." additional labeling elements or requirements that differ from those on federal labels. The goal is to establish that federal EPA labels set both the floor and ceiling for efforts to assure pesticides are used safely.

This would place state regulators, and farmers and pest managers in a state, at a serious disadvantage. Registrants and pesticide users will continue to request state authorities to pursue approvals of new state-level uses of pesticides via FIFRA Sections 18 and 24(c). Such new and supplemental labeling will go beyond the uses and application scenarios allowed on federal labels. So, states would sanction new ways for pesticides to be used, but without the ability to address local and region-specific risk concerns and exposure scenarios. Why? Because doing so would typically necessitate added label requirements that differ from, or go beyond those on federal labels.

It is unlikely that the Attorneys General, nor the farmers and farm organizations backing this effort, are aware of the imbalance that could arise as a result. States would retain authority to approve new uses of pesticides not on EPA-approved labels, but would not be allowed to impose requirements beyond those on federal labels needed to curtail high-risk exposures or environmental damage in a state.

Also, EPA determinations that pesticide$_x$ is unlikely to cause some, or any, adverse health effect are always predicated on measured or estimated levels of exposures falling below some threshold level. When EPA approves a use of a pesticide on a given

food crop, it limits the level of dietary exposure from residues of the pesticide in the food, and ***does not conclude and assert that the pesticide will always be safe at any and all levels of exposure.***

Most state-level regulatory actions limiting or banning pesticide uses in California that are allowed on federal labels have been driven by much higher applicator and farm worker exposure scenarios than those considered by federal EPA. In addition, some state regulatory authorities have determined that at the higher levels of exposure to a pesticide in their state, the risk of adverse health effects differs from the findings included in EPA human health risk assessments. Such additional or higher risks sometimes warrant active measures to reduce exposures. And often in California, ***regulators and scientists know this to be the case because of investigations of exposure incidents that required applicators or farm workers to seek medical attention, and in some cases, hospitalization***.

In the section “Requested Action”, the petitioners urge the EPA to issue a regulation that imposes the outcome of EPA human health risk assessments, including cancer classification decisions, on state regulatory reviews and labeling. This recommendation rests on the assumption that the use directions, precautionary statements, and warnings on federal EPA-approved pesticide labels are adequate everywhere, under all legal pesticide applications, to reduce exposures to or below the levels that EPA has deemed acceptable in light of the FIFRA and FQPA safety standards. This assumption is unfounded, and sometimes dangerous. Federal EPA is not always aware of all possible risks and high exposure scenarios, including risky application scenarios and related data that pesticide registrants are aware of, but have not shared with the EPA, as required by law.

When registrants are successful in keeping internal knowledge of new toxicology data and high-risk exposure scenarios from regulators, their actions are relevant when courts assess “failure to warn” claims. There is a provision in FIFRA that requires registrants to share such insights and data with the EPA, but some registrants have chosen, at times, to not do so. When juries are presented evidence of such bad behavior by registrants, “failure to warn” claims can resonate with juries when they contemplate damage awards.

The petition states on page 3 that the use of glyphosate-based herbicides (GBHs) on GMO crops has reduced herbicide use. This may have been true for the first few years of adoption (1996-2000), but clearly has not been true for the last two decades. The emergence and spread of glyphosate-resistant weeds has triggered the need for farmers to apply additional herbicides that work through different modes of action, and especially since 2017, the phenoxy herbicides dicamba and 2,4-D.

Ironically, most of the Attorneys General signing this petition have struggled to deal with the volatilization, drift, and crop damage stemming from the huge increases in dicamba and 2,4-D use in their states. They have argued persuasively in various venues that

herbicide registrants and federal EPA have failed to respond adequately to the adverse impacts triggered by contemporary, post-emergence applications of these herbicides. Attorneys General have pointed out the inability of state regulators, scientists, and farm communities and rural residents, to deal with this problem that can pit farmer against farmer, and farmers against rural neighbors. Plus, once in the atmosphere, dicamba and 2,4-D can move long distances and across state lines, creating another layer of regulatory and liability complexity that helps shield herbicide manufacturers from the unwelcomed impacts of their EPA-registered herbicide products.

If EPA or state legislatures preempt state laws and end "failure to warn" claims, herbicide manufacturers will have a powerful new argument to deploy in both state and federal courts dealing with herbicide drift and damage cases, including possible future cases alleging that inhalation exposures to certain herbicides that might be contributing to adverse public health outcomes.

Another California Connection

In several places, the petition discusses the conflict between cancer-related label language required on GBHs for sale in California under Proposition 65, in contrast to federal EPA labels and the glyphosate cancer classification decision reached by EPA's Office of Pesticide Programs (OPP). The different conclusions and opinions regarding the linkage between GBH use, occupational exposures, and cancer are at the heart of this California-OPP dispute, and will almost certainly not be resolved for many years.

The Attorneys General petition characterizes this CA-OPP labeling conflict as evidence in support of the need for EPA to act on their petition. But the petition does not mention that the State of California and EPA officials resolved the conflict via agreement on GBH label language that is compliant with both California state law and the position and actions of federal EPA. The resolution resolved long-standing and costly litigation. It was solidly grounded on facts and science, and brought onto GBH labels an important new cautionary statement to users of GBHs: "A wide variety of factors affect your potential risk including ***the level and duration of exposure to the chemical***." (Emphasis added). (An explanation of the genesis of the compromise language is contained in comments submitted by Dr. Charles Benbrook to the California Office of Environmental Health Hazzard Assessment (OEHHA) on the proposed compromise language; these comments will be uploaded to the docket for this rulemaking).

Erroneous References to Efficacy Data and Issues

On page 4, the petition states that the EPA will register a pesticide if it is found to be efficacious. This is no longer true, except for microbial pesticides of public health concern. Congress dropped the requirement that registrants submit efficacy data, and EPA review such data, in an 1978 amendment to FIFRA that gave the EPA Administrator authority to wave efficacy data requirements, which was done thereafter.

In the years ahead, the emergence and spread of pest phenotypes resistant to a pesticide applied to control it began complicating pesticide efficacy and benefits assessments in the pesticide reregistration process. Inability to curtail the emergence and spread of resistant pests remains a major shortcoming in federal and state pesticide laws and regulation (see Benbrook et al., 2021 for a review of major problems with FIFRA and pesticide risk and benefits assessments).

B. The Office of Pesticide Programs v. IARC Cancer Classification Conflict

The petition notes in several places that in the case of glyphosate, the EPA's Office of Pesticide Programs and international regulatory authorities have consistently reached the same "not likely to pose cancer risk" determination. But the petition fails to acknowledge that the toxicology studies and risk assessment supporting this conclusion are based upon dietary exposures to pure glyphosate. In addition, the OPP and other regulatory authorities have not requested, nor generated, the data required to quantify the risk of cancer among applicators and others who are occupational exposed. This is a serious and consequential limitation of existing regulatory reviews because:

- Occupational exposures are often far higher than dietary exposures,
- Applicators are exposed to formulated GBHs that, in the US, contain glyphosate plus polyethoxylated tallowamine (POEA) surfactants, a chemical mixture that is markedly more toxic than glyphosate alone,
- Occupational exposures occur via the dermal and/or inhalation route of exposure, as opposed to via the diet, drinking water, and other beverages.

This trifecta of differences undermines the assumption that current applicator exposures to GBHS are safe because estimated dietary exposures to glyphosate are safe. A case can be made that perpetuating this assumption borders on scientific and regulatory malpractice.

As argued elsewhere in these comments, the failure of EPA and other regulators to conduct a meaningful occupational and dermal exposure risk assessment is a serious deficiency in the data available to regulate GBH use. It is also why state regulatory authorities need to retain the ability to address and mitigate applicator and occupational risks that receive little or no attention in OPP/EPA human health risk assessments. ***Failure to assess occupational risks is not proof of the absence of such risks***.

Last, on page 8 on the topic of the conflicting judgements on cancer risk between the OPP and the International Agency for Research on Cancer (IARC), the petition states that "EPA's conclusion was both more robust and transparent than IARC's". The Attorneys General are entitled to their opinion on these two points, but their assertions are not shared by many people who have studied the science supporting OPP's "not likely to pose cancer risk" conclusion, in contrast to the science supporting IARC's "probable human carcinogen" conclusion.

One of us (Benbrook) has published two peer-reviewed papers explaining why OPP/EPA and IARC reached such different conclusions (Benbrook, 2019; Benbrook et al., 2023). The explanation is actually simple: EPA relied mostly on registrant commissioned toxicology studies, essentially all of which showed no reason for concern regarding glyphosate and cancer, while IARC relied most heavily on published, peer-reviewed studies done by independent scientists, of which about three-quarters reported some or strong evidence supporting an association between exposures to glyphosate/GBHs and cancer.

The OPP review was definitely not more robust because it essentially ignored all published and peer-reviewed genotoxicity data. Nor was it more transparent. Most of the technical sessions of the IARC Working Group that reviewed glyphosate/GBH genotoxicity and oncogenicity were attended by industry-nominated experts and EPA officials who had opportunities to share their insights on specific data and issues. Plus, the studies reviewed by the IARC Working Group, and its conclusions and reasoning, are explained fully in the IARC monograph on glyphosate.

Opinions vary on whether OPP or IARC got it right. But a solid case can be made that OPP and IARC asked and answered different questions, and drew upon different datasets in answering key scientific questions. Papers published by Benbrook explain why both OPP and IARC reached plausible conclusions based on the questions each asked and answered (Benbrook, 2019; Benbrook et al., 2023).

The above passages refer to OPP's cancer classification decision and not EPA's. This is because OPP's judgement was not shared by another part of EPA that had also reviewed the scientific basis for OPP's and IARC's cancer classification determinations. An Office of Research and Development (ORD) task force was convened in 2015 at the request of the EPA administrator to help her understand the basis for the differing conclusions. The task force of ORD subject-matter experts concluded that OPP's "not likely" to cause cancer decision was not supported by the data, and was not consistent with EPA cancer risk assessment guidelines. In an email exchange with ORD and EPA colleagues, a task force member stated and that the more defensible classification, based on their review, would have been either "possible" or "probable" carcinogen.

The ORD email chain is public (Cogliano, V.J., December 7, 2015: https://www.thenewlede.org/wp-content/uploads/2022/10/Glyphosate-RUP-EPAORD-OPP-2015-12-7-ORD-email-re-evaluation-Cogliano-Memo-2.pdf). So too is a detailed ORD memo on the animal bioassay and epidemiology data linking exposures to glyphosate and GBHs to cancer (https://www.documentcloud.org/documents/20786671-doc101719). Both of these ORD documents will be uploaded in the docket.

II. IMPORTANCE OF WARNING STATEMENTS IN ACHIEVING FIFRA GOALS

Key roles for pesticide labels are to: (1) alert applicators to possible risks and high exposure scenarios, (2) inform them of practical steps they can take to reduce exposures, and hence risk (e.g., “wear chemical-resistant rubber gloves when applying this product”), and (3) motivate them to pay attention to label requirements, and to be disciplined in how they handle and apply pesticides.

A. The Role of Cautionary Statements and Warning on Pesticide Labels

Cautionary statements and warnings on pesticide labels are supposed to provide generic guidance into reasons to adhere to required use directions, safety precautions, and PPE requirements. For example, requirements for mixer/loaders and applicators to wear PPE are particularly important for people who spray the product for extended periods and many days per year, yet very few labels cover this key point. Likewise, applicators that have an underlying health condition that makes them more vulnerable than the general public also need to be extra diligent in adhering to all label requirements and recommendations.

“If you have cancer or are in remission, or are taking immunosuppressive medications, avoid any contact with this product” is an example of a cautionary statement that should be on some pesticide labels, but might not be allowed on state supplemental labeling if the changes proposed by the Attorneys General are codified in EPA regulations.

The multi-pronged effort to eliminate or undercut “failure to warn” claims in pesticide toxic tort litigation is being driven and financed largely by Bayer/Monsanto and Syngenta. These companies are working to contain the costs and reputational damage stemming from ongoing Roundup-NHL and paraquat-Parkinson’s disease litigation. However, legislative efforts and changes in law designed to achieve such narrow, short-term goals often have significant, long-standing, and negative repercussions.

We anticipate that adoption of this petition and success in ending “failure to warn” claims in future litigation, will have consequences that the Attorneys General are either not aware of, or have not thoroughly thought through. In addition, we foresee serious, negative ramifications for farmers, as well as for pesticide companies dedicated to assuring safe use of their products via clear and convincing label directions, precautionary statements, and warnings.

Tens of thousands of Americans have cases filed in state or federal courts and are awaiting a trial date. Will changes in preemption law and policy make it more difficult for these individuals to prevail when their cases go to trial, or will the changes only apply to future litigation?

How will laws passed by a state legislature impact the outcome of cases filed in federal courts? Which judicial rulings, and what case law, will need to be revisited to align the way courts have dealt with federal preemption and “failure to warn” claims since the

May 27, 2005 Supreme Court (SCOTUS) decision in the Bates et al. v. Dow AgroSciences case (Supreme Court, 2005)?

Assuming the EPA grants the Attorneys General petition, what damage will be done to the ability of registrants, the EPA, and farmers and pest managers to enhance the safety of pesticide use while legal challenges and issues are sorted out (a process likely to take years)?

Beyond the impact on present-day and future litigation, the EPA, state legislatures, and the US Congress need to explore more thoroughly whether, and in what ways, blocking "failure to warn" claims in toxic tort and pesticide-efficacy litigation will impact the ability of FIFRA and regulators to assure that high-risk pesticide application scenarios are identified and mitigated, and hopefully in less than one or two decades, as typically now the case.

We highlight in these comments some, but not all likely impacts that could undermine efforts by registrants, scientists, and regulatory officials to assure that pesticides are likely to be safe when applied in accord with all applicable label directions, cautionary statements, and warnings.

B. Lessening the Role of States will Complicate the Challenges Confronting Federal EPA

A predictable outcome of a lessened role for state law and regulatory programs and requirements will be heightened pressure on federal EPA to address and mitigate risks that arise only in some regions, and perhaps just in a single state. In the absence of the ability to effectively address the diversity of state-specific, high-risk application scenarios on federal product labels, the EPA may choose to not initially approve, or not reregister crop uses that have been associated with high-risk applications in one or more states.

As a practical reality, the EPA would need a substantial increase in funding or user fees in order to maintain current turn-around times for action on requested label amendments and new product applications.

Dealing with all such risk scenarios at the federal level will exacerbate an already significant problem – the scope, length, and complexity of existing EPA-approved pesticide labels. The use instructions, cautionary statements, and warnings on some federal labels span several dozen pages of mostly fine print.

Roundup herbicides are registered for hundreds of agricultural crop uses, and far more non-agricultural use scenarios. There will generally be four to five, and as many as ~10 ways a labeled product can be applied. There are often application-method-specific cautionary statements, warnings, and Personal Protective Equipment (PPE) requirements on labels.

There could be many dozens of specific soil-type, geologic, ecological, and sensitive-area restrictions and warnings applicable to a subset of labeled uses. Various GBH

labels include substantial discussion of the circumstances when a labeled GBH can be tank mixed with liquid fertilizers, other pesticides, and other agrichemicals (e.g., nitrogen stabilizers). Product compatibility with specific spray nozzles sometimes must be addressed on labels.

Adding another layer of state-specific issues that federal EPA must deal with via federal labels will make already long labels even more ponderous. At some point, even diligent pesticide handlers and applicators will struggle to fully digest and integrate all the requirements, suggestions, and warnings on a label, and hence may not fully comply with all risk-mitigation provisions embedded in lengthy product labels.

III. IMPACT OF EPA DATA AND REGULATORY REQUIREMENTS ON THE NEED FOR AND SCOPE OF WARNINGS ON PESTICIDE LABELS

The sciences supporting pesticide regulation are rapidly advancing, as are the scope of risks that EPA will need to identify and quantify. Changes will also be needed in how EPA assesses and strives to mitigate the multiple human health risks arising from exposures to a given pesticide. Inevitably, risk levels will vary as a function of formulation, route of exposure, level of exposure, and timing and duration of exposures.

Today, EPA regulates, and strives to mitigate, pesticide human health risks based predominately on just the one adverse health outcome observed in registrant-commissioned toxicology studies that occurs at the lowest dose level. EPA sets the maximum level of daily exposure to a pesticide via residues in food and beverages based on this one effect, and assumes that in doing so, not other adverse human health effect for the general public will arise from labeled uses of pesticides.

A. Scope of EPA Risk Assessments

Pesticide human health risk assessments, and pesticide label provisions, must evolve and effectively mitigate ***all possible risks*** via ***all routes of exposure*** to both parent compounds and formulated products. Many industry advocates allege that EPA and other regulators are already accounting for all possible risks and routes of exposure. Regrettably, this is not true, and we expect the Attorneys General are aware of why. Most significantly:

- Daily applicator and farm worker exposures to active ingredients in some formulated products are far higher than dietary exposures to pure active ingredients,
- Exposures to active ingredients in formulated products are often more harmful, milligram for milligram, compared to exposures to active ingredients alone via the diet,
- As overall exposure levels rise, and especially for frequent applicators, risks can increase above acceptable levels for a growing number of possible adverse health outcomes that play no role in EPA risk assessments and the risk mitigation measures on labels.

The EPA's Office of Pesticide Programs has set forth ~30 toxicological data requirements that pesticide registrants must fulfill in the course of seeking OPP approval of tolerances for food use pesticides, and registrations authorizing applications of pesticides on food crops. Most of these studies, and often all of them, are carried out with a pesticide's active ingredient, and not the formulated pesticide product that handlers and applicators are exposed to.

Few people are aware that most OPP applicator exposure and risk assessments are based on studies that quantify the rate of dermal penetration (movement through the

skin epidermis) when pure active ingredient is placed on rodent or human skin, ***and not the same amount of active ingredient in a formulated product that an applicator would actually spray and be exposed to***.

OPP's focus on the toxicological properties of active ingredients when assessing exposures via food and beverages is defensible for two reasons: (1) the FIFRA statute, and OPP data requirements and risk assessments, are focused primarily on general population risks stemming from dietary exposures to active ingredients, and (2) the surfactants and other co-formulants in end-use pesticide products do not typically remain in or on food along with residues of the active ingredient. Hence, dietary risk assessments based solely on the properties and toxicity of active ingredients will usually produce reasonably reliable estimates of dietary risks.

However, this is often not the case for the other, two major routes of exposure that OPP should be assessing and regulating – dermal and inhalation exposures to formulated products among mixer/loaders and applicators, farm workers, and bystanders. These individuals are exposed to all the chemicals in a formulation, and some so-called "inert ingredients" are actually more toxic than the active ingredient they are mixed with.

There is another consequential impact following exposures to some formulated pesticide products, as opposed to exposures to pure active ingredients. The coformulants in many high-volume, widely used pesticides markedly alter:

- The physical and chemical properties of the formulation compared to the active ingredient alone, thereby changing how the pesticide moves and breaks down in the environment, food, and water, and how volatile and persistent the pesticide is likely to be. These factors can play important roles in ecological and human health risk assessments.
- The Absorption, Distribution, Metabolism, and Excretion (ADME) of active ingredients in the human body. Such impacts can enhance, decrease, or leave unchanged the toxicity and health outcomes stemming from dermal or inhalation exposures.
- The degree to which dermal and/or inhalation exposures can trigger damage to DNA in various tissues and organs in the body, thereby increasing the risk of reproductive problems, cancer, or adult-onset disease. Coformulants chosen to enhance pesticide efficacy often have additional, unintended, and negative biological impacts. Many herbicide surfactants accelerate movement of herbicides through the epidermis of weeds, but also through human skin ***and*** cell walls. Many insecticide coformulants render the mixture of chemicals in end-use products more volatile, and hence raise the risk of inhalation exposures.

B. Focus of EPA Pesticide Toxicology Data Requirements and Risk Assessments

Upon receipt of the toxicological studies on a pesticide active ingredient required by the EPA, agency scientists review the quality of studies and assess study results. It focuses

on finding ***the single adverse health effect which occurred at the lowest dose in a valid study***. Once the lowest-dose effect is chosen by OPP toxicologists, that effect is used by the OPP to calculate the acceptable daily level of dietary exposure, and usually as well, the acceptable level of applicator and occupational exposure.

But the way OPP sets exposure thresholds has significant implications regarding the need for ***label directions*** (e.g., preharvest intervals, acceptable application equipment and methods), ***cautionary statements*** (e.g., avoid applying this product where it might drift onto sensitive crops or vegetation, or within 200 feet of a field in which farm workers are present), and ***warning statements*** (e.g., do not handle this product if you are pregnant or are under treatment for cancer).

The above, three critical components of pesticide labels are grounded in risk assessments done with studies focused predominately on active ingredients, not formulations. This is why EPA risk assessments and pesticide labels so often fail to adequately protect individuals who handle, mix/load, and apply pesticides frequently as part of their job or vocation. The impacts of the changes sought via the Attorneys General "failure to warn" petition must be ***evaluated in light of the concomitant changes likely to arise in all three of the core components of pesticide labels: use directions, cautionary statements, and warnings***.

Once OPP selects the adverse impact that occurs at the lowest dose in a valid animal study, the subsequent steps in the risk assessment and regulatory process are all carried out relative to that adverse effect, and the dosage levels at which the effect was detected in an animal study.

At the end of OPP's risk assessment process, the agency makes judgments regarding what uses can be "supported" by the existing data and submitted studies, ***and under what application scenarios*** (also referred to in EPA-speak as a pesticide "use pattern"). A use pattern on tomatoes, for example, is "supported" if the OPP can conclude, based on the data it has reviewed, that spraying tomatoes with a pesticide in a particular way or ways won't trigger dietary exposures above EPA's "level of concern" (i.e., the dietary exposure threshold), nor expose workers, applicators, or bystanders to unacceptable dermal exposure risks.

Such a maximum, acceptable applicator or occupational exposure threshold is set on the basis of a "Margin of Exposure" (MOE) equal to or over 100; an MOE is calculated by dividing the applicable "No Observable Adverse Effect Level" by 100 (NOAEL, measured in mg of pesticide per kilogram of bodyweight per day).

But what the EPA never does is reach a conclusion, or state that a given pesticide, or even a use of a pesticide, will always be "safe". It cannot do so for three primary reasons:

1. The EPA knows that the data it has reviewed falls far short of what would be required to rule out any and all health risks, and that even state-of-the-art testing

and risk assessment science cannot identify all ways that a pesticide might trigger adverse public health outcomes (e.g., genetic damage, disrupted endocrine function, impacts on the microbiome, reproductive problems, impaired neural development or neural decline).

2. The EPA knows that some people do not read or follow label instructions. Some applicators decide to not use required or recommended PPE. Application equipment sometimes leaks. Frequent users are also exposed, and sometimes heavily, when cleaning, repairing, or maintaining spraying equipment. Some people come to believe that a given pesticide is safe because they were told it was, and they never experienced adverse acute symptoms, even when heavily exposed.

3. Any given pesticide label cannot come close to addressing all the unique application scenarios that can, under some circumstances, lead to higher exposures than those expected by EPA and registrants, and those used in EPA risk assessments.

4. Many label directions are ambiguous, and reasonable interpretations can result in much higher or lower exposures and risks than registrants and EPA expect to occur under “normal” application circumstances.

An important, contemporary example of point four is lawn and garden GBH labels that base the acceptable rate of application on versions of this instruction – “Spray until weeds are thoroughly wet”. What, exactly, does thoroughly mean? Is it likely all users properly understand this key use direction that often has a direct impact on exposure levels.

Nor does the EPA extend its applicator and occupational risk assessments to encompass people spraying a pesticide for several hours a day for many days annually, and over several years. Or pesticide manufacturing plant workers who are exposed even more continuously. The typical EPA applicator and occupational risk assessment is based on a person applying a pesticide just a few times in a week or month, for a few hours each day, and experiencing “typical” exposure. When the EPA determines that such exposure episodes can be deemed safe (i.e., MOE>100), then the EPA makes a mammoth leap of faith – assuming any combination of frequent, heavy, and long-term use and exposures must also be safe.

C. A Systemic Flaw in FIFRA and Regulatory Requirements is Germane in the Assessment of Label Warnings and “Failure to Warm” Claims

There is a critical, systemic problem with the science upon which EPA pesticide regulatory decisions rest. Most pesticide active ingredients cause several different adverse effects in the different species in which the ~30 toxicology studies are carried

out. Different studies will report a diversity of effects that occur and impact different organ systems and metabolic processes. Risk levels will vary greatly as a function of how test animals – or people -- are exposed (diet, dermal, inhalation), as well as levels of exposure, and how often and for how long they are exposed.

Some of these identified adverse effects are not serious or life threatening, while others can be serious, and even fatal. Some are readily treatable by physicians and reversible, others are not. But EPA risk assessments and regulation are based on just one effect, and often not the most serious adverse effect evident in a pesticide's toxicology database.

EPA also generally does not take into account, or places little weight, on adverse effects reported in studies done by independent scientists and published in peer-reviewed science journals.

So in the real world, when a person is exposed to a pesticide, the EPA's assessment of risks, and label directions, cautionary statements, and warnings are focused on avoiding the adverse effect that occurred at the lowest level in an animal study. In some cases, the adverse effect will be among those that are not life threatening and readily treatable.

For many pesticides, exposures might lead to one or more adverse effects at higher doses, or via a different route of exposure, than the effect upon which OPP is regulating the pesticide. Such secondary effects might be both more serious and harder to treat. But labels are not designed to alert users to those other, secondary risks. Plus, ***OPP risk assessments and labels largely ignore the sometimes uniquely high occupational exposures and risks stemming from applications of or handling formulated products***.

The key point is that the way EPA conducts risk assessments leads to labels that are focused on minimizing one type of risk associated, but are usually silent on other, sometimes more serious risks that could occur at higher dose levels, or perhaps at a lower dose among people exposed many times per year over many years, or in vulnerable population cohorts.

An important contemporary example of this systemic shortcoming of EPA risk assessments and regulation is the relatively high chronic dietary Reference Dose now set at 1.0 mg/kg/day for glyphosate. This exposure threshold is based on a very old, short-term rabbit study about which methodological questions and concerns have persisted for decades. Today, the primary unresolved safety issue with GBHs is the linkage between blood cancers, and heavy and multiple applicator exposures to formulated product. The rat and mouse cancer bioassays done by registrants mostly in the 1980s and 1990s used very high dose ranges of pure glyphosate, and not a formulated product, and produced equivocal and inconsistent evidence of cancer risk.

Much more is known today about the mechanisms through which exposures to GBHs can increase the risk of damage to DNA known to be associated with specific cancers,

and especially NHL (Benbrook, 2025, Chang et al., 2023a, 2023b, 2024, Rana et al., 2023). ***It is indisputable that no one, including the OPP and Bayer/Monsanto, knows the dermal dose of glyphosate sufficient to damage DNA in hematopoietic stem cells (HSCs) in bone marrow enough to start the proliferation of mutated lymphocytes along the path to NHL***. But is that sufficient reason to essentially ignore GBH-NHL risk in EPA risk assessments, and when Bayer/Monsanto crafts and OPP approves use directions and warnings on GBH labels?

If the petition advanced by the Attorneys General were codified in EPA regulations or state laws, most GBH registrants will continue to oppose adding a GBH-NHL warning to labels, since, they will argue, the science is still not settled (i.e., today's status quo). A new study by the Iowa Cancer Consortium published later in 2025 might report evidence that individuals that maintained spray equipment were at substantially elevated risk of NHL because of exposures incurred in changing, cleaning, and servicing spray nozzles.

Some individuals who did this sort of work might be diagnosed with NHL or another blood cancer, and seek compensation via litigation. Their attorney would want to cite the Roundup label's failure to warn about nozzle-related exposures as a contributing factor in the etiology of the client's disease, but a judge would not allow that claim because such a warning did not appear on the federally approved label.

Another unintended outcome of the changes sought by those promoting an end to "failure to warn" claims is that the only risks that registrants and EPA will have to strive to reduce or prevent via label directions, precautionary statements, and warnings are those addressing the risks related to the single, lowest dose effect driving the establishment of exposure thresholds. For glyphosate and GBHs, ***such risks are those experienced by pregnant rabbits some 40 years ago in a study of questionable quality***.

Conducting the data collection and research needed to prove that $pesticide_x$ can cause adverse health $effect_y$ has almost always taken one or more decades, especially when registrants are determined to challenge such a conclusion. Accordingly, if the changes sought by the Attorneys General are adopted into law and regulations, adverse health effects for which there is suggestive, or even some strong data, ***might not be highlighted nor mitigated via cautionary statements or warnings on EPA-approved pesticide labels, and hence would be off limits for "failure to warn" claims in pesticide litigation***.

Hence, the changes sought by the Attorneys General would not just help protect pesticide registrations from liability risk when one of their registered products proves ineffective, or harmful to people or other animals. It would also take away some of the best tools and inducements in FIFRA that reduce liability risk among those pesticide registrants that are forthcoming and honest about possible risks they become aware of (as required by law), and who propose steps to reduce exposures in an abundance of

caution, ***in contrast to registrants that do not, and even worse, systematically keep EPA and Attorneys General in the dark about possible risks not addressed or mitigated via federal label use directions, precautionary statements, and warnings***.

D. Protecting Vulnerable Population Cohorts

There is another unfounded assumption that is required to give credence to the claims in the petition of the Attorneys General and other industry advocates supporting an end to "failure to warn" claims. The assumption is that the single, adverse health effect relied upon by EPA to set acceptable exposure thresholds among the general public, or the typical, healthy applicator, will also prove sufficient to avoid adverse health outcomes among vulnerable members of the population including, for example, the tens of million Americans who are:

- Pregnant or trying to start a family (Eaton et al., 2022),
- Taking immunosuppressive medication because of an organ transplant,
- Currently under treatment for cancer,
- In remission from a previous case of cancer and hoping to avoid a relapse,
- Have a genetic polymorphism that makes them more vulnerable to a particular type of toxic insult and/or pesticide, and
- Fighting a chronic disease or dealing with the aging process.

A strong argument can be made that additional cautionary statements and/or warnings are warranted on many existing pesticide labels to alert mixer/loaders and applicators who fall into one or more of the above categories of the need for extra caution and discipline when they handle pesticides.

But if the Attorneys General proposal is codified in law and/or regulation, it is likely that future labels will contain even fewer cautionary statements and warnings than currently the case. EPA will then have to decide whether to restrict or ban pesticide uses that expose vulnerable population groups to risks above the agency's "level of concern," or allow such uses to continue in the hope that vulnerable populations will avoid contact and exposures to certain pesticides.

IV. HOW FIFRA IS SUPPOSED TO AVOID "UNREASONABLE ADVERSE EFFECTS"

The modern version of FIFRA was crafted in a major rewrite in 1972 (P.L. 92-516). Prior to 1972, pesticide regulatory law was mostly focused on assuring that pesticide products were effective for the uses for which they were marketed. The first "FIFRA" was passed in 1947 (P.L. 92-516), and was amended in 1964 by P.L. 88-305. In short until 1972, the goal was to prevent the marketing of "snake oil" to kill or control pests.

There were many new provisions added to FIFRA in bills passed in 1972, 1975, and 1978, and 1980. The primary focus of federal pesticide regulatory law shifted from efficacy to the protection of human health and avoidance of environmental harm, like poisoning bald eagles and other birds as documented in the widely red book *Silent Spring*.

Throughout the 1970s and until the 1996 Food Quality Act (FQPA), there was a healthy, ongoing debate over the problems Congress should address in modernizing FIFRA. Successful amendments directed the EPA to focus its testing of pesticides, and regulatory decision-making, on health risks faced by the general public stemming from pesticide residues in food, drinking water, and beverages.

Congress anticipated that there would likely be disagreements and controversy over some specific EPA decisions to either allow a new pesticide on the market, or whether to impose restrictions on the use of a pesticide already in use. Such restrictions could include cancellation in extreme cases (e.g., mitigating the risks posed by DDT and other chlorinated hydrocarbon insecticides by cancelling their federal labels).

Congress also was aware that scientific progress would allow the EPA and state regulators to develop new ways to identify and quantify risks. As a result, provisions were added to FIFRA, and EPA regulations, clarifying and codifying registrant responsibilities that would hopefully assist the EPA in grounding its pesticide decisions on solid exposure data and the best, and latest risk assessment science.

A. Registrant Responsibilities When They Write Pesticide Labels

In the modern FIFRA, there are two critical provisions that will be undermined if the Attorneys General petition, or comparable changes in state or federal law, are enacted. First, FIFRA states clearly that "the label is the law." It also states that pesticide products cannot be lawfully sold or applied if "misbranded". This means pesticide labels cannot include false or misleading information, and must adhere to, and achieve the requirements of FIFRA.

The requirements of FIFRA include conducting tests called for by the EPA, and also crafting label directions, cautionary statements, and warnings needed to avoid "unreasonable adverse effects on man or the environment". FIFRA places the responsibility on registrants to write and propose label language to the EPA that will

prevent “unreasonable adverse effects”. ***This latter requirement, and registrant obligation, is critical in the context of the Attorneys General petition***.

In its reviews of studies, risks assessments, and risk management decisions, the EPA’s responsibility is to: (1) assure that all required and requested tests are completed and submitted to the agency, and comply with Good Laboratory Practices, (2) determine whether the results support approval of the pending action(s) requested by registrants, and (3) assure that the labels proposed by registrants include use directions, precautionary statements, and warnings ***sufficient to mitigate any risks of concern that the EPA or the registrant are aware of***.

But the EPA is not required by FIFRA, and does not, and indeed cannot confirm and declare that a pesticide product will always be safe, and will never cause “unreasonable adverse effects” when applied in full accord with label directions and requirements. ***The responsibility to craft a pesticide label sufficient to prevent “unreasonable adverse effects” is borne by registrants***. Any label that falls short of this goal because of some high-risk scenarios were not addressed on labels render the pesticide product misbranded, regardless of whether EPA approved the label or not.

Registrants are aware that they bear this responsibility. They also know that when a label is deficient, and a lawful application or applications of a pesticide damages private property, triggers a health problem, or kills someone’s pet or farm animals, they can be found responsible in a state or federal court by virtue of a “failure to warn” claim, or because of a flawed product design, or negligence. Many toxic tort cases site all three of these common causes of action (a “cause of action” is the justification for filling a lawsuit).

One way pesticide registrants can lessen their liability risk is to place on pesticide labels requirements for PPE and other steps that will typically reduce exposures well below maximum EPA-set thresholds, coupled with cautionary statements and warnings that alert applicators and handlers of the reasons for caution.

Labels that contain all three – risk reduction measures, cautionary statements that flag high-risk scenarios, and warnings that alert users to negative consequences if they fail to follow label requirements – ***render a registrant far less vulnerable if and when problems arise from the way a pesticide product is applied***.

But labels that lack one or more of these three elements increase the risk that courts and juries might find registrants fully or partly responsible when a lawful use of a pesticide damages private property or impairs human health. Again, GBH labels are a contemporary example. Almost all GBH labels lack cautionary statements and warnings about DNA damage and cancer. Many formulations and labels arguably contain design defects, and the failure to require mixer/loaders and applicators to wear gloves strikes some juries as negligent.

So, if pesticide industry efforts to undercut “failure to warn” claims in litigation are successful, an unintended but predictable outcome will be heightened determination among some registrants to resist adding precautionary statements and warnings on their labels, since the adverse consequences from not doing so will be markedly reduced.

B. Other Registrant Responsibilities Imposed in FIFRA

In amending FIFRA in the 1970s, Congress recognized that EPA would never have nearly as much data and understanding of the properties and toxicity of a pesticide as its registrant(s). They also knew that EPA could not be expected to keep track of all the ways a pesticide was actually being used across the country, and how different application equipment and use patterns might change exposure and risk levels. This is why Congress created a significant role for state regulatory authorities in the pesticide regulatory process.

Congress also knew that new and better risk assessment methods and testing systems would become available, and should be taken advantage of in quantifying and mitigating pesticide risks.

To meet these needs and opportunities, the Congress added a provision in FIFRA that requires registrants to provide to EPA any “new” information a registrant gains or learns of that sheds new light on the exposures and/or risks arising from use of one of their registered products (FIFRA section 6(a)2b). EPA regulations clearly explain the meaning of the word “new” in the context of FIFRA’s so-called “Adverse Effects Reporting Requirement.” Depending on the nature and significance of such new information, registrants are required to submit such new information to EPA in 30 to 120 days under most circumstances.

The provision encompasses any information in the possession of a registrant that is different from existing information known to the EPA, and which could lead the EPA to revisit safety thresholds or exposure levels. New exposure data in an exposed population or region would have to be disclosed. New metabolism and toxicology data or insights have to be disclosed. Information obtained by a registrant in the course of identifying why an applicator required medical attention after applying a pesticide, or was killed, would be subject to disclosure. “New” information is any information that might help the EPA identify where and how pesticide labels should be changed to avoid high-exposure and high-risk scenarios.

Unfortunately, FIFRA does not impose penalties on registrants sufficient to deter untimely sharing of new information that falls under section 6(a)2b. Registrants have learned that EPA rarely is aware of violations, and even when they become aware, enforcement actions typically do not occur, and when they do, fines are trivial and no serious regulatory consequences occur.

Indeed, some pesticide companies have become serial violators of this key FIFRA requirement. Some have perfected the art of explaining, after failing to disclose new data, why such data they obtained, including the results of their own inhouse studies, do not constitute “new” information, and hence did not have to be disclosed.

The Syngenta-predecessor companies that brought paraquat onto the market and expanded crop uses in the 1960s and 1970s have kept it registered for more than 30 years after solid data became available linking paraquat exposures to brain damage associated with Parkinson’s disease. This is one troubling example of a company that has largely ignored Section 6(a)2 requirements for decades.

While pesticide registrants have little to fear if and when caught violating FIFRA Section 6(a)2 obligations, serious consequences can arise in courts of law. In ongoing litigation over Roundup and NHL, and paraquat-Parkinson’s disease, registrant failures to share new data with the EPA, as required by FIFRA, has, and/or will be presented to juries. Interviews with jurors after the conclusion of some Roundup-NHL trials has confirmed that a registrant’s failure to comply with Section 6(a)2 obligations influenced the outcome of the trial, as well as the amount of money awarded to plaintiffs via punitive damages (“punitive” damages are intended to discourage continued bad behavior, like not following legal requirements, or hiding negative data, or new information on product safety or performance).

The best way for pesticide registrants to limit liability risk, if and when one of their registered pesticides is alleged to have caused some harm that leads to litigation, is to be able to present to juries evidence of how they complied with all requirements in federal and state law, including adding clear use directions and requirements for PPE on labels, as well as precautionary statements and warnings sufficient to alert users of their products to high-risk scenarios and unusual risks, if any are known to exist. The Attorneys General petition would essentially eliminate “failure to warn” claims in litigation, but does not alter registrant obligations to share new information with the EPA that might lead the agency to update risk assessments and/or impose added safety requirements.

V. THE ROOTS OF THE CURRENT CONTROVERSY OVER "FAILURE TO WARN" CLAIMS

The proper role of state agencies versus federal agencies in pesticide regulation has been among the important issues the Congress and state officials have dealt with over the last 50 years. In the major rewrite of FIFRA in 1972, Congress provided for a role for state regulatory authorities because of the vastly different pest management challenges across the country both in agricultural and non-ag settings. In addition, Congress was aware of the diversity in the ways pesticides are handled and applied, and the impacts of such diversity on human exposures and risks, and environmental and ecological impacts. In further amendments to FIFRA over the next decade, Congress refined and clarified the roles and responsibilities of state versus federal EPA regulators.

Also key – the FIFRA statute directs federal EPA to avoid unreasonable adverse effects on the general public by limiting dietary exposures to pure active ingredients. This is one of the reasons why essentially no EPA toxicology data requirements call for the testing of formulations (except the "six-pack" set of short-term acute toxicity and skin irritation studies done on formulations; these studies cannot detect most adverse health outcomes).

FIFRA is silent on what constitutes an "unreasonable adverse effect" on applicators and farm workers exposed through the skin to formulated products. By its own admission, the EPA did not evaluate applicator dermal exposures to GBHs, and associated risks in the most recent reregistration cycle. Hence, the EPA has no basis to speak to the level of risks faced by applicators, including individuals that have been heavily exposed for many years.

California regulators, on the other hand, are concerned by and focused on farm worker and applicator exposures to all pesticides. They often require multiple steps to reduce exposures that do not appear on EPA-approved federal labels. The Attorneys General petition would provide pesticide registrants a basis to argue in court that once EPA labels a pesticide, any application made in accord with federal label requirements must be presumed safe, even when they are not.

A. The Goals Sought Via Preemption

Over the years and for good reasons, the pesticide industry sought to avoid having to deal with multiple, sometimes conflicting testing and labeling requirements across the 50 states. Congress recognized this need and sought to find the proper balance between federal EPA being in charge of most aspects of pesticide testing, risk assessments, and labeling, especially as these core functions impact pesticide exposures and risks facing the general public.

But Congress was also aware that in some cases, a pesticide would need to be used in a way in an individual state different from what is allowed nationally via a federal, EPA-approved label. Consider a simple example – an EPA approved label allowing

applications of a rice herbicide via aerial application, among other methods. In California, state regulators may be aware of adverse ecological and human health effects stemming from aerial application, and deem such risks unacceptable ***under both the core provisions of FIFRA and state laws***.

Congress and FIFRA provide California regulators two options in such a case: they may not register the product for any use in California, or issue a supplemental label under FIFRA Section 24, “special local need” authority that spells out the ways the herbicide can be sprayed on rice in California, a list that would not include aerial application.

The industry and Congress was aware that in some states, pest managers face unique combinations of agricultural and non-ag pest management challenges, and pesticide risk outcomes, that differ from the use and risk scenarios examined by federal EPA.

In the 1972 amendments to FIFRA, Congress clarified several aspects of state and federal roles in pesticide regulation, and sought to find a balance of roles and responsibilities that allowed states to extend and refine how federally labelled pesticides are used within their borders. For example, Congress granted states the right to issue Section 18 “emergency exemptions” and Section 24(c) “special local need” supplemental labels could allow a federally labeled product to be applied to an addition crop, a in a new way along roadsides, or with different application equipment. Most Section 24(c) labels expanded the ways a federally labeled product could be lawfully used in a state.

Section 24 (a) labels typically altered whether, and under what circumstances a federally labeled pesticide could be used in a state. These supplemental labels added new restrictions to an approved EPA label, such as disallowing aerial application or delivery through irrigation water (aka, chemigation).

Such state-limited labels could, under certain circumstances, add a new crop not on a federal label, or change the application equipment that can be used in a state (e.g., allow or prohibit aerial application). They could require added safety precautions or PPE to avoid adverse effects that go beyond those required on federal labels. Such state-level labels would obviously contain provisions “different from” federal labels designed to hopefully reduce exposures and risks to a level allowed by FIFRA and state laws.

Congress specified that the federal requirements that registrants and pesticide users must adhere to in order to gain approval of tolerances and a federal label must not be eroded or undermined by the content of state-issued labels. But states were free to impose additional use directions, restrictions, PPE requirements, and cautionary statements and warnings associated with state-sanctioned uses of a pesticide that did not appear on a pesticide’s federal label.

Yes, FIFRA preempts, as one example, the role of state regulators, and state law, to add new toxicology testing requirements prior to federal EPA acting on a tolerance petition, or setting maximum acceptable exposure thresholds. FIFRA spells out the various

sections on pesticide labels and explains what they must cover. FIFRA forbids states from adding new or different requirements on an EPA-approved label, but ***it does not forbid states from adding new content within a category of requirements on a label, when such content is needed to mitigate unique risks known or expected to arise in a state***.

A good contemporary example should be fresh on the minds of the Attorneys General submitting this petition – setting cut-off dates for post-emergent applications of dicamba on GMO soybeans and cotton. May states recognized the need to alter cut-off dates for the last application from those on the federal label, in order to prevent drift and crop damage. Some states imposed granular differences in certain counties, others imposed a specific cut-off date "...north of Interstate 30 to the State line."

Such state supplemental labels impose different restrictions not on the federal label, but do so within a set of requirements on federal labels. States cannot add new categories of requirements not on a federal label, but they can refine the specific measures needed in a state to meet the purpose or goal sought through an existing requirement.

Sections 18 and 24 of FIFRA provide states options to issue supplemental labels that, by definition and necessity, contain content that is different from EPA-approved, national labels. Most such new content will govern how new, approved uses in a state impact exposure levels and/or adversely impact the environment, or non-target organisms (e.g., migratory birds that overwinter in flooded rice fields in California).

A Critical, Deep-in-the-Weeds Distinction

For the purposes of preemption as now sought by the pesticide industry, a "**requirement**" is a rule of law that must be followed, and for which adverse consequences may follow when someone, or some company, is caught failing to comply. Pesticide personal injury claims, or claims advanced by farmers who allege a pesticide they bought and applied failed to control a target pest listed on the label, can be based on obligations set forth in state and/or federal law, as long as the obligations merely seek to promote adherence to, and enforcement of FIFRA's existing **requirement** that pesticide labeling is adequate to avoid "unreasonable adverse effects on man or the environment".

Moreover, virtually all pesticide litigation based in whole or part on state law obligations does not strive to affirmatively change or add content to EPA-approved, federal labels. Hence, litigation that rests to some degree on violation of state-law obligations does not conflict with FIFRA's **requirement** that federal pesticide labels include EPA-approved labeling language (and especially, use directions, precautionary statements, and warnings).

It is unclear how the Attorneys General petition would impact the opportunity for states to address unique pest control needs, and pesticide risk scenarios, via the granting of Section 18, 24(a), and 24(c) supplemental labels. This is one of the unknown, and

possibly unwelcomed impacts of the Attorneys General petition that warrants further study.

In 1981-1983, one of the co-authors of these comments (Benbrook) served as the Staff Director of the subcommittee in the House of Representatives that had jurisdiction over FIFRA. In that period following the election of President Ronald Reagan, the pesticide industry worked with Congress and the EPA in an effort to reach agreement on many changes in FIFRA, including amendments that would have established EPA-approved labels as both the floor and the ceiling in all state and federal labels and litigation (i.e. what the pesticide industry and Attorneys General are striving to accomplish now). Back in the 1980s and to this day, proposals from the pesticide industry to preempt the role of states in pesticide regulation have been controversial, and largely unsuccessful.

During subcommittee hearings in 1981-1983, officials from several states, and in particular California, argued that some EPA-approved labels were allowing unsafe application scenarios in their state, including in particular farm worker and applicator exposures on farms growing high-value fruit and vegetable crops. California regulators testified that they were struggling to deal with such exposures, across more than 100 economically important crops, with the tools available to them. They acknowledged that the EPA could not realistically collect the data, and conduct the diversity of added risk assessments, that would be needed to meet core FIFRA and state-law goals in California, a state in which pesticides are vital and routinely applied in thousands of ag and non-ag application scenarios. Moreover in California and other western states, several pesticides are intensively applied many times in a year, and often in close proximity to farm workers in fields, children in schools, and other population centers, as well as vulnerable natural habitats teaming with life.

EPA officials testifying before the Subcommittee in 1981-1983 stated that it would be difficult for EPA to deal with the unique pesticide use patterns and high-risk scenarios in any one state, let alone all 50, via a single, federal label. In addition, if EPA attempted to do so, the agency explained that ***it would be difficult to avoid confusing pesticide users who would be exposed to multiple, sometimes conflicting use directions and label requirements applicable just to specific states***.

Despite continuous efforts by the pesticide industry and many farm groups in the 1980s and 1990s, no major changes have been made in FIFRA altering the state versus federal roles in pesticide regulation. But the debate over preemption in pesticide regulation was far from over, and indeed was about to markedly intensify because of a major change in pesticide chemistry impacting farmers all over the country.

B. Herbicide Carryover Leads to Significant Economic Losses for Farmers and Litigation Pitting Farmers Versus Herbicide Registrants

In the late 1970s and through the 1990s, the industry discovered and brought to market new classes of herbicides that could be applied before planting at much lower rates, thereby hopefully reducing both human and environmental risks. Some of the new

imidazolinone and sulfonylurea herbicides were effective at just 0.01 pound of active ingredient per acre treated, a rate about 100-times lower than the herbicides they replaced. But the vastly heightened, weed killing potency of these herbicides per ounce applied was coupled with a tendency to persist for weeks or months in soil, or even most of a year in certain soils and farming systems.

Some peanut farmers in Texas started to use one of the newly registered herbicides, the Dow AgroSciences sulfonylurea herbicide diclosulam. The farmers benefited from excellent weed control, but experienced problems with the next crop they planted. It took some time and university research to trace the problem to its cause – diclosulam carryover in certain soil conditions that was sufficient to kill or set back the next crop planted in a previously treated field.

In 2005 the Supreme Court heard a case brought by Texas peanut farmers who alleged the lack of a necessary warning about diclosulam's persistence in certain soil conditions had led to crop damage and economic losses for which the farmers were entitled to compensation. Defendant Dow AgroSciences argued that such claims for compensation ***were pre-empted by the FIFRA statute, because the contents of the herbicide's label had been approved by the EPA***.

The Supreme Court's ruling in favor of the plaintiffs highlighted an important reality in the management of pesticide risks, as well as the importance of key FIFRA provisions:

> "Given the inherently dangerous nature of pesticides, most safety gains are achieved not through modifying a pesticide's design, but by improving the warnings and instructions contained on its label."

It is worth noting that ***the current legal framework governing how preemption and "failure to warn" claims are dealt with in litigation over alleged harms caused by pesticides emerged from a case brought by farmers against a herbicide manufacturer***. Moreover, in the resolution of the case, the Supreme Court cited the FIFRA-imposed responsibility of registrants to foresee and mitigate risks via label directions, requirements, precautionary statements, and warnings in order to assure their products are not deemed "misbranded" because the labels written by registrants fail to prevent "unreasonable adverse effects".

C. Technical Problems and Unforeseen Consequences If FIFRA's "Failure to Warn" Claims are Preempted

The petition filed by the Attorneys General state that the only warnings that can be placed on a federal pesticide label are those that are consistent with a final, EPA pesticide human health risk assessment.

All currently registered pesticides must go through the reregistration process every approximate 15 years. Throughout such cycles, there will be an initial EPA document that identifies data gaps that must be fulfilled prior to reregistration. During years five-to-10 of the process, there will be a series of requests by EPA to registrants to conduct

newer, better studies to fulfill specific data requirements; generate new data on pesticide levels in soil, water, the air in order to sharpen exposure estimates; or new studies to help resolve differences of opinion between registrant and EPA scientists.

EPA rarely brings a reregistration review to closure until the agency feels it has adequate, high-quality data sufficient to produce acceptably accurate estimates of risks and benefits that it can rely on in determining needed risk mitigation measures, if any.

Toward the end of a 15-year reregistration review process, EPA typically issues a nearly final, but still draft human health risk assessment. This document will be made available via a Federal Register notice, and comments will be sought from the public, and are typically due in 60 to 120 days. Prior to issuing a final risk assessment, OPP must review and respond to all submitted public comments. These will include typically voluminous comments from registrants challenging any risk assessment judgments that deviate from the registrant's view of available data. When a registrant has alerted users of its product to the possible loss of currently labelled uses, the EPA also often receives a high number of comments from farmers and other pesticide users that must be evaluated and responded to.

Sometimes public comments raise new issues and concerns that lead the EPA to ask registrants to carry out additional studies or collect new field data. Such new information will then have to be reviewed, and the results incorporated in a new draft risk assessment, which also will have to be subject to notice and comment. Upon the issuance of a final human health risk assessment and proposed regulatory actions, the science EPA relied on, and its risk management decisions, are often challenged by either registrants or those who feel the EPA has not sufficiently mitigated real-world risks.

Such legal challenges can lead to a court order to the EPA calling upon the agency to revisit the basis of its risk estimates and risk mitigation judgements. To do so, the EPA may decide it needs to request new studies and data from registrants that will have to be conducted, reviewed and incorporated in an updated human health risk assessment. This starts the process anew: new studies>new assessments>new public comments>new draft human health risk assessment subject to another round of public comments, and so on.

This is why 10 to 20 years can pass between EPA issuing a "final" human health risk assessment for a widely used pesticide and a final reregistration decision. If EPA acts to accept the Attorneys General petition as written, state regulators would be forced to regulate on the basis of the last, final EPA human health risk assessment that might have been completed 20 or more years ago. This is another unforeseen consequence of the Attorneys General proposal. This will expose farmers and the public to unnecessary risks, since state regulatory activities, and court proceedings, might not be allowed to draw upon new science and updated data for a decade or more after it was available to EPA.

Another issue warrants emphasis. As the pesticide reregistration process unfolds over 15-20+ years, a new president may be elected. Control of Congress may change. Some new pest or pest management problem may emerge and pose serious challenges (e.g., the spread of resistant weeds and insects, mosquito-borne west Nile virus that is killing horses). These and other exogenous factors can influence the way OPP risk managers strive to comply with all FIFRA requirements across the approximate 800 active ingredients and many tens of thousands registered pesticide products. Agency officials and scientists have to continuously make decisions regarding how to allocate limited resources in light of a virtually endless list of tasks that could sharpen the accuracy of risk assessments and reduce farmer, general public, and environmental risks.

Science and risk management issues can fade away, and return with a vengeance. This can occur as a result of new science, or recent recognition that exposures to a registered pesticides have been contributing to reproductive problems or cancer. As a result, the issues that command the attention of OPP managers and risk assessment scientists can change abruptly over time, and not necessarily because new information has emerged that resolves past, and even long-standing, risk concerns.

Some people might interpret absence of discussion in a draft or final human health risk assessment as evidence the EPA has determined there is no longer any reason for concern, but that assumption will often be misplaced. Applicator and occupational exposures to GBHs is one example. Another is the neurodevelopmental harm following prenatal exposures to chlorpyrifos. The heightened risk of Parkinson's disease from exposures to paraquat also has waxed and waned as an OPP priority over the last 40 years.

Registrants have honed their skill in designing and conducting studies that produce data satisfying EPA data requirements and that purportedly support the actions the registrants need EPA to take for the company to achieve its commercial and profit goals. Registrants interpret the results of their studies prior to submitting them to EPA. Registrants state the findings of their studies and explain why the data support the requested actions. Registrants work assiduously to assure EPA reaches the same basic conclusions on whether a study "supports" continued and unimpeded registration of their products.

Registrants include in their submissions the reasons why the EPA should not be concerned about any evidence in a study that points to a possible health risk. Registrants are skilled at deploying a range of tactics to convince EPA scientists that any questions or concerns arising from currently available data are "not treatment related" or are "biologically insignificant".

D. Registrants Compete for Market Share by Crafting Labels that Downplay Risks Compared to Competitive Products

In order to gain and hold market share, registrants know from past experience that the scope and content of PPE requirements on labels, cautionary statements, and warnings

have an impact when farmers and pest managers decide which of several registered alternatives to purchase to address a given pest management challenge. They know that when a pesticide is deemed sufficiently toxic and risky to warrant classification as a “restricted use” product, there will likely be an adverse impact on sales.

Pesticide product labeling, by design and in accord with core FIFRA requirements, is supposed to clearly communicate on product labels the types and levels of risk possibly stemming from use of the product. But registrants often seek to gain an edge in marketing by securing EPA-approval of labeling that accentuates the purported absence of risk. Manufacturers sometimes alter the selection of coformulants, and product composition, to secure a lower-risk signal word, or to avoid having to place a requirement for PPE on a label, or a cancer warning.

Some registrants are dogged and disciplined in securing EPA labeling that provides a meaningful edge in the market. Registrants consistently remind EPA officials of what they feel the agency should do in accord with sound science, and also make clear what the company will, and will not accept. Registrants often inform EPA officials of what the company will do if the EPA insists on taking actions that the company feels are unwarranted. As this process of frequent communication unfolds, EPA officials gain a good understanding of what registrants are likely to accept without a protracted fight.

As a result, the EPA picks and chooses where it decides to insist on label changes. EPA tends to shy away from changes that will trigger stiff opposition from registrants and farmers, especially when label changes under consideration would achieve modest progress in reducing risks. This is why, overtime, the labeling on some pesticides becomes progressively divorced from addressing and mitigating real-world risks.

Over the years Monsanto has been remarkably successful in the halls of EPA in minimizing any discussion of possible health problems from applicator exposures to Roundup. The absence of low-cost, proven exposure reduction measures on Roundup labels like “wear gloves when mixing and loading, or applying this product” are examples of steps the company could have taken to lower exposures and risk, but did not.

If the Attorneys General petition, and/or related changes in law are adopted, it could become less likely that registrants will add new precautionary statements and warnings onto their labels, especially if registrants sense that the agency will not devote the resources and time required to force new provisions on labels. Registrants can add risk mitigation measures as part of routine label amendments and EPA would almost always welcome and approve such changes.

The episode that arose in 2019 when the EPA pesticide registration division issued a letter to GBH registrants informing them that they could not place a cancer warning on GBH labels in response to Prop 65 in California was unusual, without force of law, and politically motivated. It was superseded by the agreement between EPA and the State of

California on a GBH cancer warning that is compliant with California state law and FIFRA.

E. Registrant-EPA Interactions and Agreements Often Play a Role in Litigation

The dynamic flow of information between OPP officials and scientists and registrants is often well documented in memos and communications in the files of the EPA and registrants. During litigation, these files are typically secured and become part of the discovery record. Juries sometimes learn about successful efforts by a registrant over many years, if not decades, to forestall product formulation changes that would make products safer, or label additions that would clearly reduce exposures and more effectively warn users of potential risks. Such disclosures of registrant reticence to add exposure-reduction provisions onto labels can play a role in jury deliberations and influence the outcome of cases and the size of damage awards.

In the modern FIFRA, Congress clearly placed the primary responsibility for pesticide active ingredient toxicological assessments, and the setting of exposure thresholds and tolerances, on the federal EPA. For this reason, states play little or no role in these aspects of pesticide risk assessment and regulation. A state role in these tasks and judgements is preempted.

But the pesticide risk assessment process combines toxicity thresholds with estimates of exposure. The Congress reasoned that the EPA should be responsible for the data-intensive assessment of pesticide hazards and the setting of maximum, hopefully “safe” exposure thresholds. But Congress also recognized that the federal EPA could not be expected to stay on top of, and address all exposure-related issues and circumstances that could lead to “unreasonable adverse effects on man or the environment.” Hence, ***Congress did not preempt a substantive role for states on use directions and on the exposure side of the pesticide risk assessment and risk management equation.***

Providing pathways for state regulatory agencies, and researchers and public health authorities in a state, to generate and share more accurate information on pesticide exposures, as products are used in a state, remains important in reducing the frequency of unwelcomed surprises. State engagement is also important in responding in a timely and appropriate way when new evidence identifies unacceptable risk outcomes (i.e. an “unreasonable adverse effect...” arising from a labeled use of a pesticide). Efforts to preempt the role of states and state law in pesticide regulation and litigation will undermine the role of states in dealing with unique risks within their borders.

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