FIFRA v. the Courts: Redefining Federal Pesticide Policy, One Case at a Time

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Since the early 1970s, two federal statutes, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Food Drug and Cosmetic Act (FFDCA) have provided the statutory framework for federal review and regulation of agricultural pesticide labeling, distribution, and use. During the past ten years, however, federal courts have rendered significant decisions subjecting FIFRA registrations to the procedural and substantive requirements of the Clean Water Act (CWA) and Endangered Species Act (ESA). Federal courts have also increased pesticide manufacturers' exposure to state product liability laws that interpret federal labeling decisions narrowly or disregard the federal label altogether. As a result, while FIFRA's text has remained relatively unchanged since the last major amendments in 1996, third-party plaintiffs have used other environmental statutes and legal principles to effect dramatic changes in federal pesticide policy through the courts.

The U.S. Environmental Protection Agency (EPA) has already entered into a series of settlements resulting in geographical-use limitations for dozens of commonly used agricultural pesticides, many of which place particular restrictions on pest-control practices in the southern and western states. EPA and the states are gearing up to implement National Pollutant Discharge Elimination System (NPDES) permitting regulations governing the millions of pesticide applications to or near water, an action that will affect hundreds of thousands of growers across the fifty states. These changes, combined with the upsurge in state tort liability claims against pesticide manufacturers, are likely to place new strains on an industry that is already struggling to remain competitive in an increasingly global agricultural economy.

Pesticide Use and Regulation in the United States

Agriculture in the United States is a risky business. Profits are highly susceptible to fluctuating fuel prices, interest rates, and capital costs, as well as natural variables like rainfall, pest pressures, and weather patterns. Among the tools many growers use to reduce the uncertainties of the growing season are herbicides, insecticides, and other crop-protection chemicals. When used judiciously and in accordance with the federal label, the right pesticides can help mitigate the grower's risk of excessive crop loss or damage from a range of weeds, microbes, insects, fungi, and the like, allowing growers to use their land for the highest-value crops.

Of course, the same chemical products that growers rely upon to manage agricultural pests can also pose risks to the safety, health, and environment of the surrounding community, the larger ecosystem, and even the global climate and stratosphere, if those products are not selected, used, stored, and disposed of properly. It is this duality of pesticides that makes federal pesticide regulation such a critical component of both agricultural and environmental policy.

The United States has responded by developing a tightly controlled pesticide regulatory system in which virtually every chemical marketed as a pesticide must undergo pre-market review and registration by EPA. In making such decisions, EPA brings together teams of experts from multiple fields (including toxicology, biology, weed science, hydrology, economics, and veterinary medicine) that are tasked with assessing and managing risk based on the stringent safety standards required under FIFRA and, in the case of pesticides used on food or feed, the FFDCA. The final terms of the registration are distilled in the federal pesticide label, articulating in detail the approved uses, use instructions, required safety precautions and warnings, and other relevant information required for the product to meet federal safety standards.

In effect, the registration, as reflected in the accompanying label, constitutes a limited license establishing the terms and conditions under which the products may be lawfully sold, distributed, and used. Consistent with this limited approval, regulators often distill the fundamental theme of federal pesticide policy with a simple phrase: "The label is the law." *See, e.g.*, EPA, *Pesticide Registration Manual* (*BlueBook*) (last updated Oct. 2010), *available at* www.epa.gov/pesticides/bluebook/index.html.

In recent years, however, when interpreting the applicability of other environmental laws, courts have questioned the primacy of the federal pesticide label and the adequacy of the federal registration process itself. This has created uncertainties regarding the future marketability and availability of some pesticides in certain regions or states and, more generally, has created new uncertainties regarding the crop-protection tools that growers will have at their disposal in the future. This article discusses three of the most striking examples of this trend.

FIFRA versus the Clean Water Act

Since Congress passed the 1972 CWA amendments, federal

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Published in *Natural Resources & Environment* Volume 26, Number 1, Summer 2011.

law has prohibited "point sources" from "discharging" "pollutants" into "waters of the U.S." without a federal or state NPDES permit. 33 U.S.C. § 1342. This permitting requirement constitutes one of the most significant sources of regulatory authority available to federal and state regulators with respect to controlling effluent from industrial, commercial, and agricultural point sources. Yet, for the first thirty-five years after the CWA's passage, EPA *never* issued an NPDES permit for label-approved applications of pesticide to or near water. This policy reflected the fact that EPA, as part of the review, registration, and labeling process, had already conducted a statutory risk assessment and management process. On a more technical note, prior to 2001, neither EPA nor the courts had considered pesticide applications to water, when conducted in accordance with a FIFRA label, to constitute a "point source" "discharge" of a "pollutant."

Between 2001 and 2009, however, a series of federal court cases revisited and redefined the scope of these core terms and ultimately expanded the jurisdictional scope of the CWA while chipping away at the force and effect of a FIFRA label.

First, in 2001, the Ninth Circuit ruled, in *Headwaters, Inc. v. Talent Irrigation Dist.*, that where excess herbicide remained in jurisdictional U.S. waters following a legal pesticide application, those residual herbicides constituted "pollutants," and the irrigation canals constituted "point sources" subject to the CWA's NPDES permitting requirement. 243 F.3d 526 (9th Cir. 2001). The following year, the Ninth Circuit held that aerial applications of pesticides to forestlands containing jurisdictional waters constituted point-source discharges of pollutants requiring a permit. *League for Wildlife Defenders v. Forsgren*, 309 F.3d 1181(9th Cir. 2002). Also in 2002, a Second Circuit panel raised, in *dicta*, the possibility that pesticide applications to wetlands for mosquito control might also trigger the permit requirement. *Altman v. Town of Amherst*, 47 Fed. Appx. 62, 67 (2d Cir. 2002).

In July of 2003, EPA responded to this growing line of cases by issuing a memorandum entitled "Interim Statement and Guidance on Application of Pesticides to Waters of the United States in Compliance with FIFRA." Interim Statement, *available at* www.epa.gov/npdes/pubs/pesticide_interim_guidance.pdf. The Interim Statement explained that "complying with environmental requirements under FIFRA will mean that the activity is not also subject to the distinct NPDES permitting requirements of the CWA." *Id.* at 6. EPA reiterated and refined this position in a 2005 proposed rule and a subsequent 2006 final rule explaining that pesticides were not "pollutants" for the purposes of the CWA, when applied in or near water in strict accordance with the FIFRA label. EPA, *Application of Pesticides to Waters of the United States in Compliance with FIFRA*, 71 Fed. Reg. 68,483 (Nov. 27, 2006).

While the 2006 rule reaffirmed the primacy of FIFRA in the context of label-compliant pesticide use, its substantive effect was short-lived. Both industry and environmental stakeholders found fault with aspects of the rule, triggering an avalanche of legal challenges across the eleven circuits. On January 9, 2009, the Sixth Circuit issued an opinion that shook the agricultural community nationwide—and rejected thirty years of FIFRA policy. In *National Cotton Council v. EPA*, the Sixth Circuit vacated the EPA rule that excepted FIFRA-compliant pesticide applications from the NPDES requirement, concluding that pesticide applications in or near water are subject to the permitting requirement if they result in any residual pesticides, and in *any case* where biological pesticides are used. 553 F. 3d 927, 940 (6th Cir. 2009). While the decision itself was only binding within the Sixth Circuit, once the Obama administration elected not to appeal the ruling it arguably subjected more than 365,000 growers and pesticide applicators nationally to a presumptive NPDES permitting obligation.

Rather than appeal the decision, the administration requested and received a two-year stay providing federal and state regulators until April 2011 to develop implementing regulations. In June 2010, EPA proposed terms for a general permit covering some of the most common pesticide uses, a strategy intended to reduce the burden of complying with the NPDES permit process by allowing applicants to "opt in" to pre-specified use restrictions and limitations, thereby foregoing the need for time and resource-intensive individualized permit reviews. *See, e.g.*, EPA, *Pesticide General Permit (PGP) for Point Source Discharges to Waters of the United States from the Application of Pesticides (Draft)* (Apr. 10, 2010), *available at* www.epa.gov/npdes/pubs/proposed_pgp.pdf. Still, EPA's proposed General Permit covered only four uses: (1) mosquito and other flying insect pest control; (2) aquatic weed and algae control; (3) aquatic nuisance animal control; and (4) forest canopy pest control, leaving open the question as to what requirements would apply to nonconforming uses in the agricultural sector and how EPA and the states would manage the resulting increases to their permitting obligations. *Id.* at 1.1.1.

By March 2011 concern over the pesticide permitting requirement had escalated within the regulated community and among policymakers from agricultural states. EPA had yet to finalize a federal pesticide general permit, and the court-ordered stay on enforcing the pesticide permitting requirement was set to expire on April 9, 2011. Without a general permit in place, many affected industries and municipalities faced the specter of citizen-suit liability for unpermitted pesticide applications, notwithstanding compliance with the FIFRA label and the lack of a viable permitting process to follow. 33 U.S.C. §1365(a). Even with a working pesticide permit program in place, affected industries and municipalities would suddenly be subject to a "double permitting" obligation at the very time that the administration had committed to reviewing and streamlining federal regulations.

On March 2, 2011, EPA filed a request to extend the court-ordered stay on the permitting requirement until October 31, 2011, citing the need to complete endangered species consultation activities, complete an electronic database to manage general permit requests, and give states time to implement state permitting programs. EPA, National Pollution Discharge Elimination System; Pesticides (NPDES-Pesticides Homepage), *available at* http://cfpub.epa.gov/npdes/home.cfm?program_id=410 (last viewed Apr. 10, 2011). That same day, Congressman Bob Gibbs (R-OH) introduced a bill to exempt label-compliant

pesticide applications to water from coverage under the NPDES permitting requirement. The Regulatory Burdens Act, H.R. 872 (Mar. 2, 2011). The Sixth Circuit granted the stay extension on March 28, 2011, just two weeks before the permitting obligation would have taken effect and four days before EPA released a pre-publication copy of its final NPDES permit.

FIFRA versus the Endangered Species Act

Congress enacted the current ESA framework in 1973, prohibiting both public and private actions that would result in "takings" of listed species and requiring federal agencies to consult with key federal natural resources agencies before authorizing, funding, or carrying out actions likely to jeopardize the continued existence of listed species or destroy designated critical habitat. 42 U.S.C. § 1536(a)(2). Since then, Congress has amended the statute several times, including a 1988 amendment directing EPA and the Departments of Interior and Agriculture to "evaluate methods for implementing an endangered species labeling program" that "would comply with the Endangered Species Act [and] allow persons to continue production of agricultural food and fiber commodities." Pub. L. 100–478 (1988).

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EPA, working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Service Agencies), has developed, revised, and refined its endangered species impact assessment and consultation process over time, seeking to adapt the consultation process to the high-volume, time-sensitive, and economically critical nature of the federal registration and registration review process under FIFRA. EPA adopted a pesticide-by-pesticide approach to consultations, assessing potential impacts from all proposed uses of a pesticide, one chemical at a time, and then initiating consultations as needed for specific species. Later, EPA took on a cluster approach, reviewing pesticides based on specific registered uses and use sites. EPA has also attempted species-based consultations, in which EPA and the Service Agencies consider the full range of pesticides to which any given listed species would be exposed and then expand the review to evaluate any other species impacts from those chemicals.

Each approach offered certain advantages but also revealed shortcomings, particularly when applied to such a large and diverse universe of pesticides, uses, market segments, and species, all subject to review under tight time frames. To address this challenge, in 2004 EPA and the Service Agencies promulgated joint regulations providing EPA with greater flexibility to manage this task. The rule eliminated the need for formal consultation between EPA and the Service Agencies for FIFRA actions that EPA determined were unlikely to affect any endangered species, ostensibly providing all parties more time and resources to focus on priority consultation issues. 69 Fed. Reg. 47,732 (Aug. 5, 2004). These efforts to gain flexibility and breathing room were short lived, however, as over the next eighteen months, federal courts first rejected EPA's effort to assert FIFRA's primacy over the ESA, *Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1036 (9th Cir. 2005) (*Washington Toxics I*), and then struck down the joint rules developed by EPA to focus consultation on higher-priority pesticides, *Wash. Toxics Coalition v. U.S. Dep't of Interior*, 457 F. Supp. 2d 1158, 1194 (W.D. Wash. 2006) (*Washington Toxics II*).

Since *Washington Toxics I*, EPA has moved toward a strategy of settling rather than litigating new ESA consultation cases. To date, EPA has settled numerous cases, negotiating consultation deadlines as well as risk-management actions (e.g., buffer zones, regional restrictions). While EPA's settlement strategy is understandable, it raises several policy concerns. First, allowing litigation and settlements to drive EPA's ESA policy may prompt EPA to impose more frequent and more extensive risk-mitigation requirements than it might otherwise impose based on the science alone. Second, to date, a disproportionate number of the ESA pesticide suits have targeted species in western states, creating agricultural and competitive hardships for western growers, particularly growers in the Pacific Northwest. More generally, the threat of prolonged court action and litigation under the ESA's citizen-suit provision has given third-party plaintiffs an unprecedented role in setting federal pesticide policy priorities, not just within the ESA consultation process, but with the agency's broader allocation of pesticide regulatory resources. Indeed, EPA's website on its priority-setting process contains this telling statement:

> While registration and registration review will be the primary programs through which EPA carries out its Endangered Species Act responsibilities and therefore sets its priorities for review of pesticide effects on listed species, there may be special circumstances that lead EPA to assess potential effects and make effects determinations, outside those ongoing processes. For example, there may be situations in which information is brought to EPA's attention that indicates a listed species may be exposed to a particular pesticide in a manner resulting in unacceptable risk; or EPA may assess risks to listed species on schedules ordered by a Court as a result of litigation.

EPA, *Endangered Species Effects Determinations*, *available at* www.epa.gov/espp/litstatus/eseffects.htm.

Finally, third-party plaintiffs show no sign that they will reduce their use of the ESA as a basis for challenging pesticide actions in the future. In late January 2011, the Center for Biological Diversity (CBD), a frequent litigant on ESA issues, filed its largest EPA challenge to date, alleging ESA violations for over 300 pesticides claimed to affect over 200 species. CBD, *Center for Biological Diversity v. EPA*, Complaint for Declaratory and Injunctive Relief (N.D. Cal. Jan. 20, 2011), *available at* www.biologicaldiversity.org/news/press_releases/2011/pesticides-01-20-2011.html. The same group has previously indicated its intent to challenge up to 400 pesticides, close to half of the active ingredients registered today, asserting effects on up to 850 endangered species. A broad range of stakeholders from the agricultural and chemical industries have since intervened in the case, indicating that the debate over FIFRA and ESA procedural and substantive policy is likely to grow louder in the coming year. *Center for Biological Diversity v. EPA*, Docket Report dated Apr. 10, 2011.

FIFRA versus the Common Law

Under FIFRA, a pesticide is misbranded if its label does not contain adequate instructions for use or if its label omits necessary warnings or cautionary statements. 7 U.S.C. §§ 136(q)(1)(F), (G). While states may regulate the use of any federally registered pesticide or device more stringently than federal law, the statute contains an express prohibition on imposing "requirements for labeling or packaging in addition to or different from those required under FIFRA." *Id.* § 136v.

Prior to 2005, a majority of circuits had construed this type of language as preempting duty-to-warn tort claims as well as more general common-law tort claims like "negligent testing," "negligent manufacture," and strict liability claims, reasoning that such claims contained an implicit assertion that the federal labels were inadequate and constituted indirect inducements to modify labels. In spring 2005, however, FIFRA preemption policy took a significant turn with the Supreme Court decision in *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 436 (2005). In *Bates*, peanut farmers in areas with alkaline soil sought damages from a pesticide manufacturer under common-law tort theories of strict liability, negligence, fraud, and breach of express warranty. The lower courts found that FIFRA preempted any state-law claim in which "a judgment against [the Defendant] would induce it to alter its product label." *Dow Agroscience LLC v. Bates*, 332 F. 3d 323, 331 (5th Cir. 2003). The Supreme Court reversed, concluding first that FIFRA did not preempt common-law claims for defective design, defective manufacture, negligent testing, and breach of express warranty as such claims do not require manufacturers to label or package their products in any particular way. 544 U.S. 431 (2005). The Court further concluded that even a claim based on a state law labeling requirement might not be preempted by FIFRA if it were "equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id.* at 436.

Subsequent federal preemption cases have continued to open the door to state common-law claims against a variety of federally regulated products and industries. Most notably, in August 2010, the Third Circuit revisited the issue of FIFRA preemption in a case involving allegations that farmers in New Jersey suffered crop damage after using a pesticide labeled for use on blueberries. *Indian Brand Farms, Inc. v. Novartis Crop Protection, Inc.*, 617 F.3d 207 (3rd Cir. 2010). In that case, the plaintiffs sought damages asserting strict liability, failure to warn, latent design defect, negligent misrepresentation/fraud, and breach of express warranty. *Id.* at 211. The lower court initially granted summary judgment against the plaintiffs on all claims, citing preemption and other grounds. *Id.* at 212. On appeal, the Third Circuit reversed the district court's findings regarding preemption for the strict product liability, negligent testing, and breach of express warranty claims, citing *Bates*. *Id.* The Third Circuit remanded the claims of negligent misrepresentation/fraud, violation of the state consumer fraud statute, and the duty-to-warn claim for further review to clarify whether the plaintiffs had relied on oral versus written misrepresentations. *Id.* On remand, the lower court again dismissed the remaining claims on preemption grounds, concluding that the marketing brochures distributed to the growers constituted labeling for the purposes of FIFRA. *Id.* On appeal, the Third Circuit Court again reversed, holding that the marketing materials the plaintiffs claimed to have relied upon did not constitute "FIFRA labeling" and, thus, enforcement of state tort claims based on misrepresentation would not constitute additional labeling requirements. *Id.* at 218. Echoing *Bates*' parallel requirement theory, the court even allowed the failure-to-warn claim to advance, finding "no basis for concluding that New Jersey law imposes a duty to warn different than or in addition to the scope of the requirement imposed

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by FIFRA." *Id.* at 224–25. *See also DJ Coleman, Inc. v. Nufarm Ams., Inc.*, 693 F. Supp. 2d 1055, 1080 (D.N.D. 2010); *Golden Wolf Ptnrs v. BASF Corp.*, 2010 U.S. Dist. LEXIS 131365, 21–22 (E.D. Cal. Dec. 13, 2010); *Minkoff v. Action Remediation, Inc.*, 2010 NY Slip Op 51750U, 5 (N.Y. Sup. Ct. 2010).

Legislators and policymakers must continue to develop sound, workable federal pesticide policies. The larger question is how such policies should be formulated and which body is best situated to develop them.

These cases illustrate the erosion of the FIFRA preemption doctrine since *Bates* and highlight several sources of uncertainty for pesticide manufacturers. By preserving "equivalent" and "consistent" state labeling requirements, *Bates* allows private litigants to second guess federal labeling decisions in a manner not envisioned by FIFRA. FIFRA itself does not provide a private right of action to third parties alleging violation of federal labeling and packaging standards. Thus, a challenge to a manufacturer's label under state law will, at best, duplicate the federal government's enforcement efforts. At worst, state-based lawsuits allow individual states to reinterpret federal labeling requirements more strictly than federal enforcement officials, forcing manufacturers to juggle fifty different interpretations of what constitutes adequate warning language, adequate instructions, and adequate warranty language. Opening registrants to broad state tort liability may also have negative effects for users of the pesticides, particularly in states with more activist courts or more complicated growing conditions. Faced with increased liability at the state level for unexpected or unique crop failures (there was evidence in the *Bates* case suggesting that factors other than the pesticide may have caused the crop failures), manufacturers may elect to narrow the scope of their registrations, labeling claims, and regional coverage, further limiting the availability of crop-protection tools in areas already reeling from other regulatory restrictions.

Charting a Future for FIFRA

The issues raised in this article regarding judicial encroachment on FIFRA's regulatory authority are not criticisms of efforts to protect endangered species, water quality and safety, or the rights of pesticide users, workers, and their families. Federal legislators and policymakers must continue to consider these issues in developing sound and workable federal pesticide policies. The larger question is how such policy should be formulated, and which body is best situated to develop these policies.

Many socially valuable pesticides are inherently dangerous if used improperly, and regardless of what safety standards decision makers apply in reviewing pesticide products and uses, regulatory policy contains an inherent risk-benefit balancing component that requires consideration of many different, and sometimes competing, environmental, health, social, and economic interests. FIFRA was crafted to consider and integrate this wide range of interests and competing priorities into cogent regulatory policies, and the multidisciplinary teams tasked with making decisions under the Act reflect that charge. While third-party plaintiffs have found considerable success in using the courts and other sources of legal authority to shape the FIFRA decision-making process toward their interests, it is not clear that the broader outcomes are in line with the larger societal goals FIFRA was designed to serve. *But see* Briber and Bossi, *Officious Intermeddlers or Citizen Experts? Petitions and Public Production of Information in Environmental Law*, 58 UCLA L. Rev. 321 (Dec. 2010) (listing petitions and litigation under the ESA succeed in identifying species that are "at least as deserving of protection under the Act as species identified by the agency on its own").

Not surprisingly, these recent challenges to FIFRA are receiving attention from policymakers. In late January 2011, the Chair of the House Agriculture Committee and seventeen other House Members from the Pacific Northwest sent the administration a letter expressing concerns regarding the impact that the ESA consultation litigation and resulting settlements was having on EPA decision making and the availability of pesticides in California, Idaho, Oregon, and Washington. In late March, fifty-seven House Democrats join a unified Republican caucus to pass Rep. Gibbs' bill to exempt pesticide applications from NPDES permitting. U.S. House of Representatives, Office of the Clerk, Final Vote Results for Roll Call 206 (Mar. 31, 2011).

The administration, in turn, has signaled its intent to revisit both existing and proposed regulatory programs to ensure that they protect public health, safety, and the environment while promoting economic growth, innovation, and competitiveness. In doing so, the president has reaffirmed his commitment to applying the best available science, encouraging public participation, and using the best, "most innovative, and least burdensome tools for achieving regulatory ends." E.O. 13563 (Jan. 18, 2011).

These are welcome messages for growers and other pesticide regulatory stakeholders seeking to improve the predictability and reduce the uncertainty of federal pesticide policy decisions. Perhaps the larger question is whether the courts are listening, too.

Published in *Natural Resources & Environment* Volume 26, Number 1, Summer 2011.