

Pesticides and FIFRA

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Wiley is at the forefront of law firms representing clients in addressing the legal, regulatory, and economic issues arising under federal and state pesticide, chemical, and food safety laws. Our attorneys represent and counsel the major trade association of agricultural chemical manufacturers, the trade association of generic pesticide manufacturers and ingredient suppliers, task forces of manufacturers that are jointly responding to regulatory challenges, and individual manufacturers, distributors, and retailers.

We represent clients in virtually all areas of law involving the manufacture, marketing, and use of commercial chemicals and toxic substances including product development, testing, approval, labeling, right-to-know obligations, transportation, maintenance, and defense. Also, as the market for biologically based biopesticides continues to grow exponentially, we offer strong capability to provide counsel on the often novel and unique legal issues that these products raise. We work at the national, state, and international levels.

We routinely handle matters arising under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Food Quality Protection Act (FQPA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Plant Protection Act. In addition, because of our team's broad experience, we are directly involved in challenges relating to regulation under these programs and their interactions with the Endangered Species Act (ESA) and related statutes.

Under FIFRA, we assist clients with registration, re-registration, and registration review matters, import and export issues, data compensation disputes (representing both claimants and respondents), enforcement actions, and ESA challenges to U.S. Environmental Protection Agency (EPA) actions. We routinely document product and business line transfers and cost-sharing arrangements. We also counsel companies on product development strategies, compliance with EPA and U.S. Food and Drug Administration (FDA) advertising regulations, and regulation of genetically engineered organisms by EPA, FDA, and the U.S. Department of Agriculture (USDA).

Our team offers unrivaled experience on cutting-edge issues surrounding the interface between the various environmental and food safety statutes and copyright and patent law. For example, partner Tracy Heinzman is one of the nation's leading authorities on the regulation of ozone depleting fumigants under the CAA, and partner David B. Weinberg successfully handled a number of precedential suits challenging pesticide registrations under the ESA. Of counsel Keith Matthews, who served in EPA for over 16 years, was instrumental in the development of EPA's regulations and guidance governing genetically engineered organisms; he then served as the Director of the Biopesticides and Pollution Prevention Division (BPPD), where he oversaw the

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EPA program responsible for regulating GE organisms and biologically based biopesticides. To read more about our capabilities with biopesticides and biostimulants, click here.

Representative Experience

- Representing the principal trade association of agricultural chemical manufacturers as intervenors in litigation in Washington and California challenging EPA's compliance with the ESA, and supporting the association's regulatory activities in related areas. Obtained in April 2013 a decision from U.S. District Court for the Northern District of California dismissing on jurisdictional grounds the "mega case" challenging EPA's registration of over 300 pesticides in alleged violation of the ESA; in February 2013 a decision from the U.S. Court of Appeals for the Fourth Circuit vacating the first "biological opinion" prepared by the National Marine Fisheries Service evaluating the potential impacts of pesticide use on salmon in California and the Pacific Northwest; and in 2010 a decision from the U.S. Court of Appeals for the Ninth Circuit limiting the basis which environmental activists may challenge pesticide registrations on health, safety, and environmental protection grounds. Currently litigating in the U.S. Court of Appeals for the Ninth Circuit, on behalf of one of the world's largest agrichemical companies, ESA-based challenges to EPA registration of novel pesticides to be employed on genetically-modified corn and soybean seed.
- Obtaining a decision from the U.S. Court of Appeals for the Fourth Circuit establishing jurisdiction for challenging "biological opinions" regarding pesticides issued under the ESA.
- Successfully defending on behalf of industry stakeholders EPA regulations allocating methyl bromide allowances under the CAA.
- Successfully representing a task force of pesticide registrants in a data compensation dispute with another company and counseled several companies about data compensation obligations. (Our team has handled dozens of these disputes.)
- Counseling a biotech company that is developing new products from recently off-patent plant incorporated protectant (PIP) genes, including assisting them in navigating the FIFRA data compensation process.
- Serving as primary outside regulatory counsel to numerous pesticide and consumer products companies.
- Representing a consortium of manufacturers and distributors in negotiations with EPA on the reregistration of soil fumigants.
- For a major agribusiness company, developing a comprehensive analysis of statutory, regulatory, and common law requirements and principles applicable to the development, sale, and distribution of genetically engineered food crops in the United States.
- Counseling numerous companies on the complex regulatory scheme applicable to genetically engineered crops, insects, and animals in the United States.
- Counseling on the ability to make COVID-19 related claims on myriad consumer products including hand sanitizers, hard surface cleaners, oral antiseptic rinse products, etc.

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- Counseling companies on the applicability of FIFRA pesticide registration and/or requirements relating
 to pesticidal devices on emerging technologies relating to the suppression or elimination of COVID-19
 and other similar pests of public health significance.
- Provide guidance on the COVID-19 related personal protective equipment requirements set forth by the Occupational Safety and Health Administration.
- Assisting multinational corporations with internal reviews across product lines for FIFRA compliance in connection with existing advertising and new claims added in connection with COVID-19.
- Assisting companies in understanding and complying with temporary enforcement discretion policies and other interpretive guidance published during the COVID-19 pandemic.

Contact Us

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