

# The Pesticide Regulation Handbook that speaks volumes.



## About the Book

June 25, 2007 will mark the 60th anniversary of Congress's passage of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which, for the first time, prohibited the interstate sale of a pesticide unless first registered with the United States Department of Agriculture ("USDA"). The past 60 years have seen remarkable changes in the pesticide industry and in pesticide regulation. In 1970, President Nixon created the United States Environmental Protection Agency ("EPA") and transferred FIFRA's regulatory authority from USDA to EPA. In 1972, Congress overhauled FIFRA by passing the Federal Environmental Pesticide Control Act, which significantly expanded EPA's pesticide regulatory authority. As EPA's pesticide regulatory program came of age in 1970s and 1980s, the Agency principally focused on the environmental effects of pesticides. In 1996, through the Food Quality Protection Act of 1996 ("FQPA"), Congress directed EPA to focus on food safety and the aggregate and cumulative exposures to pesticides, including their dietary residues. On August 3, 2006, FQPA's tenth anniversary, EPA announced that it had completed 9,637 pesticide tolerance reassessment decisions and reregistered 599 active ingredients under FQPA's new food safety standards. On August 9, 2006, EPA announced its new registration review program, which will review each registered pesticide and its associated tolerances every 15 years.

Today, pesticide regulation is increasingly shaped by federal and state laws other than FIFRA. Courts have enjoined the application of pesticides until EPA consults with the Fish and Wildlife Service and/or the National Marine Fisheries Services regarding a pesticide's effects on listed endangered species or designated critical habitats. Interest groups challenge the discharge of pesticides to waters of the United States under the Clean Water Act, even when EPA has registered a pesticide for application to water to control aquatic pests. Our lengthiest chapter, 14, summarizes the principal features of California's pesticide regulatory program and attests to this state's importance as a regulator of pesticides.

Over the past 60 years, the most notable change in the pesticide industry likely is the development and widespread cultivation of genetically engineered crops, including plant-incorporated protectants ("PIPs"), which are regulated by EPA as pesticides under FIFRA. In 2006, U.S. farmers planted approximately 135 million acres of genetically engineered crops, which accounted for 53 percent of the worldwide acreage.\* The significant resources required to develop genetically engineered crops, including PIPs, and the cost of registering new active ingredients have prompted consolidation in the crop protection industry.

We first published the Pesticide Regulation Handbook in 1983. FIFRA's 60th anniversary is a fitting time to re-publish our Handbook in a tabbed, notebook format, which we will update and revise, as developments require. We invite your comments on our Handbook and also welcome your suggestions for future topics. In addition to serving as a practical guide to pesticide regulation in the United States, we designed the Handbook to serve as the textbook for a FIFRA regulatory course that we periodically offer. Accordingly, the book is organized to follow a pesticide's regulatory life cycle under the principal federal laws that regulate pesticides, FIFRA and FFDCA, from the evaluation of a research and development substance for potential use as a pesticide to the post-cancellation disposal of a formerly registered pesticide product.

Chapter 1 of the Handbook orients the reader with a brief overview of pesticide regulation and of EPA's Office of Pesticide Programs. Chapter 2 explains how a substance becomes a pesticide when the seller intends it to have a pesticidal effect, as demonstrated, for example, by the seller's making a pesticidal claim for the substance. Chapters 3 and 4 explain how a pesticide is registered and how EPA regulates inert ingredients in a pesticide product. Chapter 5 discusses data protection and compensation. Chapter 6 reviews EPA's regulation of pesticide containers and refilling and repackaging operations. Chapter 7 explains how EPA assesses a pesticide's risks and balances those risks against the pesticide's benefits, and Chapter 8 explains how EPA may remove a pesticide from the market, principally through cancellation and suspension. Chapters 9 and 10 lay out the obligations of persons who sell pesticides to keep records and to file reports and discusses EPA's inspection and enforcement authorities. Chapter 11 explains when courts may review EPA's regulation of pesticides, and Chapter 12 reviews how other federal laws, namely, the Clean Water Act, the Endangered Species Act, and the Toxic Substances Control Act, regulate pesticides. States also regulate pesticides independently of EPA. Accordingly, Chapter 13 discusses the authority of states and local governments to regulate pesticides, and Chapter 14 discusses California's regulation of pesticides in detail. Lastly, Chapter 15 explains EPA's, USDA's, and FDA's regulation of agricultural biotechnology products, including PIPs.

A word about websites: Our footnotes refer the reader to websites, especially EPA's Office of Pesticide Programs websites. Our Handbook does not set forth a complete list of EPA pesticide websites, because experience teaches us that they change often and that a published list would be quickly out of date. EPA's Office of Pesticide Program's homepage (<http://www.epa.gov/pesticides>) is a logical starting point for most searches.

Lastly, we wish to thank the many individuals here at McKenna Long & Aldridge LLP who patiently read and reread, edited, proofed, and cite checked the Handbook, including Cathy Lucas and Juanita Greenfield. We dedicate this Handbook to our former partner, colleague, and friend, John D. Conner, Sr. Over his many years of private practice in our law firm, he not only pioneered the development of pesticide law, he served as a gracious role model and mentor to many of us. He died on December 18, 2006, and we will miss him.

We also wish to acknowledge the contribution that Edward C. Gray made to the field of pesticide regulation. Ed served in EPA's Office of General Counsel for 20 years, where he shaped the Agency's pesticide program during its formative years after FIFRA's amendment in 1972, and, thereafter, as a consultant in the field of pesticide regulation. He died on October 10, 2005.

The Authors  
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\* Clive James, *ISAAA Brief 35-2006 [Global Status of Commercialized Biotech/GM Crops: 2006]: Highlights*, <http://www.isaaa.org/Resources/Publications/briefs/35/highlights/default.html>



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[McKenna Long & Aldridge LLP \("MLA"\)](#) enjoys the oldest, largest and most diversified pesticide regulatory and litigation practice in the United States and abroad, which includes more than 20 attorneys in Washington, D.C., San Francisco and Los Angeles, California, and Brussels, Belgium. Seven senior attorneys practicing in Washington, D.C. and California bring more than 175 years of pesticide regulatory and litigation experience. MLA's Brussels office enjoys the oldest and largest plant protection and biocidal products practice in the European Union.

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