



TUTOR[®]

CURRICULUM



Bergeson & Campbell, P.C. (B&C[®]) is pleased to offer FIFRA Tutor[®] online, on-demand training courses developed and presented by members of B&C's renowned FIFRA practice group to provide expert, efficient, and essential FIFRA training.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) product approval process is protracted, and often challenging, for any given product. Further complicating matters are the ensuing -- often expensive -- data, recordkeeping, and advocacy requirements associated with obtaining FIFRA product approvals. These courses are intended to provide on-demand knowledge to assist with the strategic planning that is critical to global product development. The subtleties of FIFRA are presented in a clear and business-focused context.

Courses can be completed at the learner's own pace, and enrollment is valid for one full year. Registrants receive detailed handout materials, including copies of all presentations and relevant materials from the U.S. Environmental Protection Agency (EPA), which are theirs to keep. Interested professionals should visit www.FIFRAtutor.com to view sample course segments and enroll in the training.

The full FIFRA Tutor program includes approximately 27 hours of training.

FIFRA Tutor -- Curriculum

ONE HOUR SESSIONS:

F101 - FIFRA Overview -- This module provides a general overview of FIFRA -- its legislative intent, key components, and role in the management of agricultural and biocidal chemicals. This module is especially useful for anyone who is engaged in commercial activities any component of which is regulated by FIFRA, including pesticide producers, importers, end-use product formulators, distributors, retailers, and pesticide device manufacturers. This overview is especially important for any entity wishing to enter the pesticide market and needing to obtain a clear understanding of the federal government's approach to product registration. An increasing number of states are also substantively regulating pesticide products in addition to maintaining their traditional role of requiring state registrations.

F102 - Import and Export of Pesticides -- This module focuses on FIFRA import and export requirements applicable to pesticides and devices, including an overview of how to work with foreign suppliers on importing pesticides and/or pesticide ingredients and satisfying recordkeeping and reporting obligations. This module also includes an overview of how the U.S. Environmental Protection Agency (EPA) works with the U.S. Customs and Border Protection to regulate the import and export of pesticides and devices, the significance of a Notice of Arrival of Pesticides and Devices, and purchaser acknowledgment statements for exports of unregistered pesticide products.

F103 - Managing Effectively Confidential and Proprietary Business Information -- Protecting a company's confidential and proprietary Confidential Statement of Formula, process information, registration data, and related information considered confidential under FIFRA is commercially critical. This module focuses on how to protect confidential information and how to ensure that

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data supporting the registration are protected and leveraged to ensure that they remain compensable. Topics covered include mandatory public disclosure of health and safety data, special protection for product composition and manufacturing process information, protection for voluntarily submitted information, redacting and segregating proprietary information, substantiating confidentiality claims, and obtaining review of an adverse confidentiality determination.

F104 - Reporting and Recordkeeping Requirements -- FIFRA is data- and information-driven, and stakeholders are required to generate and maintain copious amounts of data and information, some of which must be shared with EPA and the public through an EPA electronic database. Curating this information is critically important for both compliance purposes and in terms of managing a narrative for your commercial partners, neighbors, competitors, and shareholders. This module reviews these critically important requirements, including pesticide-producing establishment reporting and recordkeeping.

F105 - Due Diligence and Transferring FIFRA Registrations -- This module provides an overview of FIFRA due diligence considerations that companies must undertake for a broad range of transactions, including acquisitions, divestures, and financing investigations and a “how-to” for transferring a FIFRA registration and any data, with exclusive use and/or compensation rights associated with such data, that support the registration.

F106 - State Registration Requirements -- All states, and Puerto Rico and the District of Columbia, require a pesticide to be registered prior to its commercial sale or distribution. This module discusses the varying registration requirements for federally registered products, supplementally distributed products, pesticidal devices, and minimum risk pesticides. In addition, this module explains the requirements for approval of a pesticide under special circumstances: Special Local Needs (SLN) registrations under FIFRA Section 24(c), allowing states (during a local need) to register an additional use of a registered pesticide or a new end-use product; FIFRA Section 18 emergency exemptions, authorizing state lead agencies to permit additional uses of federally registered pesticides; Experimental Use Permits (EUP) under FIFRA Section 5, authorizing any state to issue an EUP in accordance with an EPA-approved state plan. Some states impose more substantive registration requirements that could involve data development. Understanding the evolving and varying state requirements is critically important to avoid formidable barriers to market entry.

F107 – Inert Ingredients -- Pesticide product formulations include “inert” ingredients. What these substances are and how they are regulated by EPA under FIFRA are important concepts and may surprise viewers unfamiliar with the registration process. This module provides an overview of the role of inert ingredients in product formulations and how EPA regulates them under FIFRA. This module also discusses the approval process for new inert ingredient and related data compensation considerations.

F108 - Pest Control Devices -- Instruments that trap, destroy, repel, or mitigate a pest without a chemical mode of action are regulated as pest control devices. While exempt from registration requirements, devices are subject to other FIFRA requirements. This module discusses the scope



of the device definition, applicable federal requirements, and registration requirements in select states.

F109 - Defining Tolerances and Their Regulation -- This module explores how EPA sets a tolerance, the maximum amount of a pesticide that can remain in or on a food. It also discusses import tolerances.

F110 - Adverse Effects Reporting Requirements -- FIFRA requires all pesticide registrants to submit to EPA information regarding unreasonable adverse effects on the environment. While the statutory requirement under FIFRA Section 6(a)(2) (risk/benefit information) appears straightforward, it is not, and this critically important requirement generates significant EPA enforcement scrutiny and penalties. This module reviews the law and EPA's somewhat complicated interpretation and implementation of it.

TWO HOUR SESSIONS:

F201 - Understanding FIFRA-Regulated Products -- It is critically important to understand what is and what is not a pesticide and when FIFRA jurisdiction applies. This module explains in detail what a pesticide is under FIFRA as far as EPA is concerned, what products are excluded from FIFRA regulation, what products are exempt from FIFRA, and why. These exclusions and exemptions cover a wide variety of products and in some cases cross jurisdictional boundaries with other federal agencies, including but not limited to products regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA) by the U.S. Food and Drug Administration (FDA), and potential state requirements.

F202 - FIFRA Registration Strategy and Process -- Registering a pesticide is as much a business strategy as it is a federal administrative and legal process. Understanding the costs of registration, timelines, and whether to cite someone else's data or generate data are consequential decisions that require careful decision-making. Product formulation and its sourcing, including the active and inert ingredients, are important concepts and may surprise viewers unfamiliar with the registration process. Also important is an understanding of the circumstances under which EPA may agree conditionally to register a product. This module explains these concepts to help illustrate in real terms the importance of understanding both the law and business of FIFRA registrations.

F203 - Building a Registration Application -- This module focuses on the administrative side of the registration process, as any company wishing to sell its own pesticide product must either obtain a federal registration for its own product or become a supplemental registrant for a product that is already federally registered. The application submission must contain specific information, including the forms (*e.g.*, application for pesticide registration, confidential statement of formula, data matrix, formulator's exemption), volumes of properly formatted generated data, and labeling. Electronic submission of the application via EPA's Central Data Exchange (CDX) Pesticide Submission Portal (PSP) is efficient and strongly encouraged by EPA. Taking time to ensure that the submission follows the requirements will avoid rejection of the application during EPA's initial content review and technical screen review. This module explores all of these concepts in detail.

F204 - FIFRA Data Production Requirements and Regulatory Risk Assessment -- FIFRA is data intensive. EPA requires data to register a product and regularly reviews pesticide products to ensure that registrations reflect the most current scientific information. This module reviews these data requirements and provides a primer on the FIFRA risk assessment process so that viewers are familiar with how EPA assesses risk and establishes new data requirements to support product registrations.

F205 - Developing the Pesticide Label -- Developing a product label is critically important to the success of a pesticide product. Understanding the correlation between data and label claims is critically important, as are the art and science of negotiating with EPA on the label content. It also is important to understand how the EPA-approved label affects other labeling, marketing, and advertising of the pesticide product. This module does a deep dive into label development and maintenance.

F206 - Antimicrobial Pesticide Registrations -- Antimicrobial pesticides are subject to specific efficacy data requirements that are frequently misunderstood or overlooked entirely. Business entities must understand certain key concepts, including public health pesticides, the jurisdictional divide between EPA regulation and regulation by the FDA under the FFDCA, and when registration is not required at all because of the treated article exemption. This module explores all of the concepts in detail.

F207 - Regulation of Biopesticides -- Biologically based pesticides are a growing business in the United States and in other mature markets. Understanding of how these products are registered is evolving. Equally important is when agricultural chemicals are not subject to FIFRA registration at all because they are not considered pesticides but rather plant stimulants or soil amendments. This module provides an in-depth overview of this complicated area of the law.

F208 - Data Citation, Data Compensation, and Data Sharing -- When Congress enacted FIFRA, it intended that entities would share data to support registrations to promote competition and animal welfare. Data sharing comes with a cost, however, and understanding when to cite another's data and when to generate your own and other threshold business decisions require thoughtful analysis and a clear understanding of a company's business goals. This module reviews deciding whether to cite existing data or generate new data, calculating appropriate compensation for use of existing data, joint development of new data, establishing data development consortia and task forces, and utilizing arbitration to resolve data compensation or data development disputes.

F209 - Preparing for a FIFRA Enforcement Inspection and Any Resulting Enforcement -- Any commercial entity engaged in the manufacture, import, process, and/or use of chemicals regulated under FIFRA is subject to EPA enforcement and compliance inspection authority. When EPA elects to conduct such inspections, it does not typically give facility operators much time to prepare. Knowing what EPA will ask for before it sends a formal letter is critically important in determining how well a company fares under an inspection. Understanding EPA's inspection procedures and its enforcement options is likewise important. The penalties that can be assessed under FIFRA are not trivial -- over \$24,000 per violation, per day. Although no one intends to be found in non-compliance with FIFRA, it is possible that it could occur, and knowing how EPA

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calculates potential penalties is important in negotiating with EPA. This module covers these areas and EPA penalty policies, including those circumstances in which a company finds non-compliance during internal review processes and elects to self-confess to EPA.

Costs

FIFRA Tutor online courses are offered at \$100 for one-hour modules and \$200 for two-hour modules. Course bundles are available at a reduced cost per course. Enrollment and payment are handled on the online training platform. Volume discounts and invoice billing are available for companies wishing to purchase courses for multiple employees.

Contact Emily Scherer, escherer@lawbc.com, for more information on volume discounts or general questions regarding FIFRA Tutor.