

HCPA's Annual Pesticide Regulation Workshop
Crowell & Moring LLP, Washington, D.C.
 October 18-20, 2022

Day One		
	Registration and Breakfast	8:15 to 9:00 AM EDT
1	An Overview of Pesticide Regulation. The important sections of FIFRA. Why FIFRA is a mix of registration and misbranding law. The business objectives of regulatory compliance. Important resources. The roles of EPA and the states.	1 hour <i>Michael Boucher (Crowell)</i>
2	Understanding Regulated Products. The intent test for pesticides. Differences between pesticides, devices, treated articles, and application equipment. Substances excluded from FIFRA regulation. Products that are not pesticides for various reasons. Pesticides that are exempted from FIFRA regulation. Pesticides that may be distributed or sold without registration. Increased prominence of devices and device issues, including but not limited to qualifying and substantiating product performance (efficacy) claims.	1 hour <i>Warren Lehrenbaum (Crowell)</i>
	Break	15 minutes
3	Types of Registrations. Technical-grade active ingredients, other manufacturing-use products, and end-use products. Experimental use permits and exemptions. Supplemental distribution (distributor products). Section 18 emergency exemptions, section 24(c) special local needs registrations, and section 25(b) minimum-risk pesticides.	45 minutes <i>Kelly Rahn (TSG)</i> <i>Jonathan Walsh (TSG)</i>
	Lunch	Noon to 1:00 PM EDT
4	EPA Guest Speakers – Antimicrobial and Registration Division Directors. Overview and update of activities within Antimicrobial and Registration Divisions at EPA.	1 hour <i>Anita Pease (EPA)</i> <i>Marietta Echeverria (EPA)</i>
5	Key Considerations for Pesticide Product Development. Elements of a successful strategy to obtain approvals and bring new pesticide products to the market: product formulation, labeling claims, data requirements, budget development, timelines, and state law considerations.	1 hour <i>Abigail Wacek (TSG)</i> <i>Pete Stevenson (TSG)</i>
	Break	15 minutes
6	Data Development and Formulation Considerations. Chemical formulation. Toxicology, including inhalation toxicity studies. Efficacy studies for public health claims. Other data requirements.	45 minutes <i>Wendy McCombie (TSG)</i> <i>Milady Brutofsky (TSG)</i>
7	Product Label Development. How the results of studies affect the product label. Other considerations. Mandatory labeling. Significant changes expected in the next 3-5 years, e.g., the Office of Pesticide Program Electronic Label (OPPEL).	1 hour <i>Jonathan Walsh (TSG)</i> <i>Julie Ownbey (TSG)</i>
	Reception Hosted by Crowell	5:00 to 6:00 PM EDT

Day Two		
	Breakfast	8:00 to 8:30 AM EDT
8	Building an Application Package. Administrative forms. Data volumes. Labeling. CDX portal requirements (submissions that can use the portal). E-CSF.	45 minutes <i>Jonathan Walsh (TSG)</i>
9	Pesticide Registration Improvement Act (PRIA) 5. Overview of PRIA. What's new in the on-going discussions to make improvements to PRIA 5.	45 minutes <i>Dr. Steven Bennett (HCPA)</i> <i>Michael Gruber (HCPA)</i>
	Break	15 minutes
10	Importing and Exporting Pesticides. Importing pesticides and devices, including the Notice of Arrival of Pesticides and Devices, the electronic equivalent (eNOA), and potential problems with product performance (efficacy) claims for devices. Options for importing misbranded products. Exporting pesticides and devices, including the labeling of pesticides and devices for export. Purchaser acknowledgment statements for exports of unregistered pesticides.	1 hour <i>Amy Symonds (Crowell)</i>
11	EPA Guest Speaker – Endangered Species Act. How EPA's Office of Pesticide Programs will meet its obligations under the Endangered Species Act: an overview of EPA's work plan, "Balancing Wildlife Protection and Responsible Pesticide Use".	45 minutes <i>Jake Li (EPA)</i>
	Lunch	Noon to 1:00 PM EDT
12	Reporting and Recordkeeping. Reporting and recordkeeping under FIFRA. Establishment registration and reporting. Recordkeeping requirements for producers. Risk/benefit ("adverse effects") reporting under section 6(a)(2) of FIFRA.	45 minutes <i>Warren Lehrenbaum (Crowell)</i>
13	FIFRA Enforcement. Overview of FIFRA's unlawful acts. How EPA determines FIFRA violations. Enforcement responses available to EPA under FIFRA, including stop sale, use, or removal orders. How EPA calculates civil monetary penalties. Avoiding FIFRA enforcement by self-auditing under EPA's voluntary disclosure policies.	45 minutes <i>Michael Boucher (Crowell)</i>
	Break	15 minutes
14	Registration Review. How to prepare and respond, including options for responding to EPA data call-in notices. The lessons of EPA's recent notice of intent to suspend DCPA. The importance of joint data development task forces.	30 minutes <i>Abigail Wacek (TSG)</i> <i>Michael Boucher (Crowell)</i>
15	Lower-risk pesticides. Conventional reduced risk pesticides. Integrated pest management (IPM). FIFRA § 25(b) minimum-risk pesticides. Safer Choice (sanitizers). PRIA additions. California Department of Pesticide Regulation's preferential fee schedule. Encouraging the adoption of lower-risk pesticides generally.	1 hour <i>Kelly Rahn (TSG)</i> <i>April Kitchen (TSG)</i>
16	EPA Guest Speaker – Enforcement. Enforcement priorities and trends under FIFRA.	45 minutes <i>Royan Teter (EPA)</i>
	Reception Hosted by TSG 1150 18th Street NW, Washington DC 20036, Suite 475	5:30 to 7:00 PM EDT

Day Three		
	Breakfast	8:30 to 9:00 AM EDT
17	Understanding Data Compensation. Claim preparation. The arbitration process. Recent trends.	30 minutes <i>Peter Gray (Crowell)</i>
18	Inert Ingredient and Tolerance Petitions. EPA databases. PRIA fees. Data requirements.	1 hour <i>Abigail Wacek (TSG)</i>
	Break	15 minutes
19	Environmental Non-Governmental Organization Speaker – Encouraging lower risk pesticides like Design for the Environment antimicrobials and PRIA 5 priorities.	30 minutes <i>Dr. Jennifer Sass (NRDC)</i>
20	State Regulation of Pesticides. An overview of state regulation. Types of state-specific product registrations (adjuvants, devices, minimum-risk pesticides, fertilizers, etc.).	1 hour <i>Kelly Rahn (TSG)</i> <i>April Kitchen (TSG)</i>
	Workshop Ends	12:15 PM EDT