

**HCPA's Annual Pesticide Regulation Workshop  
Steptoe & Johnson LLP, Washington, D.C.**

October 24-26, 2023

Day One		
	<b>Registration and Breakfast</b>	8:30 to 9:00 AM EDT
1	<b>An Overview of Pesticide Regulation.</b> 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 (Steptoe)</i>
2	<b>Understanding Regulated Products.</b> 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.	30 minutes <i>Michael Boucher (Steptoe)</i>
	<b>Break</b>	15 minutes
3	<b>Types of Registrations.</b> Technical-grade active ingredients, other manufacturing-use products, and end-use products. Supplemental distribution (distributor products).	45 minutes <i>Jonathan Walsh (TSG)</i>
	<b>Lunch and EPA Speaker: Director, Registration Division.</b> Overview of and update regarding activities within the Registration Division at EPA.	11:30 to 1:00 PM EDT <i>Charles "Billy" Smith (EPA)</i>
4	<b>Section 25(b) Minimum-Risk Pesticides.</b> FIFRA requirements for minimum-risk pesticides. State registration requirements for minimum-risk pesticides. The role of AAPCO in coordinating state requirements for minimum-risk pesticides.	30 minutes <i>Kelly Rahn (TSG)</i>
5	<b>Pesticide Devices.</b> FIFRA requirements for devices and PRIA M009 Device Determinations. Increased prominence of devices and device issues, including but not limited to qualifying and substantiating product performance (efficacy) claims. State registration requirements for devices.	30 minutes <i>Kelly Rahn (TSG)</i>
6	<b>Key Considerations for Pesticide Product Development.</b> 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.	45 minutes <i>Jonathan Walsh (TSG)</i>
	<b>Break</b>	15 minutes
7	<b>Data Development and Formulation Considerations.</b> Chemical formulation. Toxicology, including inhalation toxicity studies. Efficacy studies for public health claims. Other data requirements.	30 minutes <i>Pete Stevenson (TSG)</i>
8	<b>Product Label Development.</b> 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).	30 minutes <i>Jonathan Walsh (TSG)</i>
9	<b>Breakout Sessions</b> <b>A: Experimental Use Permits and Exemptions, Section 18 Emergency Exemptions, and Section 24(c) Special Local Needs Registrations.</b> <b>B: Lower-Risk Pesticides.</b> Conventional reduced-risk pesticides. Integrated pest management (IPM). Safer Choice (sanitizers). PRIA additions. Encouraging the adoption of lower-risk pesticides generally. <b>C: Commercialization Strategy.</b> Includes a discussion about retail shelving windows and seasonality and how that affects building timelines.	1 hour <i>Kelly Rahn (TSG)</i>  <i>Pete Stevenson (TSG)</i>  <i>Jonathan Walsh (TSG)</i>
	<b>Reception Hosted by Steptoe</b>	5:00 to 6:00 PM EDT

Day Two		
	<b>Breakfast</b>	8:00 to 8:30 AM EDT
10	<b>Building an Application Package.</b> Administrative forms. Data volumes. Labeling. CDX portal requirements (submissions that can use the portal). e-CSF.	30 minutes <i>Jonathan Walsh (TSG)</i>
11	<b>EPA Speaker: Director, Antimicrobials.</b> Overview of and update regarding activities within the Antimicrobials Division at EPA.	1 hour <i>Anita Pease (EPA)</i>
	<b>Break</b>	15 minutes
12	<b>Reporting and Recordkeeping.</b> 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>Michael Boucher (Steptoe)</i>
13	<b>Inert Ingredient and Tolerance Petitions.</b> EPA databases. PRIA fees. Data requirements.	30 minutes <i>Jonathan Walsh (TSG)</i>
14	<b>Understanding Data Compensation.</b> Claim preparation. The arbitration process. Recent trends.	30 minutes <i>Michael Boucher (Steptoe)</i>
	<b>Lunch</b>	Noon to 1:00 PM EDT
15	<b>Breakout Sessions</b> <b>A: Importing and Exporting Pesticides.</b> Importing pesticides and devices, including the Notice of Arrival of Pesticides and Devices and the electronic equivalent (eNOA). 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. <b>B: Deep Dive into the Data Requirements Listed in 40 C.F.R. 158</b> <b>C: State Regulation of Non-Pesticides.</b> Adjuvants, Biostimulants, Fertilizers and soil amendments	1 hour <i>Michael Boucher (Steptoe)</i>  <i>Jonathan Walsh (TSG)</i> <i>Kelly Rahn (TSG)</i>
16	<b>Implementation of Pesticide Registration Improvement Act (PRIA) 5.</b> Overview of what’s new in PRIA 5 and various implementation activities to date.	1 hour <i>Michael Gruber (HCPA)</i>
17	<b>Registration Review.</b> How to prepare and respond, including options for responding to EPA data call-in (DCI) notices. The lessons of a recent EPA suspension hearing finding that a registrant’s response to a DCI notice for DCPA was legally inadequate. The importance of joint data development task forces.	30 minutes <i>Jonathan Walsh (TSG)</i> <i>Michael Boucher (Steptoe)</i>
	<b>Break</b>	15 minutes
18	<b>FIFRA Enforcement.</b> 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 (Steptoe)</i>
19	<b>EPA Speaker: Senior Advisor, Waste and Chemical Enforcement Division.</b> Enforcement priorities and trends under FIFRA.	30 minutes <i>Royan Teter (EPA)</i>
	<b>Dinner on Your Own</b>	5:00 PM EDT

Day Three		
	<b>Breakfast</b>	8:00 to 8:30 AM EDT
20	<b>State Regulation of Pesticides.</b> An overview of state pesticide regulation. Types of state-specific product registrations (adjuvants, devices, minimum-risk pesticides, fertilizers, etc.).	1 hour 15 minutes <i>Kelly Rahn (TSG)</i>
	<b>Break</b>	15 minutes
21	<b>State Registration Perspective - Virginia</b>	1 hour Liza Fleeson-Trossbach Virginia Department of Agriculture and Consumer Services
22	<b>Tips, Tricks, and Using the Available California Databases to Your Advantage</b>	30 minutes <i>Kelly Rahn (TSG)</i>
23	<b>Ask the Experts:</b> Open Q&A panel.	30 minutes <i>All presenters</i>
<b>Workshop Ends</b>		Noon EDT