

Pesticide Regulation in 2019
Crowell & Moring LLP, Washington, D.C.
 October 8-10, 2019

Day One - FIFRA

REGISTRATION & BREAKFAST		7:45 – 8:30 am
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.	8:30 – 9:15 am JOHN CONNER (Crowell)
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.	9:15 – 10:00 am WARREN LEHRENBAUM (Crowell)
BREAK		10:00 – 10:15 am
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. Pesticidal devices.	10:15 – 11:00 am LISA AMADIO (TSG)
4	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.	11:00 am – 12:00 pm MICAH REYNOLDS (TSG) LISA AMADIO (TSG)
LUNCH & GUEST SPEAKER		12:00 – 12:45 pm MICHAEL GOODIS Director, Registration Division, Office of Pesticide Programs, EPA
5	Critical Issues in and Common Observations about Submissions of CSFs. EPA staff will share observations about critical issues and pitfalls that commonly cause EPA to reject CSFs. EPA staff also will discuss ways to improve the quality of submissions to EPA and reduce burdens on registrants. EPA staff will answer questions at the end of the session.	12:45 – 1:30 pm MICHAEL GOODIS (EPA) AND EPA STAFF
6	Data Development and Formulation Considerations. Chemical formulation. Toxicology, including inhalation toxicity studies. Efficacy studies for public health claims. Other data requirements.	1:30 – 2:15 pm LESLIE PATTON (TSG) MICAH REYNOLDS (TSG)
7	Product Label Development. How the results of studies affect the product label. Other considerations. Mandatory labeling.	2:15 – 3:00 pm LESLIE PATTON (TSG) LISA AMADIO (TSG)
BREAK		3:00 – 3:15 pm
8	Building an Application Package. Administrative forms. Data volumes. Labeling. CDX Portal requirements (submissions that can use the portal). E-CSF. Office of Pesticide Program Electronic Label (formerly, SmartLabel).	3:15 – 4:00 pm LISA AMADIO (TSG)
9	Pesticide Registration Improvement Act (PRIA) 4. Overview. What's new for efficacy? New uses. Inert ingredients. Miscellaneous codes.	4:00 – 4:30 pm MICAH REYNOLDS (TSG)
10	Understanding Data Compensation. Claim preparation. The arbitration process. Recent trends.	4:30 – 5:00 pm PETER GRAY (Crowell)
RECEPTION		5:00 – 6:00 pm

Day Two - FIFRA

	BREAKFAST	8:00 – 8:30 am
11	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.	8:30 – 9:15 am WARREN LEHRENBAUM (Crowell)
12	Importing and Exporting Pesticides. Importing pesticides and devices, including the Notice of Arrival of Pesticides and 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. Industry perspective on import and export issues.	9:15 – 10:00 am AMY SYMONDS (Crowell) Industry Speaker TBD
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.	10:00 – 10:30 am MICHAEL BOUCHER (Crowell)
	BREAK	10:30 – 10:45 am
14	Registration Review. How to prepare and respond, including options for responding to EPA data call-in notices. The importance of joint data development task forces.	10:45 – 11:15 am JOHN CONNER (Crowell) ABIGAIL WACEK (TSG)
15	Ingredient Disclosure and Retailer Initiatives. The intersection of FIFRA’s ingredient disclosure requirements and Walmart’s “on pack” ingredient disclosure requirements for “Aisle 13” pesticide products. Whether EPA’s replacement for Pesticide Registration Notice 98-10 will allow industry to request inert ingredient disclosure by notification.	11:15 am – 12:00 pm JIM JONES (HCPA) Speaker TBD
	LUNCH	12:00 – 1:00 pm
16	Biopesticides and Biostimulants. The special application and data requirements for lower risk pesticides.	1:00 – 2:00 pm KELLY RAHN (TSG) LESLIE PATTON (TSG)
17	Inert Ingredient Petitions. EPA databases. PRIA fees. Data requirements.	2:00 – 3:00 pm ABIGAIL WACEK (TSG) LESLIE PATTON (TSG)
	BREAK	3:00 – 3:15 pm
18	Enforcement Trends under FIFRA.	3:15 – 4:00 pm DIANA SAENZ, Associate Director, Waste & Chemical Enforcement Division, Office of Civil Enforcement, EPA

Day Three – State Regulation with California Focus

	BREAKFAST	7:30 – 8:00 am
19	State Regulation of Pesticides. An overview of state regulation. Types of state-specific product registrations (adjuvants, devices, minimum-risk pesticides, fertilizers, etc.).	8:00 – 8:45 am KELLY RAHN (TSG)
20	Overview of California Registration. Data requirements. Elements of a registration package. Understanding the Department of Pesticide Regulation’s (DPR’s) website.	8:45 – 9:30 am KELLY RAHN (TSG)
21	Registration Application Review Process. Understanding DPR’s review process (evaluation stations). New Notice of Decision requirements under California Notice 2018-26.	9:30 – 10:30 am KELLY RAHN (TSG) MICHAEL BOUCHER (Crowell)
	BREAK	10:30 – 10:45 am
22	Post-registration Requirements. Renewals, sales reporting, special reviews, incident and other adverse effects information reporting.	10:45 – 11:30 am KELLY RAHN (TSG)
23	California’s Mill Assessment. Overview of requirements. Preparing for an audit.	11:30 am – 12:00 pm MICHAEL BOUCHER (Crowell)
	LUNCH	12:00 – 1:00 pm
24	California Air Resources Board. Regulation of volatile organic compounds.	1:00 – 1:30 pm RICHARD MCNEIL (Crowell)
25	Proposition 65. Overview. New safe harbor warning for pesticides. Exposure assessment.	1:30 – 2:15 am RICHARD MCNEIL (Crowell)
26	California SB 258 Ingredient Disclosure. The Cleaning Products Right to Know Act of 2017: overview and case study.	2:15 – 3:00 pm STEVE BENNETT (HCPA)
	CONCLUSION	3:00 pm