

Exponent®
Engineering & Scientific Consulting


## Stephanie Stephens

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## Professional Profile

Stephanie Stephens is a principal scientist in Exponent's Chemical Regulation & Food Safety practice with more than 26 years of experience in EPA pesticide regulatory consulting, USDA APHIS permitting, pesticide regulatory compliance auditing, and pesticide litigation support. She advises agrochemical companies, biotechnology firms, law firms, and government agencies on FIFRA registrations, conventional chemical and biopesticide approvals, regulatory reevaluation programs, and multi-agency regulatory strategy. Ms. Stephens provides expert consulting and expert reports in support of pesticide-related litigation matters.

### EPA Pesticide Regulatory Support

Ms. Stephens provides comprehensive regulatory consulting to conventional agrochemical and biotechnology clients navigating the EPA pesticide registration and reevaluation process under FIFRA. Her services span strategic registration planning, data development planning and management, agency liaison activities, submission preparation, and follow-on review support for new food and non-food use active ingredient registrations, product registrations, inert ingredient approvals, tolerance, tolerance exemption, and import tolerances.

Ms. Stephens has significant experience managing multi-year EPA pesticide reevaluation and registration review programs for existing chemicals, preparing and negotiating EPA responses on both technical and administrative regulatory issues, and advising clients on strategies to protect existing registrations and achieve timely approvals. She brings a uniquely integrated perspective to EPA pesticide regulatory work, having served in industry, consulting, and the federal government, giving her direct insight into how EPA staff evaluate submissions and what it takes to navigate the approval process effectively.

### USDA APHIS Permitting

Ms. Stephens is an expert in USDA APHIS permitting programs, with experience managing APHIS regulatory projects both as a federal employee and as a private consultant. Her USDA APHIS expertise spans permitting for non-genetically modified and genetically modified organisms (GMOs), compliance program management for USDA Wildlife Services vertebrate control programs, and regulatory project management for APHIS program areas including VS feral swine programs, BRS permitting, and PPQ commodity inspection activities. She has also managed FDA regulatory compliance issues for animal drugs on behalf of USDA's Wildlife Services, including assessing data requirements for New Animal Drug approvals (NADs) and obtaining and managing Investigational New Animal Drug approvals (INADs). Her federal government background gives her direct working knowledge of how USDA APHIS programs operate from the inside.

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### Pesticide Compliance Audits

Ms. Stephens conducts facility- and program-wide pesticide regulatory compliance audits for both industry and federal agency clients under FIFRA and related regulatory frameworks. Her audit work covers conventional chemical pesticides, microbial and biopesticide products, and multi-agency jurisdiction scenarios involving EPA, USDA, and FDA. She has conducted on-site and off-site audits, presented findings and corrective action plans to client staff and senior leadership, and implemented program-wide improvements based on audit results.

Ms. Stephens has also prepared, managed, and reviewed compliance projects under the National Environmental Policy Act (NEPA), including environmental assessments (EAs) and environmental impact statements (EISs), for both federal and industry clients. Her compliance audit expertise is grounded in her hands-on federal government experience, giving her practical insight into the standard of care expected by regulatory agencies.

### Biopesticide Registration

In addition to conventional chemical pesticides, Ms. Stephens has led large-scale, multi-year registration programs for microbial biopesticides, biochemical biopesticides, and inert ingredients in the U.S. and internationally. Her registration expertise spans the full product lifecycle, from initial data gap analysis and registration strategy development through study placement and monitoring at contract laboratories, data package assembly, agency submission, and post-submission review management.

Ms. Stephens has specific expertise in planning global registration strategies with multidisciplinary teams; coordinating multi-agency jurisdiction scenarios involving EPA, USDA, and FDA; and managing import tolerance petitions for pesticide products in the U.S., Canada, and other countries. Ms. Stephens also has experience with FDA-regulated animal drug approvals, including New Animal Drug (NAD) and Investigational New Animal Drug (INAD) approval processes.

### Pesticide Litigation Support

Ms. Stephens provides expert consulting and expert report generation in support of pesticide-related litigation matters, including FIFRA data compensation cases, regulatory compliance disputes, and matters involving pesticide registration requirements and agency standard of care. Her litigation support experience includes leading due diligence and data compensation projects, managing multidisciplinary scientist teams, assisting clients in preparing for testimony in data compensation proceedings, and preparing findings reports. She also provides FIFRA regulatory training to industry clients, law firms, and federal agency staff, helping legal teams develop a thorough understanding of the pesticide regulatory framework relevant to their matters.

## Academic Credentials & Professional Honors

M.S., Environmental Management, University of Maryland, College Park, 2005

B.A., Biology, Colorado College, 1987

Phi Kappa Phi academic honor society

## Publications

Kurl RN, Holmes SC, Verney E, Sidransky H. Nuclear envelope glycoprotein with poly(a)polymerase activity of rat liver: isolation, characterization, and immunohistochemical localization. Biochemistry 1988; 27 (25):8974-8980.

Kurl RN, Holmes SC, Verney E, Sidransky H. Tryptophan binding to nuclei of rat liver and hepatoma. The Journal of Nutritional Biochemistry (Impact Factor: 4.55) 1995; 6(2):73-79.

## Project Experience

### EPA Pesticide Regulatory Support

Ms. Stephens has led complex, multi-year EPA pesticide regulatory programs for agrochemical and biotechnology clients, managing every phase from initial strategy development through final agency submission and review. Her work spans new active ingredient registrations, product registrations, reevaluation programs, and multi-agency coordination under FIFRA.

- Led multiple large-scale, multi-year data development programs for new pesticide registrations under FIFRA on behalf of conventional agrochemical and biotechnology clients; prepared registration strategy plans, negotiated data requirements directly with EPA staff, placed and monitored studies at contract laboratories, reviewed study reports, assembled and submitted complete data packages, and managed the agency review process for both food and non-food use conventional chemical and biopesticide registrations.
- Led multiple multi-year EPA pesticide reevaluation (registration review) programs for existing chemicals under EPA review; prepared agency responses, negotiated with EPA staff on technical and administrative regulatory issues, and advised clients on strategies and approaches for responding to EPA during the reevaluation process.
- Negotiated and managed the jurisdictional determination process for chemicals with potential multi-agency jurisdiction involving EPA, USDA, and FDA; assisted federal and industry clients in establishing lead jurisdiction agency, resolving regulatory ambiguity across complex multi-agency product scenarios.
- Prepared, submitted, and managed the review process for numerous import tolerance petitions for pesticide products submitted to the U.S., Canada, and other countries; coordinated agency interactions and provided strategic guidance to clients on international registration requirements and timelines.
- Led registration programs with multi-agency jurisdiction spanning EPA, USDA, and FDA; served as primary liaison between agencies and advised clients on integrated regulatory strategies and approaches for achieving timely approvals and registrations.
- Prepared and conducted multiple FIFRA regulatory training seminars for USDA employees, industry clients, and law firm staff; developed training content covering FIFRA registration requirements, data development processes, and agency review procedures.

### USDA APHIS Permitting

Ms. Stephens brings direct federal government experience to her USDA APHIS permitting work, having managed APHIS regulatory program activities both as a federal employee and as a private consultant. Her expertise spans GMO and non-GMO permitting, vertebrate pest control program compliance, and animal drug regulatory management.

- Managed regulatory compliance for animal drugs with FDA on behalf of USDA's Wildlife Services; assessed data requirements for New Animal Drug (NAD) approvals and obtained and managed Investigational New Animal Drug (INAD) approvals for wildlife management programs.
- Managed the compliance program for USDA's Wildlife Services Vertebrate Pest Control Program; provided technical and regulatory project management for multiple USDA APHIS program areas

including the VS feral swine program, BRS permitting program, and PPQ commodity inspection activities.

- Managed USDA APHIS permitting projects for non-genetically modified and genetically modified organisms (GMOs); provided strategic guidance on permitting pathways and data requirements for clients navigating complex APHIS regulatory requirements.

### Pesticide Compliance Audits

Ms. Stephens has conducted facility- and program-wide pesticide regulatory compliance audits for industry and federal agency clients, delivering findings reports and corrective action plans that address FIFRA compliance gaps and document regulatory standard of care.

- Conducted numerous facility-wide pesticide regulatory compliance audits for industry clients, both on-site and off-site; identified compliance gaps, presented prioritized findings and action items to client management, and provided follow-on support for addressing audit findings.
- Conducted program-wide pesticide regulatory compliance audits for USDA and associated services; presented audit findings to staff and senior leadership and implemented program-wide corrective actions based on findings.
- Authored multiple National Environmental Policy Act (NEPA) compliance documents including environmental assessments (EAs), environmental impact statements (EISs), and technical support documents for federal and industry clients; managed agency review processes and coordinated multidisciplinary input to deliver compliant NEPA analyses.

### Biopesticide Registration

Ms. Stephens has managed the full registration lifecycle for microbial biopesticides, biochemical biopesticides, and inert ingredients, guiding clients through complex data development programs and multi-agency registration processes in the U.S. and internationally.

- Led multiple large-scale, multi-year data development programs for new biopesticide registrations; managed multidisciplinary teams, placed and monitored toxicology, and efficacy studies at contract laboratories, and assembled and submitted complete data packages to EPA for new active ingredient and product registrations covering food and non-food uses.
- Developed and executed global pesticide registration strategies for agrochemical clients with multi-country registration needs; coordinated multidisciplinary teams and leveraged key agency contacts to support registration efforts across North America and other international markets in partnership with Exponent's global regulatory network.

### Pesticide Litigation Support

Ms. Stephens provides expert consulting, due diligence analysis, and expert reports in support of pesticide-related litigation matters, including FIFRA data compensation cases, regulatory compliance disputes, and matters requiring pesticide regulatory standard-of-care analysis.

- Led multiple due diligence and data compensation projects under FIFRA; managed multidisciplinary teams, evaluated data packages for completeness and regulatory adequacy, assisted clients in preparing for data compensation testimony, and prepared detailed findings reports for clients.

- Provided pesticide regulatory expert consulting in support of litigation matters involving FIFRA registration requirements and agency standard of care; analyzed regulatory submissions, agency correspondence, and compliance records to support client legal teams.
- Conducted program-wide pesticide regulatory compliance audits producing detailed findings reports for federal and industry clients; audited findings documents to provide regulatory standard-of-care analysis directly applicable to compliance-related litigation and enforcement defense matters.

## Advisory Appointments

Regulatory Advisor, USDA National Institute of Food and Agriculture, Emergency Citrus Disease Research and Extension Program: Advanced testing and commercialization of novel defensin peptides and therapies for HLB control