

# Karen Ellis Carr

PARTNER AND FDA PRACTICE LEADER

Karen counsels, advocates, and litigates on behalf of agriculture and food companies and industry groups, with a focus on agricultural technology, food, biotechnology, pesticides and other chemical substances, and environmental law. Karen leads ArentFox Schiff's Agriculture & AgTech industry group.



## **Industries**

Consumer Products
Fashion & Retail Law
Life Sciences
Media & Entertainment
Nonprofits & Associations
Energy & Cleantech

## **Practices**

Food, Drug, Medical Device & Cosmetic Complex Litigation Environmental Pro Bono Trademark

## International

Australia

## **Education**

University of Oregon School of Law, JD, 2005 University of North Carolina at Chapel Hill, BA, 2000 Offices Phone Email

Washington, DC 202.715.8531 Karen.Carr@afslaw.com

Karen has experience in litigation and regulatory counseling, strategy, and advocacy, with a primary focus on products regulated by the United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA). Karen advises on pathways to commercialization for new products and technologies, advertising and labeling, testing and reporting, data use and compensation disputes, and litigation relating to product approvals and agency rulemaking. Karen has specific experience with the Plant Protection Act, the National Bioengineered Food Disclosure Standard, the National Organic Program and other USDA-administered food labeling programs, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA), the National Environmental Policy Act (NEPA), the Endangered Species Act (ESA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Administrative Procedure Act.

In addition to her work with individual companies, Karen represents industry associations and coalitions as outside general counsel, advising on regulatory strategy and policy and federal and state legislative issues, and in litigation matters as parties or *amici*.

Karen has first- and second-chaired litigation matters in state and federal trial and appellate courts throughout the country and in arbitration and mediation, and has experience in all phases of litigation, from pre-litigation strategy and counseling to settlement negotiation and appeals. Karen also helps clients with enforcement and other regulatory matters at the state and federal levels, and assists with risk assessment and due diligence reviews of agricultural technology companies involved in mergers, acquisitions, and other corporate transactions.

## Client Work

Karen's representative litigation matters include:

 Representing trade associations in defending USDA's revised rule governing genetically engineered organisms. *National Family Farm Coalition v. USDA*, 758 F.Supp.3d 1060 (N.D. Cal., 2024)

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- Representing industry trade association and agricultural grower groups in challenges to EPA's framework for the regulation of treated seeds. *Center for Food Safety v. EPA*, 757 F.Supp.3d 997 (N.D. Cal., 2025); *Anderson v. EPA*, 2016 WL 6834215 (N.D. Cal., Nov. 21, 2016)
- Representing an industry coalition defending in litigation USDA's authority to certify organic growers who use hydroponic and other container growing methods to produce agricultural products. *Center for Food Safety v. Perdue* F.Supp.3d 2021 WL 1220949 (N.D. Cal., March 19, 2021)
- Representing a biotechnology developer in a federal court challenge to FDA's first approval of a genetically engineered animal for food use. *Institute for Fisheries Resources v. Hahn*, 424
   F.Supp.3d 740 (N.D. Cal. 2019); 499 F.Supp.3d 657 2020 (N.D. Cal. Nov. 5, 2020)
- Representing crop protection developers and industry trade associations in challenges to EPA's approval of agricultural herbicides (various federal District and Circuit courts, some ongoing)
- Representing a biotechnology company defending permits granted by USDA under the Plant Protection Act, NEPA, and Endangered Species Act. *Center for Biological Diversity v. APHIS*, 2011 WL 4737405 (S.D. Fla., Oct. 6, 2011)
- Representing crop protection developers in data compensation arbitrations under FIFRA
- Representing industry trade association as amicus/intervenor in biotechnology-related NEPA lawsuits, including challenges to USDA's approval of crops produced using biotechnology (D.D.C.)

## Representative regulatory matters include:

- Assisting companies in obtaining approvals for new, genetically engineered varieties of plants, animals, and microbes from USDA, FDA, and EPA
- Serving as outside counsel to biotechnology, seed, crop protection, controlled environment agriculture, and farmland industry associations
- Representing an industry coalition successfully seeking passage of a uniform federal disclosure standard for bioengineered foods and in associated rulemaking proceedings
- Providing pre-litigation strategy and counseling for agricultural products companies on matters relating to biotechnology

## **Professional Activities**

Karen is a member of the Farm Foundation Board of Directors and is a Round Table Fellow. She is also on the Board of Directors for Legal Counsel for the Elderly, a DC-based legal services provider.

At ArentFox Schiff, in addition to leading the Food, Drug, Medical Device & Cosmetic practice and Agriculture & AgTech industry group, Karen serves on the firm's Strategic Advisory Committee and is active in the firm's Women's Initiative.

## **Publications, Presentations & Recognitions**

## Presentations

Karen routinely speaks on AgTech topics. Her speaking engagements include:

- "Science and Policy: The Battle Shaping Ag Biotechnology," The International Fresh Produce Association (IFPA) Fresh Takes on Tech podcast; June 17, 2025 (virtual)
- "Navigating Regulatory Changes in Seed Treatment," CropLife America & RISE Regulatory Conference; April 24, 2025 (Arlington, VA)
- Moderator, "Fireside Chat Policy," AgBio 2025: Innovating Agricultural Resilience; April 9, 2025 (Research Triangle Park, NC)
- Moderator, Regulatory Panel, Farm Foundation Round Table; January 16, 2025 (Raleigh, NC)
- "Food and Agriculture in a Post-Chevron World," ArentFox Schiff & Invariant Webinar; October 1, 2024 (virtual)

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- "What's New with Genetically Engineered Microbes for Use in Agriculture: A Regulatory Update," American Agricultural Law Association Webinar; August 29, 2024 (virtual)
- "Hot Topics in Agriculture Today," Farm Foundation Round Table; June 21, 2024 (Broomfield, CO)
- Moderator, "Biodiversity in Action: Innovation in Plants, Microbes, and Animals," BIO Agriculture & Innovation Summit; April 18, 2024 (Washington, DC)
- "Seed Treatment," CropLife America & RISE Spring Regulatory Conference; April 17, 2024 (Arlington, VA)
- "Update on Biotechnology in Food and Agriculture," Institute of Food Technologists Food Policy Impact 2024; February 28, 2024 (Washington, DC)
- "Gene Editing and Agriculture: The Importance of Flexible and Adaptable Regulatory Frameworks" & "Precision Fermentation in Agriculture: The Legal Issue," 2023 AALA Agricultural Law Education Symposium; November 9-11, 2023 (Charlotte, NC)
- "Biological Products and Legal Liability," BPIA Webinar; August 29, 2023 (virtual)
- "The Revolution of the Food Industry into the Life Sciences Helm," IBA World Life Sciences Conference; June 1, 2023 (Washington, DC)
- "Biofuels: Agriculture and Energy," Our EnergyPolicy EnergyLeaders Webinar; May 3, 2023 (virtual)
- "Update on Biotechnology in Food and Agriculture," Institute of Food Technologists Food Policy Impact Conference; February 8, 2023 (Washington, DC)
- "Hot Topics in Agriculture for 2023," Farm Foundation Round Table; January 13, 2023 (Savannah, GA)
- "Perspectives on the Future of PACA: Recent Cases and Opportunities for Modernization," 2022
   AALA Agricultural Law Education Symposium; November 11, 2022 (New Orleans, LA)
- 2022 USW-NAWG Fall Joint Board Meeting; November 8, 2022 (virtual)
- "The Role of Produce in Organic Policy & Politics," IFPA The Washington Conference;
   September 28, 2022 (Washington, DC)
- "Legal Issues for Indoor Agriculture," American Agricultural Law Association Webinar; August 30, 2022 (virtual)
- "From Agriculture to the End Consumer: Fostering Collaboration for a More Resilient Food System," Branchfood Food Edge Summit; May 3, 2022 (virtual)
- "Federal Preemption of FIFRA," CropLife America, RISE & CPDA Regulatory Conference;
   April 21, 2022 (Washington, DC)
- "FIFRA Compliance & Enforcement," ABA Section of Environment, Energy and Resources & CropLife America Annual Conference: New Developments in Pesticide Law and Policy; November 10, 2021 (virtual)
- "Technology & Agriculture: A New Age of Sustainability?," Environmental Law Institute Webinar; March 31, 2021 (virtual)
- Virtual Tour, AquaBounty Technologies, Farm Foundation® Round Table; January 13, 2021 (virtual)
- Introductory Remarks, US Biotech Regulatory Landscape Panel, ABA Section of Environment, Energy and Resources and CropLife America Annual Event: New Developments in Pesticide Law and Policy; November 18, 2020 (virtual)
- "AgTech: Emerging Legal Challenges and Opportunities," "Genetic Editing in Agriculture Will
  the Cartagena Protocol on Biosafety Restrict Access to Foreign Markets, Causing Litigation over
  Market Disruption?," AALA Agricultural Law Education Symposium; November 12-14, 2020
  (virtual)
- USDA Final Rule and Proposed EPA Regulation, Wheat Breeding Innovation Committee Meeting; November 2, 2020 (virtual)
- "Emerging Technologies: Regulatory Oversight of Intentional Genomic Alterations in Animals,"
   FDLI Annual Conference: Exploring Advanced Topics in Food and Drug Law; October 7, 2020 (virtual)

- "USDA's Part 340 Rule: Modernizing Regulation of Agricultural Biotechnology," American Agricultural Law Association Webinar; June 2, 2020 (virtual)
- "National Environmental Policy Act," National Agricultural Law Center Webinar; April 1, 2020 (virtual)
- "Update on State Issues and Federal Preemption," Institute of Food Technologists Food Policy Impact Conference; February 10-11, 2020 (Washington, DC)
- "Regulation of Emerging Technologies in the Meat and Poultry Industry," American Agricultural Law Association Annual Symposium; November 9, 2019 (Arlington, VA)
- "Gene Editing in Agriculture Regulatory Status and Legal Issues," American Agricultural Law Association Annual Symposium; November 8, 2019 (Arlington, VA)
- Guest Lecturer, "Regulatory Environment for Biotechnology and Drug Industry: Ag Biotechnology," Yeshiva University Katz School of Science and Health; November 6, 2019 (New York, NY)
- "Biotech Regulation Panel," AALA Annual Educational Symposium; October 25-27, 2018 (Portland, OR)
- Gene Editing Roundtable, 6th Plant Genomics & Gene Editing Congress: USA; October 1-2, 2018 (Philadelphia, PA)
- "Upcoming USDA Bioengineered Food Regulations," FDLI's Food Advertising, Labeling, and Litigation Conference; on September 26-27, 2018 (Washington, DC)
- "Science, Law, and the Regulation of Food Disruptors: Lab-Created Protein and Gene Editing,"
   American Agricultural Law Association Webinar; August 9, 2018 (virtual)
- "Hot Topics in Pesticide Regulation and Litigation," Ag Tech and the Law Conference; August 16, 2018 (Little Rock, AR)
- "Gene Editing: Opportunities and Challenges," Farm Foundation® Forum; July 17, 2018 (Washington, DC)
- "National Bioengineered Food Disclosure Standard," 30th Annual Food Label Conference; May 21, 2018 (Washington, DC)
- "New Developments in Pesticide Law & Policy," 2018 ABA SEER Pesticides, Chemical Regulation and Right-to-Know Committee; May 8, 2018 (Washington, DC)
- "GE Labeling Update," IFT Food Policy Impact; February 6, 2018 (Washington, DC)
- "Industry & Consumer Responses & Action Related to GMO Labeling," Q1 Productions' Food Labeling Conference; January 29, 2018 (Arlington, VA)
- "From Farm to Table The Future of GMO Plants and Animals," NYSBA Food, Drug & Cosmetic Law Section Meeting; January 25, 2018 (New York, NY)

## Recognitions

Karen has been recognized as one of the nation's leading Food & Beverages: Regulatory & Litigation lawyers by *Chambers USA* since 2023. In addition, she was recognized by The Best Lawyers in America 2025 in FDA Law and has been recognized by *Super Lawyers* as a "Rising Star" in the Complex Litigation category.

## **Bar Admissions**

District of Columbia Virginia

## **Court Admissions**

US District Court, District of Maryland

US District Court, Eastern District of Virginia

US District Court, Western District of Virginia

US District Court, District of Columbia

US Court of Appeals, 4th Circuit

US Court of Appeals, 5th Circuit

US Court of Appeals, 9th Circuit

US Court of Appeals, District of Columbia Circuit