

# Karen Ellis Carr

PARTNER AND FDA PRACTICE LEADER

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



#### **Industries**

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

#### **Practices**

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

#### 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. Karen has specific expertise with the Plant Protection Act, the National Bioengineered Food Disclosure Standard, the National Organic Program, 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 has extensive experience 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. Karen is also a Fellow of the Farm Foundation Round Table.

### **Client Work**

Karen's representative litigation matters include:

 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)

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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 industry trade association and agricultural grower groups in a challenge to EPA's framework for the regulation of treated seeds. *Anderson v. EPA*, 2016 WL 6834215 (N.D. Cal., Nov. 21, 2016)
- 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 an industry trade association as *amicus*/intervenor in multiple 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, and controlled environment agriculture 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

## Firm Activities and Pro Bono

Karen serves in numerous firm leadership positions and maintains an active pro bono practice. She currently serves on the Board of Directors for Legal Counsel for the Elderly, a DC-based legal services provider.

Karen is a member of the firm's Strategic Advisory Committee, Financial Management Committee, and Pro Bono Committee and is active in the firm's Women's Initiative.

## **Previous Work**

Before joining ArentFox Schiff, Karen served as a law clerk for the Honorable James P. Jones, then Chief Judge of the US District Court for the Western District of Virginia. While in law school, Karen served as a judicial extern for Judge Ann Aiken, US District Court for the District of Oregon, as a law clerk for the Special Litigation Unit of the Oregon Department of Justice, and as an executive editor of *Oregon Law Review*. She also served as a fellow for the Wayne Morse Center for Law and Politics.

## **Publications, Presentations & Recognitions**

Karen routinely speaks on biotechnology, crop protection and chemical regulation, and food labeling, and environmental law. Her speaking engagements include:

- 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)

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- "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," OurEnergyPolicy 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)

Karen writes often on biotechnology, crop protection, and food labeling topics. Her recent publications include:

- "Rise in VCM Business May Trigger CFTC Oversight on Sales of Carbon Offset Credits," ArentFox Schiff Client Alert; May 30, 2023
- "FCC Announces March 28 Meeting of Precision Agriculture Connectivity Task Force,"
   ArentFox Schiff Client Alert; March 16, 2023
- "Proposed Legislation Would Authorize CFIUS to Scrutinize Farmland Purchases by Foreign Buyers," ArentFox Schiff Client Alert; February 13, 2023
- "2023 Federal Forecast Agriculture," ArentFox Schiff Client Alert; January 26, 2023
- "What Can the Agriculture Sector Expect from Rep. Andy Harris on Agriculture and BioTech Appropriations," ArentFox Schiff Client Alert; January 23, 2023
- "Where In the World Did My Food Come From: FDA's Food Traceability Rule Takes Effect," ArentFox Schiff Client Alert; January 20, 2023
- "A Bounty of Benefits," ArentFox Schiff Client Alert; December 9, 2022
- "US Patent Office Seeks to Positively Impact Climate by Accelerating Examination," ArentFox Schiff Client Alert; November 10, 2022
- "Ninth Circuit Finds Hydroponically Grown Crops Can Be 'Organic' as Advocated by ArentFox Schiff," ArentFox Schiff Client Alert; October 3, 2022
- "California Federal Court Substantially Upholds Bioengineered Food Disclosure But Remands QR Code and Text Message Disclosure Options to USDA for Further Rulemaking," *ArentFox Schiff Client Alert*; September 29, 2022
- "Biden's Executive Order Focusing on Biotechnology Offers Opportunities for AgTech Industry,"
   ArentFox Schiff Client Alert; September 20, 2022
- "EU Seeks Input on Policy for Plants Developed Using New Genomic Techniques," ArentFox Schiff Client Alert; May 20, 2022
- "From Farm to Runway The Rise of Regenerative Farming in Fashion," ArentFox Schiff Client

- Alert; April 1, 2022
- "First Genome-Edited Beef Cattle Cleared for Marketing by FDA," ArentFox Schiff Client Alert; March 14, 2022
- "FCC Announces Working Group Members for Its Precision Agriculture Connectivity Task Force," ArentFox Schiff Client Alert; February 22, 2022
- "2022 Sparks Opportunity for AgTech Certified B Corps With Environmental, Social, and Corporate Governance (ESG) Goals," ArentFox Schiff Client Alert; January 27, 2022
- "FCC Announces Members of Precision Agriculture Connectivity Task Force," ArentFox Schiff Client Alert; December 13, 2021
- "What's In Your Product? EPA Wants to Know," ArentFox Schiff Client Alert; November 3, 2021
- "SEC Environmental, Social, and Corporate Governance (ESG) Disclosure Rule Could Help AgTech Attract Investors," ArentFox Schiff Client Alert; July 30, 2021
- "Top 5 Things to Watch for When Selling Carbon Credits," ArentFox Schiff Client Alert; June 30, 2021
- "FCC Schedules Next Meeting for Precision Agriculture Connectivity Task Force (July 8, 2021),"
   ArentFox Schiff Client Alert; June 25, 2021
- "Think Your Pesticide Deserves an Exemption? EPA Wants To Hear From You," ArentFox Schiff Client Alert; June 2, 2021
- "AgTech Turns to Public Benefit Corporations to Pursue Environmental, Social, and Corporate Governance (ESG) Goals," ArentFox Schiff Client Alert; April 13, 2021
- "Biden Administration Promises Regulatory Changes for Pesticide Industry," ArentFox Schiff Client Alert; March 5, 2021
- "Top 5 Things to Watch When Evaluating Carbon Offset Purchase Agreements," ArentFox Schiff Client Alert; March 29, 2021
- "Agriculture & Blockchain: The Early Bird Catches the Worm," ArentFox Schiff Client Alert; February 23, 2021
- "USDA Secretary Nominee Receives Unanimous Support by Senate Agriculture Committee, Heads Swiftly to Full Senate for Vote," ArentFox Schiff Client Alert; February 5, 2021
- "FCC Releases Report Addressing Impact of Rural Broadband on Farm Productivity," ArentFox Schiff Client Alert; December 17, 2020
- "EPA Updates Draft Guidance on Plant Biostimulant Products," ArentFox Schiff Client Alert;
   December 2, 2020
- "FCC Approves \$1 Billion to Facilitate Precision Agriculture," ArentFox Schiff Client Alert;
   October 28, 2020
- "Indoor Farming Start-Up To Go Public Following Merger With SPAC," ArentFox Schiff Client Alert; October 7, 2020
- "EPA Proposes Expanded FIFRA Exemptions for Certain Plant-Incorporated Protectants (PIPs)
   Created Using Gene Editing," ArentFox Schiff Client Alert; September 30, 2020
- "FCC Steps Up Support of Agricultural Technology With \$1 Billion Proposed for Precision Agriculture," ArentFox Schiff Client Alert; September 29, 2020
- Arent Fox Association Digest, ArentFox Schiff Client Alert; September 14, 2020
- "EPA Approves New Crop Protection Tools for Hemp Farmers," ArentFox Schiff Client Alert; December 20, 2019
- "EU Court Offers Preview of Potential Regulatory Approach for Gene Edited Plants," ArentFox Schiff Client Alert; February 15, 2018
- "Biotech Policy Takes Shape: Rural Task Force Encourages Innovation and Regulatory Coordination," ArentFox Schiff Client Alert; January 22, 2018
- "Status and Outlook of Food Labeling Proposals," co-written with Brian Ronholm, Food Safety Tech; October 17, 2017
- "More Controls Needed to Prevent Organic Import Fraud, Says USDA OIG," ArentFox Schiff

Client Alert; October 12, 2017

- "Another Front Opens Up on Food Disclosure," ArentFox Schiff Client Alert; October 10, 2017
- "USDA Releases Bioengineered Food Disclosure Report," ArentFox Schiff Client Alert; September 14, 2017

Karen was recognized as one of the nation's leading Food & Beverages: Regulatory & Litigation lawyers by *Chambers USA* in 2023. She has also 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