

Novel Products and Technologies Regulation

Wiley counsels and represents clients that develop and commercialize new products at the forefront of technological innovation. The system of federal and state regulation in the United States is driven by the particular use of the new innovation. For example, we have substantial expertise in representing stakeholders before the Coordinated Framework agencies (EPA, FDA, USDA) to obtain regulatory approvals for genetically engineered products in agriculture, processed food production, pest control, and industrial manufacturing.

Under the current product regulation paradigm, each use of a product must fit within an existing regulatory framework administered by a specific federal agency. In the case of multiple uses of an innovation, this means that more than one agency and approval program may be involved. Sometimes, however, a technology or use is so novel that the existing rules and agency boundaries are not clear on where jurisdiction falls. With the speed of technological change, cases like this are arising more and more frequently. It is an area where Wiley attorneys excel.

We utilize our firm's extensive cross-disciplinary talent from our Food & Drug, Intellectual Property, and Telecom, Media & Technology practices to counsel both established and early-stage startup companies on the development of biosimilars, IP portfolios, and connected & autonomous vehicle (CAV) technologies.

Artificial Intelligence and the Environment

Greening the digital economy, lightweighting of materials while not compromising on strength and resiliency, connected & autonomous vehicle (CAV) technologies, transmission and charging station infrastructure overhauls, and energy efficient building designs are emerging considerations for reaching recently announced net zero emissions policies at a national and global scale. Reductions in energy consumption may require turning to renewable sources of power generation. Wiley's Environment & Product Regulation team, in collaboration with our Telecom, Media & Technology attorneys, counsels clients on regulatory strategies involving these integrated technologies.

Biopesticides

Wiley boasts unique experience in the evolving regulatory area of biopesticides and biostimulants. Our team includes a former Director of the EPA's Biopesticides and Pollution Prevention Division, who had previously served as chief legal counsel to BPPD while an attorney with the EPA's Office of General Counsel. For more information on our pesticide capabilities, [click here](#).

Biosimilars

Electric Batteries

A significant aspect of advancing battery technology will be new ingredients. Regulatory clearance of these new ingredients, including mixtures of metals, carbon nanotubes, and graphene, depends upon a clear agency understanding of how these chemicals will be manufactured, processed, and used with attention toward potential human and environmental exposure. Wiley attorneys advise companies that purchase these chemicals for use in their products by engaging heavily in the regulatory clearance process to avoid delays in their manufacturing plans. Learn more on our unique TSCA capabilities [here](#).

Genetic Engineering Techniques

We regularly advise clients on regulatory requirements applicable to biotechnology, including new biotechnological techniques such as CRISPR, meganucleases, RNA interference technology, TALENs, and zinc-finger nucleases. This work involves distinct regulatory requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Plant Protection Act.

Industrial Biotechnology

Nanotechnology

Wiley counsels companies on issues involving the manufacture and use of nanomaterials in industrial, food, pesticide, and consumer applications. We advise brand owners on matters relating to product labeling and marketing claims. We served as a leading negotiator for U.S. interests in the development of international labeling standards for consumer products containing manufactured nanomaterials.

Plastics, Recycling, and Sustainability

Reducing plastic waste is a bipartisan and international issue. Traction in 2020 included the Save our Seas 2.0 Act, which incentivizes the nation to reduce, recycle, and prevent marine debris (e.g., plastics) by establishing a Marine Debris Response Trust Fund, a Marine Debris Foundation, a Genius Prize for Save Our Seas Innovations, a strategy to improve waste management and recycling infrastructure, a Waste Management Revolving Fund for states, a Waste Management Infrastructure Grant program, a Drinking Water Infrastructure Grant program, a Wastewater Infrastructure Grant program, and a Trash-Free Water Grant program. The U.S. Department of Energy (DOE) has launched a Plastics Innovation Challenge Draft Roadmap that aims to make domestic processing of plastic waste economically viable and energy efficient, develop new and improved plastic materials lacking the same end-of-life concerns as current materials, and reduce plastic waste accumulation. It has four strategic goals – to develop biological and chemical methods for deconstructing plastic wastes into useful chemicals; develop technologies to upcycle waste chemical streams into higher-value products, encouraging increased recycling; design new, renewable plastics and bioplastics that have the properties of today's plastics; and support an energy- and material-efficient domestic plastics supply

chain by helping companies scale and deploy new technologies in domestic and global markets, while improving existing recycling technologies such as collection, sorting, and mechanical recycling. In 2020, plastic waste was added as a Prior Informed Consent (PIC) waste stream to the Basel Convention, with clear carve-outs for high-quality recycled plastic bales. In 2021, the Canadian government's measure under Schedule 1 of the Canada Environmental Protection Act (CEPA) to label all "plastic manufactured items" as "toxic substances" could present a new set of challenges for U.S. suppliers. Wiley's attorneys provide strategic counsel for navigating these and other challenges.

Representative Experience

- Counsels and represents numerous companies developing groundbreaking pest control products that are regulated by the EPA under FIFRA.
- Representing a trade association of processors and downstream users of nanotechnology on regulatory issues with a focus on advancing U.S. manufacturing sectors.
- Advising clients on TSCA Section 8 requirements for nanomaterials on the TSCA inventory.
- Successfully negotiating with the EPA TSCA program to secure regulatory approval for the use of fullerenes, carbon nanotubes, and nanocellulose.
- Served as a leading negotiator for U.S. interests in the development of international labeling standards for consumer products containing manufactured nanomaterials.
- For a major agribusiness company, developed a comprehensive analysis of statutory, regulatory, and common law requirements applicable to the development, sale, and distribution of genetically engineered food crops in the United States.
- Assisting companies in addressing safety and potential liability risks arising from the sale and distribution of consumer products containing nanotubes and nanosilver.

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